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## China - Peoples Republic of

**Post:** Beijing

### **MOA Regulation on Feed and Feed Additive Import Registration**

**Report Categories:**

FAIRS Subject Report

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**Report Highlights:**

On January 13, 2014, China's Ministry of Agriculture published No.2 Decree on "Regulation on Feed and Feed Additive Import Registration." Enforcement will begin July 1, 2014. The 2014 regulation contains changes from the draft version (GAIN CH12024) **and will replace** the previous Regulation on Feed and Feed Additive Import Registration which was enforced on August 17, 2000 and amended on July 1, 2004. The amended draft regulation was published for comments on March 1, 2012 (GAIN CH12024).

## **Executive Summary:**

On January 13, 2014, China's Ministry of Agriculture (MOA) published 2014 No.2 Decree on "Regulation on Feed and Feed Additive Import Registration." This report contains an UNOFFICIAL translation of the regulation. Enforcement will begin on July 1, 2014. The regulation contains changes from the previously published draft (GAIN CH12024). Exporters are recommended to consult with their importer for specific requirements. The amended draft regulation was published for comments on March 1, 2012 (GAIN CH12024).

The report contains an UNOFFICIAL translation of this regulation.

## **BEGIN UNOFFICIAL TRANSLATION**

### **Ministry of Agriculture 2014 Decree No. 2**

**The Regulation on Feed and Feed Additive Import Registration was passed at the 11<sup>th</sup> Ministry of Agriculture executive meeting held on December 27, 2013, and is hereby published and will be enforced from July 1, 2014. From the date this Regulation is enforced,** the Regulation on Feed and Feed Additive Import Registration which was enforced on August 17, 2000 and amended on July 1, 2004 shall be abolished.

Minister of Agriculture

Date: January 13, 2014

### **"Regulation on Feed and Feed Additive Import Registration"**

#### Article 1

This regulation is formulated based on the "Administrative Measures for Feed and Feed Additives," and for the purpose of strengthening the supervision of feed and feed additive imports, and ensuring the quality and safety of animal products.

#### Article 2

Feed in this regulation means the product made with industrialized processed ingredients for animals, including single feed, premixed feed, concentrate, compound and supplementary feed.

Feed additive in this regulation means the substance added to feed during the processing, formulation and use in a small or minimum volume, including nutritional feed additives and common feed additives.

#### Article 3

The overseas enterprise shall file an application for import registration with the Ministry of Agriculture and obtain an import registration license for feed and feed additives before exporting a feed and feed additive to China for the first time.

Imported feed and feed additives shall not be sold and used in China without an import registration license.

#### Article 4

The overseas enterprise shall file an application to register feed and feed additives imports through a China-based agent.

#### Article 5

The imported feed and feed additive shall comply with the requirements stipulated by the relevant laws, regulations and technical standards of both the country of manufacture and China.

Feed and feed additive products that have not been approved for production and use or that have been banned by the country of origin for production or use shall not be registered.

#### Article 6

When applying for registration of imported feed and feed additives, the applicant should submit application documents in a factual, complete, and standardized manner (with two copies in both Chinese and English) and samples.

#### Article 7

The application documents should be composed of:

1. An application form to register imported feed and feed additives.
2. A letter of delegation and a qualification certificate of the representative agent: if an overseas enterprise has a representative office established in China, then an original letter of delegation and a copy of the representative office registration license shall be provided; if an overseas enterprise uses a local agent in China, an original letter of delegation and a copy of the corporate business license of the agent shall be provided.
3. Approval certificate for production and use issued by the country of origin, registration documents issued by country or regions outside of the country of origin, and information on the product promotion and use.
4. Name of imported feed product, composition, physical and chemical features, application scope, and instructions for use; name of imported feed additive, main composition, physical and chemical features, product origin, purpose of use, scope of usage, and use methodology.
5. Processing technology, quality standard, test methodology and test report.
6. Original label at manufacturing, trade mark, and sample label in Chinese.
7. For micro-bio organisms or fermented products, the bacteria strain number issued by the competent authority should also be provided.

The following materials shall be provided in case of exports of feed and feed additives to China as listed under Article 13:

1. Review report on chemical structure for effective components or review report on classification of animal, plant and micro-organisms.
2. A report on effectiveness evaluation and a safety evaluation trial report (including evaluation report on tolerance by target animals, toxicity safety evaluation report, metabolism and residue evaluation report) shall be provided by the organization designated by the Ministry of Agriculture; for feed additive registration applications, provide an analysis and evaluation report of the impact on human health caused by feed additive residue in the cultured products.
3. A test report on stability and a report on environmental impact.
4. If a maximum dosage is applied, maximum dosage limit volume and the effective component test methodology shall be indicated.

#### Article 8

The sample shall comply with the following requirements:

1. For each product, 3 batches of samples with 2 samples per batch shall be provided, and the volume of each sample shall be no less than 5 times the test required volume.
2. When needed, provide the relevant standard sample product or chemical comparison product.

#### Article 9

The Ministry of Agriculture shall conduct a review and evaluation within 10 working days upon receipt of the application documents; if the application documents meet the requirements, the Ministry of Agriculture shall notify the applicant to send samples to the Ministry designated test organization for verification testing.

#### Article 10

The verification testing of product quality is composed of a quality standard review and testing of the sample product. The sample test methodology shall comply with national or industry standards if these standards are available. The applicant provided test methodology shall be used if neither national standard nor industry standard available. The laboratory conducting the testing can adjust the test methodology based on the practical situation.

The verification testing should be completed within three months, and the verification testing report shall be sent to the Ministry of Agriculture with a copy sent to the applicant.

#### Article 11

If the overseas enterprise disagrees with the verification testing results, the appeal for retesting shall be filed within 15 working days upon receipt of the verification testing report.

#### Article 12

If the verification test results meet the requirements, the Ministry of Agriculture shall issue the registered license for import feed and feed additive within 10 working days and make it public.

#### Article 13

In case of application for registration of the following feed and feed additives under one of the following circumstances, the Ministry of Agriculture shall conduct a review and evaluation based on the review and evaluation procedure for new feed and new feed additives.

1. Application for registration of feed and feed additive products approved for production and use in the country of origin but not approved for use in China.
2. Application for expansion of the scope of use for a feed additive.
3. The feed additive content is below the safety requirement for feed additive, excluding the feed additive mixed with a carrier or diluent in set proportions.
4. A significant change of processing technology for feed additives.
5. The product was granted a new feed or feed additive registration certificate from the Ministry of Agriculture, but has not been produced within 3 years of the receipt of the license.
6. Other situations that present a quality or safety risk.

#### Article 14

The feed and feed additive import registration license remains valid for 5 years. To continue to export feed and feed additives, a renewal application should be filed six months before the registration license expires.

#### Article 15

The following documents shall be provided for a renewal application:

1. Application form for the renewal of feed and feed additive import registration license
2. Copy of import registration license
3. Letter of delegation and qualification certificate of the agent in China

4. Approval certificate for production and use by the country of origin
5. Quality standard, test methodology and product test report
6. Label and trade mark for the product used in the origin of production and sample of label in Chinese

#### Article 16

In case of the following, a sample should be submitted for verification testing as part of the renewal application:

1. Quality and safety test items need to be adjusted based on the relevant laws, regulations, or technical specifications
2. Change of test methodology
3. Violations are recorded in the supervision sample test

#### Article 17

If the production location, product standard, processing technology, application scope, etcetera, is changed within the validity period of the import registration license, the applicant shall re-apply for registration.

#### Article 18

In case of the following circumstances, an application for alteration shall be filed within the validity period of the import registration license:

1. Change of the Chinese name or English name of the product
2. Change of applicant name
4. Change of manufacturing facility name
3. Change of the name of manufacturing location

#### Article 19

The following documents shall be provided for an application for alteration:

1. Application form for alteration for feed and feed additive import registration
2. Letter of delegation and qualification document of the agent in China
3. Original import registration license
4. An illustration of the alteration and other relevant certification document

Upon receipt of the application for alteration, the Ministry of Agriculture shall decide within 10 working days to approve or deny the application.

#### Article 20

The relevant organization and personnel responsible for import registration of feed and feed additives shall keep confidential all technical data provided by the applicant which needs to be confidential.

#### Article 21

The overseas enterprise should establish a sales agent in China according to the laws or designate a qualified sales agent within the territory of China to sell the registered feed or feed additive. The overseas enterprise is not permitted to directly sell the feed or feed additive within the territory of China.

#### Article 22

The overseas enterprise shall, within 6 months after issuance of the registration license for its feed and feed additive, establish a sales organization within China's territory or designate a sales agent, and report this information to the Ministry of Agriculture.

The enterprise shall report to the Ministry of Agriculture within one month any change to the above mentioned sales organization within China's territory or designate sales agent.

#### Article 23

The imported feed and feed additive shall be packed properly, and the packing shall comply with China's safety and hygienic requirements and be attached with a label in Chinese according to requirements.

#### Article 24

If the imported feed and feed additive are proven harmful to animal and human health or damage the environment during feeding use, the Ministry of Agriculture shall ban its use and revoke the import registration license.

Within the validity period of the license, if the country of origin bans the production or use of the feed and feed additive or revokes the approval for production and use, the overseas enterprise shall report to the Ministry of Agriculture, and the Ministry of Agriculture shall revoke the import registration license and publically announce this accordingly.

#### Article 25

If the overseas enterprise finds out its imported feed and feed additive to China has a harmful impact on animals and human or has other potential safety risks, the overseas enterprise should notify the sales agent established or designated within the territory of China immediately and report to the Ministry of Agriculture.

The sales agent established or designated within the territory of China by the overseas enterprise should recall the product and make a record and report to the local feed administrative agency.

The recalled product shall be rendered harmless or destroyed under the supervision of the feed administrative agency at county level or above.

#### Article 26

The feed administrative agency of the Ministry of Agriculture and the government of county level and above shall conduct regular or irregular inspection sample checks of imported feed and feed additives if necessary; the inspection sample test for imported feed and feed additives shall be conducted by technically qualified organizations designated by the feed administrative agency of Ministry of Agriculture or the government of province, autonomous region and municipality.

The sampling inspection on imported feed and feed additives shall be conducted according to the quality standard established during the verification testing in the registration procedure.

#### Article 27

The feed administrative agency of the Ministry of Agriculture and the government of provincial level shall publish the results of inspection sampling tests in a timely manner, and may publish the name of overseas enterprise and sales agents or representatives who have a bad record.

#### Article 28

The personnel engaged in registration of imported feed and feed additives failing to comply with this regulation or found to have engaged in abuse of power, neglect of duty, or fraudulent practices for personal gain shall face penalties according to the law, and will be subject to criminal liability in the case of a crime.

#### Article 29

The Ministry of Agriculture shall reject or deny approval for an application which is found to be providing false documents and samples or other deceptive practices; the Ministry of Agriculture will not accept import registration applications from overseas enterprises or sales agents for one year after submitting such false applications.

For an issued import registration license found to be obtained through the provision of false documents and samples or other deceptive means, the Ministry of Agriculture shall revoke the license and impose a fine on the registration agent of not less than RMB 50,000 but not more than RMB 100,000. The relevant overseas enterprise and its registration agent will not be allowed to file an application for import registration license for three years.

Article 30

Other violations of this regulation shall be penalized based on the regulations stipulated in the “Feed and Feed Additive Administrative Measures.”

Article 31

This regulation will be enforced on July 1, 2014. The Ministry of Agriculture’s “Registration Regulation on Imported Feed and Feed Additive” published on August 17, 2000 and amended on July 1, 2004, shall be abolished at the same time.

**END UNOFFICIAL TRANSLATION**