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Regulation on Feed and Feed Additive Import Registration (Amended Draft for Comments)

Report Categories:

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Report Highlights:

On March 1, 2012, China's Ministry of Agriculture (MOA) published a Notice on "Regulation on Feed and Feed Additive Import Registration (Amended Draft for Comments)" for public comments, which are due on March 31, 2012. This draft regulation replaces the current "Regulation on Feed and Feed Additive Import Registration (enforced on August 17, 2000)," and provides further details on Decree 609 (CH12008). Please note the MOA Notice provides details on major amendments to the regulation. This report contains an UNOFFICIAL translation of the draft regulation.

Executive Summary:

On March 1, 2012, China's Ministry of Agriculture (MOA) published a Notice on "Regulation on Feed and Feed Additive Import Registration (Amended Draft for Comments)" for public comments, which are due on March 31, 2012. This draft regulation replaces the current "Regulation on Feed and Feed Additive Import Registration (enforced on August 17, 2000)," and provides further details on Decree 609 (CH12008). Please note the MOA Notice provides details on major amendments to the regulation. Although not notified to the World Trade Organization, this regulation does not currently have a date of enforcement. This report contains an UNOFFICIAL translation of the draft regulation.

BEGIN UNOFFICIAL TRANSLATION

Ministry of Agriculture Notice on Soliciting Comments on "Regulation on Feed and Feed Additive Import Registration (Amended Draft for Comments)"

Published by: Department of Legislative and Policy

Date: March 1, 2012

Key words: Imported Feed, Feed Additive, Registration Regulation

In an effort to guarantee the quality and safety of feed and feed additives, and enforce the recently amended "Administrative Measures on Feed and Feed Additives," the Ministry of Agriculture drafted the "Regulation on Feed and Feed Additive Import Registration (Amended Draft for Comments)," which will eventually replace the existing "Regulation on Feed and Feed Additive Import Registration."

The "Regulation on Feed and Feed Additive Import Registration (Amended Draft for Comments)" is composed of 29 articles with the following main content:

- 1) Specifies that the overseas enterprise shall file an application for import registration for feed and feed additive products through the representative office established by the overseas enterprise within the territory of China or authorized agent within the territory of China.
- 2) Specifies that the documents the overseas enterprise shall provide in filing an application for import registration of feed and feed additives shall include an import registration application form for feed and feed additives, qualification certificate of the representative office or agent, certificate of approval for production and use issued by the manufacturing country of origin, and a registration document issued by other countries or regions.
- 3) Specifies that the Ministry of Agriculture shall conduct review and evaluation according to the evaluation procedure for new feed and feed additives and then decide whether an import registration certificate shall be issued in the following cases: the overseas enterprise file application for registration of product approved in the manufacturing country of origin for production and use but not approved in China, or the product manufactured with significant different technology although a similar product is approved for production and use in China. For other feed and feed additive products approved for production and use in China and in the manufacturing country of origin, but for the first time applying for import registration in China, the Ministry of Agriculture shall review the application documents and conduct re-test of sample, and determine whether to issue an import registration certificate for the feed or feed additives after receiving the re-test result report.
- 4) Specifies that if there is a change in producing location, product standard and processing technology and application scope etc within the period of validity of the import registration certificate, the import registration certificate shall be revoked and a re-registration shall be applied.

5) Specifies that the feed and feed additive with an import registration certificate shall be marketed within China by a sales agent established by an overseas enterprise according to the relevant laws, or by a designated qualified Chinese sales agent. The overseas enterprise is not permitted to do direct sale of feed and feed additives within China.

Additionally, specifies the qualifications for a sales agent established and/or designated by the overseas enterprise within the territory of China.

Public comments can be submitted through the following channels:

1. Connect to legislative news link at the Chinese government website (<http://www.chinalaw.gov.cn>), and find the “department draft laws/regulations for comments.”
2. Email: zyc0416@gmail.com
3. Fax: 86-10-59192777
4. Address: 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 March 31, 2012.

Published date: March 1, 2012

“Regulation on Feed and Feed Additive Import Registration (Amended Draft for Comments)”

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 cultured animal products.

Article 2

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

The feed additive in this regulation means the substance added to the feed during the processing, formulation and use with 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 certificate for feed and feed additives before exporting this feed and feed additive to China.

The feed and feed additive shall not be sold and used in China without obtaining an import registration certificate.

Article 4

The overseas enterprise shall file application for import registration of feed and feed additives through its established representative office or agent within the territory of China.

Article 5

The imported feed and feed additive shall comply with the principles of safety, effectiveness and environmental protection, and shall be in compliance with the relevant law and technical standards of the country of origin and China. Feed and feed additive products that have not been approved or have been banned by the country of origin for production and use shall not be registered.

Article 6

When filing application for import registration for feed and feed additives, the applicant should submit application documents and samples in a factual, complete, and standardized manner (with copies in Chinese and English).

Article 7

The application documents should be composed of:

1. Application form for feed and feed additive import registration,
2. Qualification certificate of the representative agent: in case of the representative office established by overseas enterprise within China is designated, an original letter of delegation and a copy of the representative office license should be provided; in case of a designated Chinese agent filing application for import registration, an original letter of delegation and a copy of the business license of the agent shall be provided.
3. Approval certificate for production and use issued by the country of origin, and registration documents issued by country or regions outside of the country of origin.
4. Name of product, effective composition, physical and chemical features, origin of product, composition components; a bacteria trait number issued by authentic agency shall also be provided for micro-bioganisms or fermented products.
5. Processing technology and manufacturing methodology.
6. Quality standard, test methodology and test result report; for product with a maximum dosage limit, the methodology for testing the effective composition in compound feed, concentrate, supplementary feed and premix feed additive shall be provided.
7. Product usage, application scope, use instruction, maximum dosage limit volume if a maximum dosage is applied.
8. Label of country of origin, label sample in Chinese, trade mark, and promotion on how to utilize the product.
9. Packing specification, packing material, storage condition, shelf life and instruction notes.
10. Safety and hygiene certificate for feed and feed additive made from animal origin ingredients or with contents of animal origin ingredient.
11. A review and evaluation report on the chemical structure of the effective component, or a classification report on the animal, plant and micro-organism.
12. An evaluation report on feeding trial, residue digestion dynamics and toxicity safety evaluation shall be provided by a laboratory designated by the Ministry of Agriculture. In case of the application for the import registration of feed additives, the purpose of this feed additive and usage instructions shall be provided, and an analytical and evaluation report on the potential health impact on humans as a result of the residue in the animal product by feeding this feed additive.
13. Stability test report; report on the environmental impact during the process of using this feed additive and pollution preventing measures.

Article 8

The sample shall comply with the following requirements:

1. Samples and test reports of three batches of the product shall be provided; two samples for each batch and each sample volume equivalent to 3 to 5 times of the required volume for test.
2. Provide the relevant standard sample product or chemical comparison product, if needed.

Article 9

In case of import registration for the following feed and feed additive, the Ministry of Agriculture, upon receipt of the application, shall conduct a review and evaluation according to the new feed and feed additive approval procedures, and shall decided, within 10 working days after receipt of the review and evaluation report, on whether to issue an import registration certificate; in case of denial of registration, the Ministry of Agriculture shall notify the applicant in writing with justification.

1. The product is approved for production and use in the country of origin but has not been approved for use in China.

2. The producing technology of the product is significantly different with the China's approved feed and feed additive.

Article 10

In case of the first time application for import registration of feed and feed additive that China has approved for production and use, the Ministry of Agriculture shall conduct review of the application documents within 10 working days upon receipt of the application; then notify the applicant to submit the samples to the laboratory designated by the Ministry of Agriculture for re-test if the review of the application documents proven to be qualified.

Article 11

The re-check of product quality is composed of quality standard review and sample test. The sample test methodology shall comply with the National or Industry Standards if these standards are available. The re-testing laboratory can adjust the test methodology based on the practical situation.

The re-test time should not exceed three months.

Article 12

In case of a dispute on the re-test result, the applicant shall request for another test within 15 working days upon receipt of the re-test report.

Article 13

The Ministry of Agriculture shall decide on whether to issue an import registration certificate to the feed and feed additive within 10 working days upon receipt of the quality re-test report. The Ministry of Agriculture should publically announce the approved registration.

Article 14

The feed and feed additive import registration certificate remains valid for 5 years. The import registration certificate shall be renewed before expiration to continue to export the product to China, and the renewal of the certificate shall be applied six months before the expiration date.

Article 15

The following documents shall be provided for renewal of the import registration certificate :

1. Application form for the renewal of feed and feed additive import registration certificate,
2. Copy of import registration certificate,
3. Qualification certificate of the agent,
4. Approval certificate for production and use by the country of origin,
5. Product name, effective composition, physical and chemical features, product of origin, composition components,
6. Quality standard, test methodology and product test report,
7. Safety and hygiene certificate for feed and feed additives made of animal origin ingredient or with contents of animal origin ingredient,
8. Label of country of origin and Chinese label for the product,
9. A report on the product sales and usage in China.

Article 16

If the production location, product standard and processing technology and application scope etc. are changed within the validity period of the import registration certificate, the import registration certificate shall be revoked and the applicant must re-register.

Article 17

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

import registration certificate:

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

Article 18

The following documents shall be provided for the alteration of registration:

1. Application form for alteration for feed and feed additive import registration,
2. Original import registration certificate,
3. An illustration on the alteration,
4. An official certificate issued by the country of origin on approval of the change,
5. Qualification document of the agent.

Article 19

The relevant organization and personnel responsible for import registration of feed and feed additive shall keep confidential of all technical data provided by the applicant.

Article 20

The feed and feed additive granted with import registration certificate shall be marketed in China by sales agent established within the territory of China by overseas enterprise according to the relevant laws, or by designated qualified sales agent within the territory of China. The overseas enterprise is not permitted to do direct sale of feed and feed additive within the territory of China.

Article 21

The sales agent established by overseas enterprise within the territory of China or a designated sales agent within the territory of China shall meet the following conditions:

Site for business operation and storage facilities suitable for operation of feed or feed additives;

Technical personnel with the knowledge of use or storage of feed or feed additives;

Necessary management system for product quality and safety.

Article 22

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 label in Chinese.

If feed and feed additives are imported in bulk, the importer shall move the goods to the facility designated by the Inspection and Quarantine Agency for packing and labeling before the goods are permitted entry. The imported bulk goods are exempted from labeling if it is moved to a feed facility designated by Inspection and Quarantine Agency directly for feed processing.

Article 23

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

Within the validity period of the certificate, if the country of origin bans the production and 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 certificate and publically announce this accordingly.

Article 24

If the overseas enterprise finds out its imported feed and feed additive to China poses harmful impact on animals and human or has other potential safety risks, the overseas enterprise shall 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 shall recall the product and make record and report to the local feed marketing administrative agency. The recalled product shall be disposed with de-harm treatment or destroyed under the supervision of the feed administrative agency at county level or above.

Article 25

The feed administrative agency of the Ministry of Agriculture and the Province shall conduct supervision on imported feed and feed additives through sampling inspection.

The sampling inspection on imported feed and feed additives shall be conducted according to the quality re-test standards.

Article 26

The Ministry of Agriculture may publically announce the names of the organizations and their representatives in charge of the organizations, the sales agent, the designated sales agent and the registration agent which has violation records of import feed and feed additive.

Article 27

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 means. The same feed and feed additive will not be accepted for re-application for registration within one year period.

For an issued import registration certificate found to be obtained through providing false documents and samples or other deceptive means, the Ministry of Agriculture shall revoke the certificate, and impose a fine of no less than RMB 50,000 but not more than RMB 100,000. The relevant registration agent will not be allowed to file an application for the import registration certificate for three years.

Article 28

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

Article 29

This regulation will be enforced on the enforcement date. The Ministry of Agriculture Decree No. 28 on “Registration Regulation on Imported Feed and Feed Additive” published on August 17, 2000 shall be abolished at the same time.

END UNOFFICIAL TRANSLATION

