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Regulation on Product Approval Numbers for Feed Additive and Premix Feed (Amended Draft for Comments)

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Report Highlights:

On March 1, 2012, China's Ministry of Agriculture (MOA) published a Notice on "Regulation on Product Approval Numbers for Feed Additives and Premix Feed (Amended Draft for Comments)" for public comments, which are due on March 31, 2012. This draft regulation replaces the current "Approval Number Regulation on Feed Additives and Premix Feed," which was enforced on December 14, 1999, and provides further details to 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 Product Approval Number for Feed Additives and Premix Feed (Amended Draft for Comments)” for public comments, which are due on March 31, 2012. This draft regulation replaces the current "Approval Number Regulation on Feed Additives and Premix Feed," which was enforced on December 14, 1999, and provides further details to 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. Although not notified to the World Trade Organization, the regulation will be enforced on May 1, 2012.

BEGIN UNOFFICIAL TRANSLATION**Ministry of Agriculture Notice on Soliciting Comments on "Regulation on Product Approval Numbers for Feed Additives and Premix Feed (Amended Draft for Comments)"**

Published by: Department of Legislative and Policy

Date: March 1, 2012

Key words: Imported Feed, Feed Additives, Registration Regulation

Appendix: Regulation on Product Approval Numbers for Feed Additives and Premix Feed (Amended Draft for Comments)

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 “Regulation on Product Approval Numbers for Feed Additives and Premix Feed (Amended Draft for Comments),” which is to replace the “Regulation on Product Approval Numbers for Feed Additives and Premix Feed,” and hereby solicit comments from the public.

The “Regulation on Product Approval Numbers for Feed Additives and Premix Feed (Amended Draft for Comments)” is composed of 19 articles with the following content:

- 1) Specifies that an approval number shall be obtained for every feed additive and premix feed prior to production; a separate approval number shall be obtained if the feed additive and premix feed is to be produced by a branch of the enterprise; the enterprise shall obtain a separate approval number for producing a product according to contract requirements by another enterprise or animal farm.
- 2) Specifies the documents the enterprise shall provide for applying for product approval number for feed additive and premix feed, including an application form for product approval numbers, a copy of the production license, product formula and production technology, product quality standard and testing methodology, label sample and use instructions, a self-test result report covering factory tested items; in case of application for a production approval number for a new feed additive, a copy of new feed additive certificate issued by the Ministry of Agriculture shall be provided.
- 3) Specifies that in case of applying for approval numbers for more than one products, the samples for re-test shall meet the following requirements: for applying approval number for feed additives, samples

should be provided for each product; in case of premix feed, one sample should be provided for a product for the same animal and same dosage for one identical category of products.

4) Specifies that the enterprise shall apply for a new approval number in case of changes in the technical index related to quality standards or the name of the product after the approval number is issued.

5) Specifies that adulteration, counterfeit and sales of approval number shall be penalized according to Article 37 and Article 38 specified in the “Administrative Measures for Feed and Feed Additives.”

Public comments are welcome and can be submitted through the following channels:

1. Connect to the legislative news link at this 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. Mailing Address: Legislative Coordination Division of Department of Legislative and Policy of the 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.

Publication date: March 1, 2012

Regulation on Product Approval Numbers for Feed Additives and Premix Feed (Amended Draft for Comments)

Article 1

This regulation is formulated based on the “Administrative Measures on Feed and Feed Additives” and for the purpose of strengthening the management of the approval numbers for feed additives and premix feed.

Article 2

The organizations and personnel engaged in production, sales, inspection, testing of feed additives and premix feed shall comply with this regulation.

Article 3

The feed additives referred to in this regulation are the substance added to feed during processing, manufacturing and use in a small or trace volume, including nutritional feed additives and common feed additives.

The premix feed referred to in the regulation is premix feed mainly composed of two or more kinds (varieties) of nutritional feed additives mixed with a carrier or diluent in certain proportion, including complex premix, trace mineral premix and vitamin premix feed.

Article 4

An approval number for each feed additive and premix feed shall be obtained prior to production.

A separate approval number shall be obtained in case the feed additives and premix feed shall be manufactured by a branch of the enterprise.

The enterprise should obtain a separate approval number if it is contracted to produce a product according to requirements of another enterprise or animal farm.

Article 5

The enterprise manufacturing feed additives and premix feed shall apply to the feed administrative agency (hereinafter referred to as the feed administrative agency) affiliated to Provincial, Municipal and Autonomous Regional government for product approval number and provide the following documents:

1. Application form for the product approval number,
2. Copy of the production license,
3. Product formula and processing technology,
4. Product quality standard and testing methodology,
5. Product label sample and use instructions,
6. Self test report covering factory tested items,
7. Copy of new feed additives certificate issued by the Ministry of Agriculture shall be provided for applying for an approval number for new feed additives.

Article 6

The feed administrative agency at the provincial level shall review application documents within ten working days upon receipt of the application; if the review passes, the feed administrative agency shall notify the applicant to deliver the sample to the designated feed test agency for re-test; if the re-test passes, the feed administrative agency at the provincial level shall issue the approval number within ten working days.

The re-test shall cover factory tested items as specified in the quality standard and hygienic items.

Article 7

In case of applying for approval numbers for more than one product at the same time, the samples for re-test shall meet the following requirements:

1. A sample shall be provided for each product for applying for the approval number for a feed additive,
2. In case of premix feed, one sample shall be provided for a product for the same animal and same dosage in one identical category of products.

Article 8

The personnel of the feed administrative agency at the provincial level and the feed test agency shall keep the applicant's technical data confidential if deemed necessary.

Article 9

In case the enterprise's production license for feed additives or premix feed is revoked, cancelled or withdrawn, the feed administrative agency at provincial level shall revoke the approval number accordingly.

Article 10

The format of a feed additive approval number is: x Si Tian Zi (xxxx) xxxxxxx

The format of premix feed approval number is: x Si Yu Zi (xxxx) xxxxxxx

“x” means the shorten name of the province, municipality and autonomous region which issued the approval number,

“(xxxx)” means the year

“xxxxxx”: with the first three digitals means the fixed number for the feed administrative region and the late three means the approval number for the approved product.

Article 11

The fee for re-test of the feed additive and premix feed shall be charged according to China’s relevant regulations.

Article 12

A new approval number shall be applied in the following cases:

1. Technical index change in the product quality standard,
2. Change of product name.

Article 13

Counterfeit, adulteration and transfer of the approval number is banned.

Article 14

If the applicant provides false and counterfeit documents and samples to obtain the approval number, the feed administrative agency at the provincial level shall revoke the approval number, and a fine of not less than RMB 50,000 but not more than RMB 100,000 shall be imposed, and the applicant is banned from applying for product approval number for three years.

Article 15

The adulteration, counterfeit and sales of approval number should be penalized according to article 37 and article 28 stipulated in the “Administrative Measures for Feed and Feed Additives.”

Article 16

The feed administrative agency at provincial level shall cancel the product approval number for the following cases:

1. The new feed additive certificate is revoked,
2. The enterprise’s production license is withdrawn, canceled and revoked.

Article 17

Other violations of this regulation should be treated according to the “Administrative Measures for Feed and Feed Additives.”

Article 18

The premix feed referred to in this regulation composes complex premix, trace mineral premix and vitamin premix.

Complex premix refers to feed mainly composed of at least two nutritional feed additives of minerals,

vitamins and amino acids, which are mixed with carriers or diluents according to a certain proportion. The content of a nutritional feed additive can meet the basic nutritional demand of a special physical stage of the applicable animal. The dosage of such an additive is no less than 0.5% and no more than 10% in the feed, supplementary feed, or animal water.

Trace mineral premix refers to mixture of two or more minerals with carriers or diluents according to a certain proportion. The content of minerals can meet the demand for minerals during special physical stage of the applicable animal. The dosage of such an additive is no less than 0.5% and no more than 10% in the feed, supplementary feed or animal water.

Vitamin premix refers to mixture of two or above vitamins with carriers or diluents according to a certain proportion. The content of vitamins can meet the demand for vitamins during special physical stage of the applicable animal. The dosage of such an additive is no less than 0.5% and no more than 10% in the feed, supplementary feed or water for animal.

Article 19

This regulation will be enforced on May 1, 2012. The Decree No. 23 “Approval Number Regulation on Feed Additives and Premix Feed” published on December 14, 1999 by Ministry of Agriculture will be abolished at the same time.

END UNOFFICIAL TRANSLATION