

REGISTRATION AND SALE OF ANIMAL FEED SUPPLEMENTS,
IMPORT PERMISSION PROCEDURE

One. GENERAL GROUNDS

1. This procedure shall regulate the registration of animal feed additives in the state registration, extension of the registration period, making changes in the registration, deregistration, issuance, sale and withdrawal of import permits.

1.2. Feed additives shall include additives produced for mixing with feed and additives produced for supplementary feeding of animals in addition to their main feed, or both feed containing them. Animal feed additives are classified according to their purpose, function, composition and nutritional value as follows.

1.2.1. "Feed supplement" means single or multi-nutrient substances contained in animal feeds to some extent, as well as substances required for their technology to produce feed additives, which support and regulate the physiological functions of animals. ingredients or feeds containing such preparations.

1.2.2. "Feed mixture" means a single or multi-ingredient preparation containing substances that are not included in the main composition of animal feed, are not nutritious and are intentionally mixed in animal feed in order to improve feed quality, prolong shelf life, protect against contamination and accelerate growth. The preparation includes mixed feeds.

1.3. This regulation shall not apply to the use of animal feed additives or feed additives without changing the basic composition of natural food salt, salt, salt, copper, sand, sand and other minerals extracted from the territory of Mongolia.

1.4. Prevent infectious and parasitic diseases of livestock and accelerate their growth ; In order to support the growth of beneficial bacteria in ruminants, single or multi-component preparations containing drugs that are intentionally mixed with animal feed, or mixtures of such preparations, shall be registered in accordance with the State Veterinary Drug Regulation.

1.5. Issues related to supplementation of animal feed specified in paragraph 1.1 of this regulation shall be discussed and resolved by the Veterinary Drug Sub-Council (hereinafter referred to as "Drug Council") under the state administrative body in charge of animal health.

1.6. This regulation shall regulate the relations specified in Article 25.2 of the Law on Animal Health.

Two. FOR REGISTRATION OF ANIMAL FEED SUPPLEMENTS IN THE STATE REGISTRATION
REQUIREMENTS AND COMPLETION DOCUMENTS

Animal feed additives shall be registered in two categories: animal feed additives and animal feed additives.

Animal feed additives shall be registered in the state registry if they meet the following basic requirements. These include:

2.2.1. The manufacturer must meet the requirements of good manufacturing practice (GMP), international (ISO: 9001, ISO: 22000) and similar standards of the country;

2.2.2. Be registered in the country of origin as either an animal feed mixture (FA) or a feed additive (PC);

2.2.3. Imported animal feed additives shall be used in the country of origin;

The following documents shall be submitted for registration of animal feed additives included in the category of feed additives in the state registry.

2.3.1. A copy of the official request of the registrant and the state registration certificate of the business entity;

2.3.2. Introduction of activities for production or import, sale and supply of animal feed additives;

2.3.3 An application for registration of animal feed additives in the state registry;

- 2.3.4. In the case of a feed additive produced by an manufacturer or an imported animal feed supplement, a free trade document for the animal feed supplement issued by the official contracted distributor;
- 2.3.5. Manufacturer's certified document confirming that the manufacturer meets the requirements of good manufacturing practice (GMP), international (ISO: 9001, ISO: 22000) and similar standards of the country, and factory description;
- 2.3.6. A document certified by the manufacturer confirming that the animal feed supplement is registered in the country of origin and used in that country;
- 2.3.7. A copy of the results of the quality analysis performed by the manufacturer on the supplied product;
- 2.3.8. Manufacturer's certificate confirming that genetically modified and non-stimulant mixtures have not been used;
- 2.3.9. If the composition of the product includes living microorganisms and plants, a description of the manufacturer clearly indicating their surnames and types in Latin names, and a Mongolian translation of the Latin name;
- 2.3.10. Developed in Mongolian language the composition, properties, action, purpose, method of application, dosage, amount, side effects, prohibitions, storage, transportation conditions and warnings of animal feed additives and is in charge of animal health issues. draft instructions for use discussed by the Pharmacopoeia Committee under the State Administrative Body;
- 2.3.11. Color pictures of primary and secondary packaging of animal feed additives; / Submit a sample to the Veterinary Medicine Sub-Council with the condition of returning it if necessary /
- 2.3.12. The registration of animal feed additives in the state registration shall be based on the original documents submitted by the producer or his / her authorized organization.
- 2.4. In addition to the items specified in 2.3.1 to 2.3.11 of this regulation, the following documents shall be required for registration of animal feed additives included in the category of feed mixture.
- 2.4.1. Information on adverse side effects of the feed mixture on humans, livestock, animals and the environment;
- 2.4.2. Safety indicators of feed mixtures and laboratory test methods to check them;
- 2.4.3. Results of tests of the State Laboratory for Veterinary Drug Testing and Certification of Mongolia;
- 2.4.4. Draft instructions for use shall include instructions for disposal and disposal of feed additives and waste;
- 2.4.5. License certificate of the business entity;
- Documents required for registration of domestically produced feed additives in the state registry:
In addition to those specified in paragraph 2.3 of this regulation, the following documents shall be required.
- 2.5.2. Test results of the State Laboratory for Veterinary Drug Testing and Certification of Mongolia;

Three. REGISTRATION, CHANGE, EXTENDATION AND CANCELLATION IN THE STATE REGISTRATION

- 3.1. To register in the state registry and change the registration
- 3.1.1. Feed additives shall be registered in the state registry by the country of origin and each producer.
- 3.1.2. In case of change of composition, instructions for use, dosage, form, label, official name and address of the animal feed additive, the state registration shall be changed and a new certificate shall be issued.
- 3.1.3. In case a business entity imports animal feed additives previously registered in the state registry from another source under the same trade name, it shall submit a new registration by submitting the documents specified in Article 2 of this regulation. A new registration number shall be assigned to another product with the same trade name, composition, label and packaging.
- 3.2. Extend the state registration period
- 3.2.1. The applicant shall submit a written request to the Veterinary Drug Sub-Council at least 1 month prior to the expiration of the state registration of feed additives. The request shall clearly state the total amount and scope of use of the animal feed supplement.

3.2.2. Feed supplements that have not been complained about by the consumer, the complaint is unfounded and unproven shall be presented to the meeting of the Veterinary Drug Sub-Council and the state registration period shall be extended for the first time.

3.2.3. In case of extension, the state registration number and code of the amendment shall be repeated.

3.3. To cancel the state registration

3.3.1. No request has been submitted to extend the state registration period for animal feed additives and the validity period has expired;

3.3.2. Poisoning and death of livestock due to its side effects during the use of animal feed additives has been determined by a professional veterinary and law enforcement agency.

3.3.3. It has been proven that the animal feed additive was forged or the documents were forged;

Four. IMPORT LICENSE FOR LIVESTOCK SUPPLEMENTS

4.1. The state central administrative body in charge of animal health shall issue a permit for the import of additional animal feed.

4.2. The model of the permit to import additional feed shall be approved by the head of the state central administrative body in charge of animal health.

4.3. The application for an import permit shall be submitted to the state administrative body in charge of animal health together with the following documents.

4.3.1. A copy of the state registration certificate of the business entity;

4.3.2. Trade agreement concluded with the manufacturer and official distributor;

4.3.3. A copy of the state registration certificate for imported animal feed additives;

4.3.4. Manufacturer's certificate that meets international quality standards;

4.3.5. Certificate of composition, origin and quality of animal feed additives;

4.3.6. Label design and instructions for use; / Have Mongolian translation /

4.3.7. Evidence that 3/4 of the validity period of the feed supplement has not expired;

4.3.8. Feed mixture is a copy of the business entity's license certificate;

4.4. Import permit shall be valid for 1 month within 3 working days after receiving the documents specified in 4.3 of this regulation.

4.5. If a business entity or organization is not registered in the state registry using its import permit, does not have a quality assurance and conformity certificate, has expired 3/4 of its validity period, and has attempted, introduced, sold or used a feed additive with false documents, The decision will revoke the import permit.

Five. SALE AND RETURN OF ANIMAL FEED SUPPLEMENTS

5.1 Animal feed additives shall be tested in the State Laboratory for Testing and Certification of Veterinary Drugs and put on sale after it is proved that the product meets the quality standards set by the manufacturer.

5.2. Explain the effect, purpose and method of application of animal feed additives to consumers and sell them by an experienced veterinarian and veterinary pharmacist.

5.3. It is prohibited to advertise animal feed additives in any form as if they are not used for the treatment of animal diseases and / or have medicinal properties.

5.4 Animal feed additives may be sold in veterinary pharmacies, veterinary service units, manufacturers, distributors and warehouses, provided that they do not affect odors, particles, environmental hygiene and storage procedures.

5.5. Canned or odorless sealed food for pets and small animals may be sold in grocery stores.

5.6. It is allowed to sell animal feed additives directly to consumers and provide advice through online trade network.

5.7. Not registered in the state registry, fake ? without quality assurance. The sale of expired or unlicensed feed additives shall be prohibited and recalled at the request of the authorized state inspector or at the seller's own expense.

5.8. If necessary, animal feed additives shall be re-tested by the State Laboratory for Veterinary Drug Testing and Certification, and a decision shall be made on whether to withdraw them based on the test results and certification conclusions.

Six. MAINTENANCE AND CERTIFICATION OF STATE REGISTRATION FOR ADDITIONAL LIVESTOCK FEEDING

6.1. Within one month after receiving the documents that meet the requirements specified in paragraph 2 of this regulation, it shall be decided whether to register animal feed additives in the state registry.

6.2. One copy of the state registration certificate for animal feed additives shall be issued to the registrant for a period of 5 years. The registration certificate shall be signed by the Chairman and Secretary of the Veterinary Drug Sub-Council and certified by the seal of the Sub-Council.

6.3. A certified copy of the registration certificate and instructions for use shall be archived by the Veterinary Drug Sub-Council together with other registration documents and used for official purposes.

6.4. The Veterinary Drug Sub-Council shall inform the public about the feed additives registered, amended, removed and withdrawn from the state registration on its website from time to time.

Seven. HARIUTSLAGA

7.1. The state veterinary inspectors authorized to exercise control over veterinary activities at all levels shall monitor the implementation of this regulation.

7.2. A person who violates this regulation shall be held liable in accordance with relevant laws and regulations.

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