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Two Administrative Measures on Feed and Feed Additives:

1) Administrative Measures of Production License for Animal Feed and Feed Additives and 2) Administrative Measures of New Feed and New Feed Additives

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Report Highlights:

On February 6, 2012, the Ministry of Agriculture (MOA) jointly published two feed related administrative Measures: 1) Administrative Measures of Production License for Animal Feed and Feed Additives (Draft for Public Comments) and 2) Administrative Measures of New Feed and New Feed Additives (Revised Draft for Public Comments). Both of these Measures provide further clarification on articles contained in the recently published document, "Administrative Measures on Feed and Feed Additives (Gain Report CH12008). Public comments are due before March 10, 2012. Although these two Measures have not been notified to the World Trade Organization, they will take effect on May 1, 2012. This report contains an UNOFFICIAL translation of these two Measures.

Executive Summary:

On February 6, 2012, the Ministry of Agriculture (MOA) published two feed related administrative Measures: 1) Administrative Measures of Production License for Animal Feed and Feed Additives (Draft for Public Comments) and 2) Administrative Measures of New Feed and New Feed Additives (Revised Draft for Public Comments). These Measures replace three former regulations, namely “Verification Measures of Enterprises Manufacturing Animal Feed”, “Administrative Measures of Production License for Feed Additives and Premix Feed” and “Administrative Measures of New Feed and New Feed Additives.” Furthermore, both Measures provide further clarification on articles contained in the recently published document, “Administrative Measures on Feed and Feed Additives” (Gain Report CH12008). Article 17 in the “Administrative Measures of New Feed and New Feed Additives” may have potential trade implications.

Public comments are due before March 10, 2012.

Although these two Measures have not been notified to the World Trade Organization, they will take effect on May 1, 2012.

This report contains an UNOFFICIAL translation of these two Measures.

General Information:
BEGIN TRANSLATION

February 6, 2012

Notice of Ministry of Agriculture on Soliciting Public Comments on Administrative Measures of Production License for Animal Feed and Feed Additive (Draft for Public Comments)

Issued by the Policy and Regulations Department of Ministry of Agriculture on February 6, 2012.

In order to guarantee the quality and safety of animal feed and feed additive, and implement the revised Regulation on the Administration of Animal Feed and Feed Additives, the Ministry of Agriculture has revised the former “Verification Measures of Enterprises Manufacturing Animal Feed”, “Administrative Measures of Production License for Feed Additives and Premix Feed” and “Administrative Measures of New Feed and New Feed Additives”, and created 2 drafts for public comment. These are: “Administrative Measures of Production License for Animal Feed and Feed Additives” (Draft for Public Comments) and “Administrative Measures of New Feed and New Feed Additives” (Revised Draft for Public Comments).

I . The Administrative Measures of Production License for Animal Feed and Feed Additives (Draft for Public Comments) has five chapters with 25 articles in total. The main points are:

1. Explicitly specifies that a production license should be obtained for producing animal feed and feed additives in accordance with the law. The production license for feed additives and premix feed shall be verified and issued by the Ministry of Agriculture; the production license for single feed, concentrated feed, compound feed, and complementary feed shall be verified and issued by the feed administration department under the People’s government at the Provincial level.
2. Uniformly stipulates the conditions and procedures for enterprises that manufacture feed and feed additives and apply for a production license. The application for establishing an enterprise that manufactures feed additive or premix feed shall be processed, examined, and verified on-spot by the feed administration department at the Provincial level, and the verification shall be submitted to the Ministry of Agriculture. The Ministry of Agriculture shall make the decision on whether to issue the production license based on the evaluation result of the Expert Evaluation Committee of the production license for feed and feed additives. The application for establishing other feed manufacturing facilities shall be processed by the feed administration department at the Provincial level, which also decides on whether to issue the production license.
3. Formulates regulations on the authorization of feed and feed additive production, and stipulates that specified requirements shall be met if a feed additive manufacturer authorizes another feed or feed additive manufacturer to produce its products. The two parties shall report respectively to the local feed administration department at the provincial level to record this business relationship, respectively. The authorized agent should organize production in compliance according to product standards, and the authorizing party should instruct and supervise the whole production process. The label of the products manufactured by the agent shall be marked with the name, place of registration, license number and

approval document number of both the authorizing party and the authorized agent.

4. Enhances the supervision for feed manufacturers that have production licenses. Feed or feed additive manufacturers are required to produce products in accordance with the license conditions; and to report to the license issuing authority in case the production conditions changes and affects the quality and safety of the product. By the end of January on an annual basis, the manufacturer should report the production of the previous year to the local department of feed administration at the Provincial level.

II. Administrative Measures of New Feed and New Feed Additives (Revised Draft for Public Comments) has 23 articles in total. The main points are:

1. Clarifies that new feed and feed additives also refers to single feed and feed additives invented domestically, including the following three categories: feed or feed additives that are not permitted in feed production both home and abroad; feed or feed additives that are used abroad but not permitted in feed production in China; feed or feed additives used domestically but its manufacturing or processing has changed significantly.

2. Stipulates that before a new feed or new feed additive is put into production, the inventor or manufacturer should submit to the Ministry of Agriculture an application for verification of the new product, and submit the application materials and samples of the new feed or feed additive based on the requirements of these Measures.

3. Elaborates upon the evaluation procedure and rules. The evaluation of new feed and feed additives shall be conducted in a meeting of experts. Experts who join in the evaluation should perform their duties according to the law and provide science-based, objective, and impartial comments; yet those who have interests with or against the inventor or manufacturer should not participate in the evaluation. The Ministry of Agriculture may, during the process of evaluation, organize an on-site examination on the applicant's experiment or production conditions, or examine or verify the experimental data.

4. Elaborates upon the relevant requirements for the monitoring period of new feed and new feed additives, and specifies that the 5 year monitoring period starts from the date the new feed or new feed additive certificate is issued. During the 5 year monitoring period, other production applications or import registration applications for the same feed or new feed additive shall not be processed, unless the current monitored feed or feed additive is not produced after three years. Other manufacturers that applied for production or import registration in accordance with the former regulations now must submit new materials as required by the Ministry of Agriculture. The Feed Evaluation Committee shall evaluate the applicant's manufacturing process for the new feed or new feed additives.

5. Stipulates that if the certificate holder of a new feed or feed additive intends to expand the application scope of the product, the holder should submit an application to the Ministry of Agriculture, accompanied with the relevant materials, including the evaluation report on the product's effectiveness and safety, which is written by an institution designated by the Ministry of Agriculture. The Ministry of Agriculture shall conduct an evaluation in accordance with the evaluation procedure for new feed and new feed additive as stipulated in this Measure.

Public comments are open until March 10, 2012. Please send your comments to:

1. Please visit China government law website (<http://www.chinalaw.gov.cn>), and click 'comments collection system for departmental regulation draft' on the left side of the homepage.
2. Please email to: zyc0416@gmail.com.
3. Please fax us at 010-59192777
4. Mailing Address: Legislative Coordination Office of Policy and Regulation Department of the Ministry of Agriculture (No.11 Nongzhan Nanli Chaoyang District Beijing 100125).

Appendixes:

1. Administrative Measures of Production License for Animal Feed and Feed Additives (Draft for Public Comments)
2. Administrative Measures of New Feed and New Feed Additives (Revised Draft for Public Comments)

Appendix 1

Administrative Measures of Production License for Animal Feed and Feed Additives (Draft for Public Comments)

Chapter 1 General Principles

Article 1

These Measures are formulated, in accordance with the Regulation on the Administration of Animal Feed and Feed Additives, in an effort to strengthen the administration of production license for feed and feed additives, maintain production order of feed and feed additives, and ensure the quality and safety of feed and feed additives.

Article 2

Manufacturing of feed or feed additives within the People's Republic of China should comply with these Measures.

Article 3

The production license for feed additives and premix feed should be verified and issued by the Ministry of Agriculture. The production license for single feed, concentrated feed, complete feed, and complementary feed should be verified and issued by the feed administration department under the people's government at the Provincial level (hereinafter referred to as the feed administration department at the Provincial level).

The feed administration department at the Provincial level may authorize its subordinate feed administration department to be responsible for the processing of applications for production license for single feed, concentrated feed and complementary feed.

Article 4

The Ministry of Agriculture establishes an Expert Evaluation Committee of production license for feed and feed additives, which is responsible for the technical evaluation on the production license for feed additives and premix feed.

The feed administration department at the Provincial level establishes the Expert Evaluation Committee of production license for feed and feed additives, which is responsible for the technical evaluation on the production license for single feed, concentrated feed and complementary feed within their respective administrative area.

Article 5

All organizations or individuals have the right to report any violations related to the production license. The Ministry of Agriculture and the feed administration department at the Provincial level should investigate and settle the cases under their jurisdiction.

Chapter 2 Verification and Issuing of Production License

Article 6

The establishment of an enterprise manufacturing feed or feed additives shall conform to the development plan and policies for the feed industry and meet the following conditions:

- (1) Equipped with facilities, equipment and storage facilities suitable for the production of feed or feed additives;
- (2) Possession of the full-time technical personnel qualified for the production of feed or feed additives;
- (3) Possession of necessary institutions for the inspection of product quality, personnel, facilities and quality management regulations;
- (4) Possession of the production environment that meets national requirements for safety and sanitation;
- (5) Possession of the pollution prevention and control measures that meet national requirements for environmental protection;
- (6) Meet other conditions prescribed in the management guidelines for quality and safety of feed and feed additives formulated by the Ministry of Agriculture.

The specific conditions for establishing an enterprise manufacturing feed and feed additives are formulated and published by the Ministry of Agriculture.

Article 7

The applicant for establishing an enterprise manufacturing feed and feed additives should file an application to the local feed administration department at the Provincial level, and submit the required application materials to the Ministry of Agriculture.

If an enterprise applies for manufacturing feed additive and premix feed, the feed administration department at the Provincial level shall, within 10 workdays starting from the date of accepting the application, carry out document examination and organize field inspection, and submit the relevant materials and examination and verification results to the Ministry of Agriculture. The Ministry of Agriculture will, upon receipt of the application materials and examination and verification results, transfer all these documents to the Expert Evaluation Committee of production license for feed and feed additives for evaluation; if content of the feed additive to be manufactured by the applicant (except feed additives which are mixed with carriers or diluents on the basis of a certain proportion) is lower than required for safe use of the feed additive, the national feed evaluation committee should conduct evaluation on its safety, effectiveness and impact on the environment. The Ministry of Agriculture shall, within 10 workdays, make the decision on whether to issue a production license based on the evaluation, and copy the decision to the feed administration department at the Provincial level.

If an enterprise applies for manufacturing single feed, concentrated feed, complete feed and complementary feed, the feed administration department at the Provincial level shall carry out document examination within 10 workdays starting from the date of accepting the application. Afterwards, if the document examination is successful, then a field inspection shall be conducted, and a decision shall be made on whether to issue a production license based on the inspection result within 10 working days.

The format of production license shall be specified uniformly by the Ministry of Agriculture.

Article 8

The applicant shall go through the procedure for industrial and commercial registration by presenting its production license.

Article 9

The enterprise that has obtained the production license for feed additive and premix feed should file an application to the feed administration department at the Provincial level for product approval number.

Article 10

If the enterprise manufacturing feed and feed additives authorizes other manufacturers of feed and feed additives to produce the product, the following requirements should be met, and the two parties should report respectively to the local feed administration department at the Provincial level for record:

1. The authorized product should be within the scope of production license of the two parties; if the authorized product is a feed additive or premix feed, the two parties should also obtain the product approval number;
2. The two parties shall sign a contract of authorization, specifying each party's rights and obligations in terms of production technology and quality control of the authorized product in accordance with the law.

The authorized party should organize production in accordance with product standard; the authorizing party should instruct and supervise the whole process of production.

The label of the authorized product should be marked with the name, place of registration, license number and product approval number of the two parties.

Article 11

The production license shall remain valid for five years.

If the production of the feed or feed additive shall continue after expiration, an extension application shall be filed to the feed administration department at the provincial level six months prior to the expiration date, accompanied by materials required by the Ministry of Agriculture.

Chapter 3 Alteration and replacement of production license

Article 12

In case of any of the following circumstances, the enterprise manufacturing feed or feed additives should apply for an alteration to its production license in accordance with the established application procedure:

1. Increase product category, variety and production line;
2. In case feed additives are manufactured with a lower content than required for the safe use of the feed additive; unless the feed additive is mixed in a certain proportion with carriers or diluents;
3. In case the production site is relocated;
4. Other circumstances which are stipulated by the Ministry of Agriculture.

Article 13

In case of any of the following circumstances, the enterprise manufacturing feed or feed additives should, within 10 days, file an application to the local feed administration department at the Provincial level for an alteration, together with relevant materials. The license issuing authority shall, in accordance with the law, process the alteration application. The production license number and validity

will remain unchanged after alteration:

- 1 Alteration to the name of the enterprise;
- 2 Alteration to the legal representative of the enterprise;
- 3 Alteration to address of registration or the name of the registered address;
- 4 Alteration to the name of the production location;
- 5 Reduce product category and variety

Article 14

In case the production license is lost or damaged and destroyed, an application for replacement shall be submitted within 10 days upon the date of loss or destroy to the issuing authority, which will issue the license replacement accordingly; if the license is lost, the license holding enterprise should also make a declaration of loss on the local media.

Chapter 4 Supervision and Administration

Article 15

The enterprise manufacturing feed or feed additives should organize production in compliance with the licensed conditions. If the production condition changes and is likely to affect the quality and safety of the product, the enterprise should report to the license issuing authority through the local county level feed administration department.

Article 16

The feed administration department at or above county level under the people's government should strengthen supervision and inspection on enterprises manufacturing feed or feed additives, investigate and prosecute violations of law, and establish record of supervision and administration on feed and feed additives with inspection and prosecution of violation records.

Article 17

The manufacturer of feed and feed additives should fill in the record form by the end of January each year reporting the general production of the previous year to the local department of feed administration at Provincial level for record. The feed administration department at the Provincial level should collect the record information of enterprises and report to the Ministry of Agriculture by the end of March each year.

Article 18

In case of the following situations, the issuing authority shall cancel the production license:

1. The production license is revoked, withdrawn or suspended in accordance with the law;
2. The production license is not renewed according to regulations after expiration;
3. The enterprise's production is suspended for one year or above, or terminated in accordance with the law;
4. If the enterprise applies for cancellation of its license;
5. If the enterprise fails to submit record materials, or the submitted materials failing to meet the requirements and the enterprise refuses to make corrections;
6. Other situations where the license should be cancelled in accordance with the law.

Chapter 5 Legal Responsibility

Article 19

If the applicant applies for a production license by concealing relevant information or providing false materials, the feed administration department shall not process the application or not issue the license, and shall give the applicant a warning; the applicant is not permitted to submit a second application within one year.

Article 20

In case a license for a new feed or feed additive is obtained by deceptive means or through bribery, the enterprise manufacturing feed or feed additives shall be penalized in accordance with Article 36 of the Regulation on the Administration of Animal Feed and Feed Additives.

Article 21

If the enterprise manufacturing feed or feed additives is engaged in any of the following situations, it shall be penalized in accordance with Article 38 of the Regulation on the Administration of Animal Feed and Feed Additives:

1. Manufacturing feed or feed additives beyond the scope of license;
2. Continues to manufacture feed or feed additives after the production license is expired;
3. Obtained a production license but does not follow the conditions stipulated in Article 6 of these Measures for the manufacturing of feed or feed additives.

Article 22

If the enterprise manufacturing feed or feed additives fails to check the relevant license for purchased single feed, feed additives, drug feed additives, or premix feed, the enterprise shall be penalized in accordance with Article 40 of the Regulation on the Administration of Animal Feed and Feed Additives.

Article 23

Any other violations of these Measures are subject to penalty in accordance with relevant stipulations of the Regulation on the Administration of Animal Feed and Feed Additives.

Chapter 6 Supplementary Provisions

Article 24

The premix feed referred to in these Measures composes complex premix, 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 nutritional feed additive can meet the basic nutritional demand of special physical stage of the applicable animal. The dosage of such additive is no less than 0.5% and no more than 10% in the feed, complementary feed or water for animal.

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 additive is no less than 0.5% and no more than 10% in the feed, complementary feed or water for animal.

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 additive is no less than 0.5% and no more than 10% in the feed, complementary feed or water for animal.

Article 25

These Measures will be enforced on May 1, 2012. The previous "Examination Measures of Enterprise Manufacturing" and "Administrative Measures of Production License for Feed Additives and Premix Feed" will be abolished at the same time.

Appendix 2

Administrative Measures of New Feed and New Feed Additives (Draft for Public Comments)

Article 1

These Measures are formulated, in accordance with the Regulation on the Administration of Animal Feed and Feed Additives, in an effort to strengthen the administration of new feed and new feed additives, and ensure the quality and safety of farmed animal products.

Article 2

The new feed and new feed additives in these Measures refers to single feed and feed additives

developed and manufactured within China, which include three categories:

1. Feed or feed additives that are not permitted to use both home and abroad;
2. Feed or feed additives that are in use abroad but not permitted to use in the production process in China;
3. Feed additives approved for use in China but with significant change in manufacturing technique.

Article 3

The research and manufacturing of new feed and new feed additives shall comply with the principle of science-based, safety, effectiveness, and environmental friendliness, and guarantee the quality and safety of new feed and new feed additives.

Article 4

The Ministry of Agriculture is responsible for the approval of new feed and new feed additives. The National Feed Evaluation Committee (hereinafter referred to as the Evaluation Committee) organizes evaluation on the safety, effectiveness and the impact on environment of the new feed and new feed additives.

Article 5

Prior to production of a new feed or new feed additive, the developer or manufacturer (hereinafter referred to as the applicant) should file an application to the Ministry of Agriculture for verification of new product, and submit the application materials and samples of the new feed or new feed additive.

Article 6

Application materials include:

1. Application form for verification of the new feed and new feed additive;
2. Name of product and the justification for the name, the purpose of developing and manufacturing this product;
3. Appraisal report on the effective components and chemical structure, physical and chemical features, or appraisal report on categorization of animals, plants and microbes; and in case of microbe products or fermented products, the bacterial strain preservation number produced by the national institution of bacteria preservation designated by the Ministry of Agriculture should be presented;
4. Scope of application, method of use, the recommended amount in the complete feed or mixed food for animals, and the maximum amount if needed;
5. Manufacturing technique, methods and stability test report;
6. Quality Standard (draft) and its compiling interpretations, and test report of product; If a maximum amount is stipulated, the test method for effective components should also be provided in the complete feed, concentrated feed, complementary feed, and premix feed;
7. The evaluation report of product effectiveness and safety produced by the experimental institution designated by the Ministry of Agriculture (including tolerance analysis report of target animal, toxicology safety analysis report, metabolism and residue analysis report); in case of an application for evaluation of a new feed additive, the analysis report on the potential impact of the residue of the new feed additive in the farmed animal product on human health should also be presented.
8. The label, packing requirement, storage conditions, shelf-life and attentions;
9. Summary of pilot scale production and “three wastes” treatment report;
10. Declaration of non-infringement to other people’s patent.

Detailed requirements for application materials will be stipulated by the Ministry of Agriculture.

Article 7

Samples should meet the following requirements:

1. Samples should be obtained from pilot scale production line or industrialized production line;
2. Samples of 3 consecutive batches and inspection reports should be provided for each product; 4 samples per batch; the amount of each sample should be no less than 3 to 5 times of the required volume for testing;
3. If needed, the related standard product or comparison chemical product should be provided.

Article 8

The experimental institution for effectiveness and safety evaluation should, in compliance with technical guideline formulated by the Ministry of Agriculture or technical standard widely accepted by the industry, conduct test in a science-based, objective and impartial manner, and should not have any interests with or against the developer or manufacturer.

Article 9

The Ministry of Agriculture shall, within 5 working days from accepting the application, transfer the application materials and samples to the feed evaluation committee for evaluation.

Article 10

The evaluation of the new feed and new feed additive shall be conducted in the form of an evaluation meeting, which should be participated by a minimum of nine or more experts from the committee, and one or two additional experts from outside the committee if needed. Experts at the meeting exercise voting rights to evaluation items. Evaluation comments and a summary of the meeting shall be written down and signed by all experts. Dissimilar comments shall be written down if any.

Article 11

Evaluation experts shall perform their responsibilities according to law, and shall make the evaluation in a science-based, fair and impartial manner.

The experts, who share or are against the interests of the developer and manufacture, shall not participate in evaluation meeting.

Article 12

If the application is passed at the evaluation meeting in principle, the evaluation committee shall transfer the samples to the feed quality inspection institute designated by the Ministry of Agriculture for quality re-test. The quality re-test institute should conduct quality test within 3 months from the date of accepting the samples, and submit the re-test report and its comments to the evaluation committee, and copy the same to the applicant at the same time. The re-test period can be extended for one month if a special test method is needed.

Quality re-test includes standard review and sample test. If the maximum dosage is applied, the testing method of the major components in the feed product shall also be verified.

If the applicant holds different comments on the quality re-test result, the applicant may apply for re-test within 15 working days from the date of accepting the test report.

Article 13

During the evaluation process, the Ministry of Agriculture may organize field inspection on the applicant's experiment or production conditions, or organize verification or inspection on the experimental data.

Article 14

The Evaluation Committee shall, within nine months after receiving samples and application materials of new feed or feed additives, produce the evaluation result to the Ministry of Agriculture. However, if the Evaluation Committee, with the approval of the Ministry of Agriculture, requests the applicant to conduct the relevant trials, the evaluation period can be extended for additional three months.

Article 15

The Ministry of Agriculture shall, within ten 10 working days counting from the date of receiving evaluation result, make a decision on whether to issue a certificate to the new feed or feed additive. If the decision is yes, it will be promulgated by the Ministry of Agriculture, together with the quality standard of this product. When the new feed or new feed additive is put into production, it shall be monitored or spot-checked according to the quality standard.

If the decision is no, the applicant shall be informed in writing with justifications by the Ministry of Agriculture.

Article 16

Prior to the production of the new feed and new feed additive, the manufacturer shall obtain the production license in accordance with the relevant regulations of the Ministry of Agriculture; and also the product approval number for the new feed additive.

Article 17

The monitoring period for new feed and new feed additives is five years, starting from the date the certificate for new feed and new feed additive is issued.

During the 5 year monitoring period, other production applications or import registration applications for the same feed or new feed additive shall not be accepted, unless the currently monitored feed or the feed additive is not produced for three years. Other manufacturers which applied for production or import registration in accordance with the former regulations should re-submit materials as required by the Ministry of Agriculture. The Feed Evaluation Committee shall evaluate the applicant's manufacturing technique for the new feed or new feed additives.

Article 18

The enterprise manufacturing new feed and new feed additive shall collect information about product quality, safety of target animal and quality and safety of farmed animal products, and report to the Ministry of Agriculture.

The Ministry of Agriculture shall monitor the quality and safety of new feed and new feed additives, and if necessary, organize re-evaluation. In case of safety problems, the Ministry of Agriculture shall revoke the certificate of new feed and new feed additives and promulgate the same.

Article 19

Relevant organization and personnel engaged in evaluation of new feed and new feed additives shall keep confidential the applicant's technical material that needs to be kept confidential.

Article 20

If the certificate holder of a new feed and feed additive intends to expand the application scope of the product, he should submit an application to the Ministry of Agriculture, accompanied by the relevant materials including the evaluation report on effectiveness and safety produced by the experimental institution designated by the Ministry of Agriculture. And it shall be evaluated by the Ministry of Agriculture in accordance with the evaluation procedure of new feed and new feed additives stipulated in these Measures.

Article 21

If the applicant applies for evaluation by providing false material, samples or by other deceptive means, the Ministry of Agriculture shall not accept or approve the application, and will give the applicant a warning. The applicant is not permitted to re-apply for evaluation on new feed and new feed additive within one year.

In case the applicant obtains a certificate of new feed and new feed additives by providing false material, samples or by other deceptive means, the applicant shall be penalized in accordance with Article 36 of the Regulation on the Administration of Animal Feed and Feed Additives.

Article 22

Any other violations of these Measures shall be penalized in accordance with relevant stipulations of the Regulation on Administration of Animal Feed and Feed Additives.

Article 23

The Measures shall be enforced on May 1, 2012.

END TRANSLATION