

Measures for the Administration of Production Licenses for Feed Additives and Additive Premix Feeds

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Measures for the Administration of Production Licenses for Feed Additives and Additive Premix Feeds

(Promulgated by the Ministry of Agriculture on December 14, 1999, and amended pursuant to the Decision of the Ministry of Agriculture on Amending the Measures for the Administration of Production Licenses for Feed Additives and Additive Premix Feeds as promulgated on April 7, 2003)

Chapter I General Provisions

Article 1 These Measures are formulated pursuant to Article 10 of the Regulation on the Administration of Feed and Feed Additives.

Article 2 The term “feed additives” as mentioned in these Measures include nutritive feed additives and common feed additives.

The term “additive premix feeds” as mentioned in these Measures refers to the well-distributed prefix feeds confected by two or more feed additives with the carrier or thinner pursuant to a certain proportion, but the proportion of additives in the confected feed may not exceed 10%.

Article 3 The categories of feed additives that are produced, managed or used shall be those as listed in the Catalogue of Feed Additives Allowed for Use as promulgated by the Ministry of Agriculture.

Chapter II Basic Conditions for Enterprises

Article 4 Personnel Requirements

- (1) The main principal of an enterprise shall have certain professional knowledge, production experiences and organization ability;
- (2) The person in charge of technologies shall have an educational background of junior college or higher or a middle-level technical title or higher, be familiar with the animal nutrition, technologies for producing products and production techniques, and have engaged in the corresponding professional work for more than two years;
- (3) The person in charge of quality management and the principal of the quality inspection department shall have an educational background of junior college or higher and have engaged in the corresponding professional work for more than three years; and
- (4) An employee engaged in the special type of work shall possess a corresponding professional certificate.

Article 5 Requirements of Production Places

- (1) The layout of factories shall be reasonable, and the production areas, offices, warehouses and living areas shall be separated from each other;
- (2) The layout of workshops shall be consistent with the requirements of production process flows, and the working procedures are coherent and rational;
- (3) There shall be proper operational rooms and areas for properly placing equipment and materials so as to prevent the materials from mixing up or from cross contamination;
- (4) There shall be proper facilities against dust, for ventilation, lighting and fire control so as to ensure the production safety; and
- (5) The storage facilities shall be adapted to the production ability, and shall tally with the

requirements for waterproofing, moisture-proofing, fireproofing and rat-proof.

Article 6 Requirements of Production Equipment

- (1)The applicant shall have the production equipment which can meet the demand of the production of products;
- (2)The production equipment shall be consistent with the production process flows and be easy to maintain;
- (3)The production equipment shall be in good condition; and
- (4)The facilities and equipment for decontaminating the air shall be provided if there are deperative requirements for the production environment.

Article 7 Requirements of Quality Inspection

- (1)A quality inspection department shall be established and shall be directly under the leadership of the principal of the enterprise;
- (2)The quality inspection department shall establish an instrument room (section), an inspection and manipulation room (section) and a room (section) for keeping samples for observation;
- (3)There shall be corresponding inspection instruments for monitoring the quality of products, and a qualified inspection institution shall be entrusted for inspection if large-scale precision instruments are required for inspecting a project;
- (4)There shall be rigorous operational rules for the quality inspection; and
- (5)The quality inspection department shall have complete inspection records and inspection reports, which shall be kept for more than two years.

Article 8 Requirements of Management System

An enterprise shall establish the following management systems:

- (1)post-related responsibility system;
- (2)production management system;
- (3)inspection and testing system;
- (4)quality management system;
- (5)safety and sanitation system;
- (6)system for keeping samples of products for observation; and
- (7)measurement management system.

Article 9 Requirements of Production Environment

The production environment shall be consistent with the environmental sanitation and labor protection requirements as prescribed by the State.

Chapter III Procedures for Licenses

Article 10 A production enterprise shall fill out and submit an Application Form for Production Licenses for Feed Additives and Additive Premix Feeds, and simultaneously provide such declaration materials as the drawing on the layout of factories and the production process flows, and the relevant certificates, and apply to the local provincial feed administrative department. The Application Form for Production Licenses for Feed Additives and Additive Premix Feeds may be obtained from the feed administrative department of the province, autonomous region or municipality directly under the Central Government (hereinafter referred to as the provincial level), at the locality of the enterprise or be downloaded at the website of chinafeed (website: <http://www.chinafeed.org.cn>).

Article 11 The provincial feed administrative department shall make a decision as to whether accept the application within 10 working days upon receipt of all declaration materials, and shall conduct the examination of materials and on-the-spot survey within 20 working days upon receipt of the said materials.

Article 12 The provincial feed administrative department shall organize the relevant persons to form

an examination and appraisal team, which shall conduct examination to the declaration materials and make on-the-spot surveys. Where it is found to be qualified upon the examination of declaration materials and on-the-spot survey, a Comprehensive Examination Form for Enterprises Producing the Feed Additives and Additive Premix Feeds shall be filled in out by the provincial feed administrative department and be affixed with its seal.

The provincial feed administrative department shall submit the Application Form for Production Licenses for Feed Additives and Additive Premix Feeds and the Comprehensive Examination Form for Enterprises Producing the Feed Additives and Additive Premix Feeds in duplicate to the Ministry of Agriculture for examination and approval.

Article 13 The Ministry of Agriculture shall, within 20 working days upon receipt of the declaration materials as submitted by the provincial feed administrative department, entrust the expert examination committee for production licenses for feed additives and additive premix feeds under the Ministry of Agriculture to make an examination and put forward suggestions on whether or not approve the applications.

The Ministry of Agriculture shall conduct examination to the examination suggestions as put forward by the expert examination committee for production licenses for feed additives and additive premix feeds, and issue a Production License for Feed Additives and Additive Premix Feeds to the enterprises that are found to be qualified upon examination, and publish the examination results on a regular basis.

Article 14 A newly-established enterprise for producing feed additives and additive premix feeds shall, upon the strength of a Production License for Feed Additives and a Production License for Additive Premix Feeds, apply to the administrative department for industry and commerce for registration, and obtain a business license.

Chapter IV Administration of Production Licenses

Article 15 No production of feed additives and additive premix may be conducted until the production license and the approval document number are obtained.

Article 16 To alter the enterprise name, production address or registered address one shall file an application to the local provincial feed administrative department for examination, which, after examination and approval, shall be reported to the Ministry of Agriculture for reissuing a production license, and the Ministry of Agriculture shall make an announcement for it.

Article 17 If an enterprise is under any of the following circumstances, it shall obtain a new production license pursuant to these Measures:

- (1)Producing products at different places;
- (2)Establishing a branch;
- (3)Altering its production address; or
- (4)Increasing the categories of products and thus exceeding the production scope as prescribed in the production license.

Article 18 An annual inspection system shall be implemented for feed additives and additive premix feeds. An enterprise shall fill out an annual inspection form pursuant to the requirements prior to the end of March each year, and report it to the provincial feed administrative department. The provincial feed administrative department shall conduct an investigation if it is found to have made any significant alteration to the production conditions of the enterprise or a serious hidden safety trouble or a safety quality problem exists during the course of annual inspection, and shall report the investigation results to the Ministry of Agriculture.

The Ministry of Agriculture shall carry out irregular supervision and check of the annual inspection work.

Article 19 The valid term of a Production License for Feed Additives and Additive Premix Feeds

shall be five years. In case an enterprise needs to produce after the expiration of the valid term of the production license, it shall apply for a new license upon the strength of the original license within six months prior to the expiration of the valid term, and a production license may be re-issued after the provincial feed administrative department and the Ministry of Agriculture have examined the application and find it up to the standards.

Article 20 The formats of the Application Form for Production Licenses for Feed Additives and Additive Premix Feeds, the Comprehensive Examination Form for Enterprises Producing the Feed Additives and Additive Premix Feeds and the Production License for Feed Additives and Additive Premix Feeds shall be uniformly formulated by the National Feed Office.

Article 21 If an enterprise is under any of the following circumstances, the feed administrative department shall rectify and improve it within the time limit. If it is still found to be unqualified after the rectification and improvement, it shall be reported to the Ministry of Agriculture for canceling its production license, and make an announcement for it:

- (1)The basic conditions of the enterprise have been significantly altered, and the basic production conditions are not satisfied;
- (2)The enterprise fails to submit the materials for annual inspection or pass the annual inspection for more than two years (included);
- (3)The production enterprise has ceased its production for more than one year (included);
- (4)The production enterprise goes bankrupt or is merged; or
- (5) The enterprise fails to notify the change of its address to the department in-charge.

Chapter V Penalty Provisions

Article 22 A production business enterprise that adds or uses prohibited drugs in the feed products or fails to use feed additives pursuant to the provisions, and causes serious consequences shall be punished pursuant to Item (3) of Paragraph 1 of Article 30 in the Regulation on the Administration of Feed and Feed Additives.

Article 23 An enterprise shall immediately stop the producing or selling of the products if its production license is cancelled, and the provincial feed administrative department shall withdraw its production license and submit it to the Ministry of Agriculture. The name list of the enterprises whose production licenses have been cancelled shall be published by the Ministry of Agriculture.

Article 24 Any other entity that violates these Measures shall be punished pursuant to the relevant provisions in the Regulation on the Administration of Feed and Feed Additives.

Chapter VI Supplementary Provisions

Article 25 The power to interpret these Measures shall remain with the Ministry of Agriculture.

Article 26 These Measures shall come into force as of the date of promulgation.
