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Regulation on the Administration of Feed and Feed Additives (FINAL)

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Report Highlights:

On November 3, 2011, China's State Council published Decree No.609 on Regulation on the Administration of Feed and Feed Additives, which was approved by China's State Council on October 26, 2011, and will enter into force on May 1, 2012. This report contains an UNOFFICIAL translation of the Regulation. The Feed and Feed Additive Regulation (Draft) was published on February 20, 2010 (GAIN 10009). The Regulation (FINAL) was not notified to the World Trade Organization. Preliminary study of the Regulation (FINAL) shows no significant changes from the Draft. U.S. industry is recommended to pay attention to Chapter 2 for Verification and Registration for exports of feed and feed additives to China.

Executive Summary:

On November 3, 2011, China's State Council published Decree No.609 on Regulation on the Administration of Feed and Feed Additives, which was approved by China's State Council on October 26, 2011, and will enter into force on May 1, 2012. The Feed and Feed Additive Regulation was firstly published and took effect on May 29, 1999. In response to development of the feed industry, China's Ministry of Agriculture amended the Regulation and published The Feed and Feed Additive Regulation (Draft) for comments on February 20, 2010. Post published a report on the Regulation (Draft) as FAIRS report CH10009. The Regulation (FINAL) was not notified to the World Trade Organization. Preliminary study of the Regulation (FINAL) shows no significant changes from the Draft. U.S. industry is recommended to pay attention to Chapter 2 for Verification and Registration for exports of feed and feed additives to China.

BEGIN TRANSLATION

Regulation on the Administration of Animal Feed and Feed Additive

Decree No.609

Regulation on the Administration of Animal Feed and Feed Additive has been revised and passed by the State Council in the 177th Standing Conference on October 26, 2011. The following is the new Regulation on the Administration of Animal Feed and Feed Additive which will be implemented on May 1st, 2012.

-Premier Wen Jiabao

November 3rd, 2011

Chapter 1 General Provisions

Article 1 These Regulations are formulated with a view to strengthening the administration of feed and feed additive, improving the quality of feed and feed additive, ensuring quality of animal products, and maintaining people's health.

Article 2 The term "feed" referred to herein means the product used as animal food after industrialized processing and manufacturing, including single feed premix, concentrated feed, complete feed and supplemental feed for herbivore's refined feed.

The term "feed additive" referred to herein means the small or minim amount of substance added during the processing, manufacturing and use of feed, including nutrititional feed additive and general feed additive.

The list of feed raw materials and the list of feed additives shall be formulated and published by the department of agriculture administration of the State Council.

Article 3 The department of agriculture administration of the State Council is responsible for nationwide supervision and administration of feed and feed additive.

The departments responsible for the administration of feed and feed additive under the people's governments at or above county level (hereinafter referred to as feed administration departments) shall be responsible for supervision and administration of feed and feed additive within their respective administrative areas.

Article 4 The local people's governments at or above county level shall strengthen supervision and administration of feed and feed additive within their respective administrative areas, establish and improve the supervision system to ensure its smooth implementation.

Article 5 The producers or operators of feed and feed additive shall establish and improve quality and safety regulations and be responsible for the quality and safety of the feed and feed additive they produce or operate.

Article 6 Any organization or individual shall have the right to report any action violating the Regulations during the production, operation and use of feed or feed additive and shall have the right to present opinions and suggestions on supervision and administration of feed and feed additive.

Chapter 2 Verification and Registration

Article 7 The State encourages research on new feed and feed additives.

The research and production of new feed and feed additives shall comply with the principles of science based, safeness, effectiveness and environment friendliness and guarantee the quality and safety of new feed and feed additives.

Article 8 With respect to a newly invented feed or feed additive, before putting into production, the inventor or the manufacturer shall submit an application of verification to the department of agriculture administration of the State Council and provide samples of the submitted new feed or new feed additive as well as the following materials:

The name, major components, physical and chemical properties, research method, production process, quality standard, test method, test report, stability test report, report of environmental impact as well as prevention and control measures of pollution of the said new feed or feed additive

The effect in feeding experiment, dissolution trends of the residues, toxicology safety analysis report of the said new feed or new feed additive issued by the experimental institutions designated by the department of agriculture administration of the State Council;

If a new feed additive is applied, the adding purpose and instruction for use shall also be illustrated. Besides, an analysis report shall be provided demonstrating possible effects on human health.

Article 9 The department of agriculture administration of the State Council shall, within five 5 workdays starting from the date of accepting the application, submit the application materials and samples to National Feed Evaluation Committee to evaluate the safety, effectiveness and environmental impact of the said new feed or new feed additive.

National Feed Evaluation Committee is composed of experts in fields of animal raising, feed processing, animal nutrition, toxicology, pharmacology, metabolism, sanitation, chemical synthesis, biotechnology, quality standard, environmental protection, food safety risk assessment and other related fields. National Feed Evaluation Committee runs the evaluation process by holding a meeting which shall be composed of at least 9 experts from the Committee. If needed, one or two experts not in the Committee will attend the meeting. Experts in the meeting exercise voting rights to evaluation items. Evaluation opinions and a summary of this meeting shall be written down and signed by all experts. Different opinions shall be written down if there is any. Evaluation experts shall discharge their responsibilities in a fair and impartial manner, keep secrets to the materials and shall follow the challenge regulations if needed to.

National Feed Evaluation Committee shall, within 9 months after receiving samples and application materials of new feed or feed additive, hand in the evaluation result to the department of agriculture administration of the State Council. However, if the National Feed Evaluation Committee decides to have the applicant to run relative trials, with approval of the department of agriculture administration, the evaluation can be delayed for 3 months.

The department of agriculture administration of the State Council shall, within ten 10 workdays starting from the date of receiving evaluation result, make a decision on whether to issue a certificate for the new feed or feed additive or not; if the decision is not to, the inventor or the manufacturer shall be informed in writing and given reasons.

Article 10 A certificate of new feed or feed additive shall be issued by the department of agriculture

administration of the State Council. In the meantime, within its authority, it shall publish the product quality standard of this new feed or feed additive.

Article 11 The monitoring period of new feed or feed additive is 5 years. During the monitoring period, other production and import registration applications with regard to the same new feed or new feed additive shall not be accepted. But an exception shall be made for not putting into production more than 3 years.

During the monitoring period, production enterprises shall collect and report the information about the quality stability of the new feed or feed additive and the impact on the quality and safety of animal products which are reported to the department of agriculture administration of the State Council. The department of agriculture administration of the State Council shall organize the tracking and monitoring of the quality and safety of new feed and feed additive. If it is confirmed that new feed or feed additive has a safety problem, the certificate shall be revoked and a public notice on suspension of its use shall be issued.

Article 12 Where feed or feed additive which is being used in a foreign country is exported to China for the first time, the exporter shall authorize an agent in China to apply for registration to the department of agriculture administration of the State Council, and provide samples of the said feed or feed additive as well as the following materials:

The trademark, label and condition of its popularization and application;

The certificates indicating the producing country has approved the production and sale, and the registration materials in countries other than the producing country;

The major components, physical and chemical properties, research method, production process, quality standard, test method, test report, stability test report, report of environmental impact as well as prevention and control measures of pollution of the said new feed or feed additive

The effect in feeding experiment, dissolution trends of residues, toxicology safety analysis report of the said new feed or new feed additive issued by the testing institutions designated by the department of agriculture administration of the State Council

If a feed additive is applied for import registration, the adding purpose and instruction for use shall also be illustrated. Besides, an analysis report shall be provided demonstrating possible effects on human

health.

Following the procedures listed in article 9, new feed or feed additive inspection shall be organized by the department of agriculture administration of the State Council which will decide later whether to issue an import registration certificate or not.

Where feed or feed additive of which use has been allowed in the People's Republic of China, and of which production and use has been approved in the exporting country, the provisions in Article 1 and Article 2 hereof shall be complied with. The department of agriculture administration of the State Council shall, within five 10 workdays starting from the date of accepting the application, review the application materials and submit the sample to a designated institution for testing. If the sample passes the test, the department of agriculture administration of the State Council shall, within ten 10 workdays, issue an import registration certificate for the said feed or feed additive.

The valid period of a registration certificate for imported feed or feed additive is 5 years. If the exporter wants to continue to export the feed or feed additive to China after expiration, it shall apply for extension of the registration 6 months prior to the expiration date.

It is forbidden to import any feed or feed additive without an import registration certificate.

Article 13 Where an applicant of the verified or registered feed or feed additive containing new compounds submits undisclosed test data obtained by the applicant and other data, the State shall protect these data.

Within 6 years starting from the verification or registration date, if any other applicant uses the preceding data to apply for the verification or registration of feed or feed additive without the consent of the applicant who has obtained verification or registration, the department of agriculture administration shall not approve the application unless otherwise the applicant submits the data obtained by itself.

Except the following circumstances, the department of agriculture administration shall not disclose the data prescribed in the first paragraph:

Need of public interest;

Measures have been taken to ensure such information won't be improperly used for commercial purpose.

Chapter 3 Production, operation and use

Article 14 The establishment of an enterprise manufacturing feed or feed additive shall conform to the development plan and policies of feed industry and possess the following conditions:

Possession of the plant, equipment and storage facilities suitable for the production of feed or feed additive;

Possession of the full-time technical personnel qualified for the production of feed or feed additive;

Possession of necessary institutions for the inspection of product quality, personnel, facilities and quality management regulations;

Possession of the production environment that meets national requirements on safety and sanitation;

Possession of the pollution prevention and control measures that meet national requirements on environmental protection;

(6) Other conditions prescribed in the management guidelines for production quality and safety of feed and feed additive formulated by the department of agriculture administration of the State Council.

Article 15 The applicant who applies for establishment of an enterprise manufacturing feed additive or premix shall file an application to the feed administration department under the people's government of the province, autonomous region or municipality directly under the Central Government. Where the establishment is applied for, the feed administration department under the people's government of the province, autonomous region or municipality directly under the Central Government shall, within 20 workdays starting from the date of accepting the application, carry out written examination and field inspection and submit related materials and examination comment to the department of agriculture administration of the State Council; the competent department of agriculture administration of the State Council shall organize evaluation after the receipt of the materials and examination comment, and shall, within 10 workdays starting from the date of receiving evaluation result, make a decision on whether to issue a production license or not, and make a copy of the decision for the feed administration department under the people's government of the province, autonomous region or municipality directly under the Central Government.

Where the establishment of any other feed production enterprise is applied for, the feed administration

department under the people's government of the province, autonomous region or municipality directly under the Central Government shall, within 10 workdays starting from the date of accepting the application, carry out written examination and organize field inspection, and shall, within 10 workdays, make a decision on whether to issue a production license or not based on the inspection result.

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

The valid period of the production license is 5 years. If the production of feed or feed additive will be continued after expiration, an extension application shall be submitted 6 months prior to the expiration date.

Article 16 After an enterprise manufacturing feed additive or premix obtains a production license issued by the department of agriculture administration of the State Council, the feed administration department under the people's government of the province, autonomous region or municipality directly under the Central Government shall issue a corresponding product approval number pursuant to the provisions of the department of agriculture administration of the State Council.

Article 17 An enterprise manufacturing feed or feed additive shall check or inspect the purchased feed raw materials, single feed, feed additives, drug feed additives, premix and ingredients for producing feed additives, pursuant to the provisions of the department of agriculture administration of the State Council and related standards.

If feed manufacturers purchase single feed, feed additive, drug feed additive or premix which is restricted in use, it should abide by restriction provisions listed by department of agriculture administration of the State Council. It is forbidden to use any substances not in the list of feed raw materials, the list of feed additives or the list of drug feed additives published by the department of agriculture administration of the State Council to produce feed.

An enterprise manufacturing feed or feed additive shall record, according to the fact, the name, origin, quantity, shelf life, approval document certificate number and quality inspection, manufacturer's name or supplier's name, its contact method and purchase date. The storage period of the record shall not be

less than 2 years.

Article 18 An enterprise manufacturing feed or feed additive shall organize its production according to the guidelines for product quality and the management standards for quality and safety of feed and feed additive issued by department of agriculture administration of the State Council, as well as standards for safety use of feed additives. It should implement effective control over production process and execute a system of recording the production and keeping some samples for observation.

Article 19 When manufacturing feed or feed additive, the enterprise shall inspect the quality of the products. If the products are up to standard upon inspection, a certificate of product quality shall be attached. The products without quality inspection, failed the inspection or without a certificate of product quality shall not be sold.

An enterprise manufacturing feed or feed additive shall record, according to the fact, the name, quantity, production date, production batch and product quality conformity number of the sold feed or feed additive as well as buyer's name and its contact methods and sales date. The storage period of the record shall not be less than 2 years.

Article 20 The sold feed or feed additive shall be packaged. The packages shall conform to national provisions on safety and sanitation.

Feed directly sold to farms by feed manufacturers can be delivered by tankers. Tankers should conform to the rules of safety and sanitation. A label made according to article 21 should be attached with the tanker.

The package of feed or feed additive which is flammable or has any other special requirements shall bear warning signs or notes, and shall specify matters needing attention in storage and transportation.

Article 21 The label shall be attached to the package of feed or feed additive. The label shall, in Chinese or by proper symbols, mark the name of the product, ingredients, pledged values of component analysis, net weight, storage condition, instructions for use, precautions, production date, shelf life, manufacturer's name and address, approval document number and product quality standard. If a drug feed additive is added, a sign of "a drug feed additive inside" as well as its common name, content and

withdraw time shall be put up there. If feed is from animal source other than milk or milk products, a sign of “Do not feed to ruminants” shall be put up there.

Article 22 An enterprise operating feed or feed additive shall meet the following requirements:

Possession of the business workshop and storage facilities suitable for the operation of feed or feed additive;

Possession of technical personnel with the knowledge on the use and storage of feed or feed additive;

(3) Possession of a product quality and safety management system.

Article 23 An enterprise operating feed or feed additive, when purchasing for stock, shall check the label of the product, the certificate of product quality and corresponding approval documents.

An enterprise operating feed or feed additive shall not open then sub-package feed or feed additive and shall not reprocess or add any substance into feed or feed additive.

It is forbidden to operate any produced substances not in the list of feed raw materials, the list of feed additives or the list of drug feed additives published by the department of agriculture administration of the State Council.

A feed and feed additive operator shall set up product purchase & sales record which records, according to the fact, product name, approval document certificate number, size, quantity, shelf life, manufacturer’s name or supplier’s name, its contact method and purchase & sales date. The record shall be kept at least 2 years.

Article 24 The imported feed and feed additive shall be packaged, according to Chinese regulations on safety and sanitation, with Chinese labels conforming to the provisions of Article 21 hereof.

Entry-exit inspection and quarantine administration shall conduct inspection and quarantine of the imported feed and feed additive according to law and check the packages and Chinese labels. Those packages or labels which do not meet the requirement are not allowed to be sold in China.

A foreign enterprise or individual who wants to sell feed or feed additive in the territory of China can not conduct direct sales to China. Instead, it shall set up a sales organization or entrust an eligible agency in the territory of China.

A foreign enterprise or individual who wants to sell feed or feed additive in the territory of China cannot conduct direct sales to China. Instead, it shall set up a sales organization or entrust an eligible agency in the territory of China.

Article 25 Farmers shall use feed according to the instructions and precautions stated on product label. If feed additives are to be mixed in feed or water, instructions and precautions of feed additives shall be followed. Safety use regulations of feed additives formulated by the department of agriculture administration of State Council should be abided by.

Farms that make their own feed shall conform to relative regulations formulated by the department of agriculture administration of the State Council and shall not sell their feed to the market.

Farms that use restricted materials to feed animals shall conform to the restriction regulations formulated by the department of agriculture administration of the State Council. It is forbidden to add any substances to feed or water and others which cause direct or potential damage to human health or feed those substances directly to animals. It is forbidden to add any animal-source components into the feed of ruminants, except milk and dairy products.

Article 26 The department of agriculture administration of the State Council and the feed administration departments under the people's governments at or above county level shall strengthen education on quality and safety of feed and feed additive, improve farmers' sense of quality and safety, and shall instruct farmers to make safe and proper use of feed and feed additive.

Article 27 In use, if a feed or feed additive is proved to be harmful to animals, human health or environment, the department of agriculture administration of the State Council shall order it to stop being used and put up a public notice.

Article 28 When an enterprise manufacturing feed or feed additive finds the feed or feed additive it produces is harmful to animal or human health or is likely to have safety problem, it shall immediately stop the production and inform the operators to stop selling and the users to stop using, report the matter to the feed administration department, initiatively recall the products and record the situation of recalling and informing. The recalled feed or feed additive shall be treated or destroyed without

generating any harm under the supervision of the feed administration department.

When an enterprise operating feed or feed additive finds the product it sells has the circumstances prescribed in the preceding paragraph, it shall immediately stop the sales, inform the manufacturer, supplier and users and report to the feed administration department and record the situation of informing.

When farmers using feed or feed additive finds the product they use has the circumstances prescribed above, it shall immediately stop the use, inform the supplier and report to the feed administration department.

Article 29 It is forbidden to produce, operate or use feed or feed additive that has no license certificate or that is being restricted to use.

It is forbidden to operate or use feed or feed additive without product label, production license or product quality certificate. It is strictly prohibited to operate or use feed additive or premix with no product authentication code. It is forbidden to operate or use imported feed or feed additive with no import registration certificate.

Article 30 It is forbidden to illustrate and publicize that feed or feed additive has the prevention and/or treatment effects on animal diseases. Nevertheless, the illustration of the functions of the drug feed additive is allowed if it is added.

Article 31 The department of agriculture administration of the State Council and the feed administration departments under local people's governments above county level may execute supervision and inspection on quality and safety of feed and feed additives, according to which quality and safety warnings shall be made.

Article 32 The department of agriculture administration of the State Council and the feed administration departments under the people's governments at or above county level shall formulate plans for supervision and spot check of feed and feed additive and organize the implementation of the plans. The work on the supervision, spot check and testing of feed and feed additive shall be undertaken

by the institutions which have the required technical capacity and are designated by the department of agriculture administration of the State Council and the feed administration departments of the provinces, autonomous regions and municipalities directly under the Central Government. The supervision and spot check shall be free of charge.

After the supervision and spot check, the department of agriculture administration of the State Council and the feed administration departments of the provinces, autonomous regions and municipalities directly under the Central Government may inform the check results and publish a list of the feed or feed additive manufacturers and operators with poor record.

Article 33 The feed administration departments under the people's governments at or above county level shall establish files of the supervision and administration of feed and feed additive, and record the results of routine supervision and inspection, and the investigation and punishment of illegal acts and other conditions.

Article 34 The department of agriculture administration of the State Council and the feed administration departments under local people's governments at or above county level may take the following measures during supervision and inspection:

Conducting field inspection of the places where feed or feed additive is produced, operated or used;

Checking and copying related contracts, notes, account books and other related materials;

Sealing up and seizing the feed raw materials, single feed, feed additives, drug feed additives, premix that are used for illegal production of feed; raw materials that are used for illegal production of feed additives; tools and facilities which that are used for illegal production of feed and feed additives; as well as feed or feed additives that are proved to be illegal production, operation and use; Sealing up the places where illegal production or operation of feed or feed additive is conducted.

Chapter 4 Legal Responsibility

Article 35 Where the department of agriculture administration of the State Council, the feed administration departments under the people's government at or above county level or other supervision administration departments under this regulation as well as their staff not resume listed responsibilities in this regulation, or abusing power, neglecting their duties, practicing favouritism and committing irregularities, punishment shall be imposed upon the immediate leaders and other immediate persons

liable; if they constitute a crime, criminal responsibility shall be investigated.

Article 36 Where a license certificate for new feed or feed additive is obtained through providing false materials and samples or by other deception means, the issuing authority shall revoke the certificate and impose a fine of RMB50,000~RMB100,000. The applicant shall not apply for a license of the same item within 3 years; if loss is incurred upon others, the delinquent party shall assume compensatory liability according to law.

Article 37 License certificates being faked, forged or sold shall be confiscated or revoked by department of agriculture administration of the State Council, the feed administration departments under the people's government at or above county level with their authorities. If a crime is constituted, the criminal responsibility shall be investigated.

Article 38 Where an enterprise manufacturing feed or feed additive conducts production without a production license, the feed administration department under the people's government at or above county level shall order it to stop production, confiscate the illegal gains, the illegally produced products, the feed raw materials, single feed, feed additives, drug feed additives, premix feed and raw materials that are used for illegal production of feed additives; and impose a fine of RMB10,000~RMB50,000 if the value of the goods is less than RMB10,000; impose a fine equal to 5~10 times of the value of the goods if the value of the goods is more than RMB10,000. If the circumstance is grave, the production equipment shall be confiscated, the main person in charge and immediate leader of the production enterprise shall not engage in the activities of production and operation of feed or feed additive within 10 years.

Where an enterprise which has obtained a production license, but no longer possesses the conditions prescribed in Article 14 hereof continues to produce feed or feed additive, the feed administration department under the people's government at or above county level shall order the enterprise to stop the production and make a correction within a time limit, and impose a fine of RMB10,000~RMB50,000; if the enterprise still doesn't make a correction within the time limit, the license issuing authority shall revoke its production license.

Where an enterprise which has obtained a production license but has no product authentication code,

produces feed additives or premix, the feed administration department under the people's government at or above county level shall order the enterprise to stop the production, confiscate the illegal gains, the illegally produced products, the feed raw materials, single feed, feed additives, drug feed additives, premix that are used for illegal production of feed; raw materials that are used for illegal production of feed additives; order this unit to get a product authentication code within a time limit, impose a fine equal to 1~3 times of the value of the goods. If the circumstance is grave, the production license shall be revoked by the license issuing authority.

Article 39 Where an enterprise manufacturing feed or feed additive conducts one of the following acts, the feed administration department under the people's government at or above county level shall order it to make a correction, confiscate the illegal gains, the illegally produced products, the feed raw materials, single feed, feed additives, drug feed additives, premix feed and raw materials that are used for illegal production of feed additives; and impose a fine of RMB10,000~RMB50,000 if the value of the goods is less than RMB10,000; impose a fine equal to 5~10 times of the value of the goods if the value of the goods is more than RMB10,000. If the circumstance is grave, the license certificates shall be revoked, the main person in charge and immediate leader of the production enterprise shall not engage in the activities of production and operation of feed or feed additive within 10 years. If a crime is constituted, the criminal responsibility shall be investigated.

(1) Producing feed with restricted feed raw materials, single feed, feed additives, drug feed additives or premix, without following restriction regulations published by the department of agriculture administration of the State Council;

(2) Using the substances not in the list of feed raw materials, the list of feed additives or the list of drug feed additives to produce feed ;

(3) Manufacturing feed or feed additive that has no license certificate or that being forbidden to use.

Article 40 Where an enterprise manufacturing feed or feed additive conducts one of the following acts, the feed administration department under the people's government at or above county level shall order it to make a correction, impose a fine of RMB10,000~RMB20,000; if correction is refused to make, the feed administration department shall confiscate the illegal gains, the illegally produced

products, the raw materials, single feed, feed additives, drug feed additives, premix feed and raw materials that are used for illegal production of feed additives; and impose a fine of RMB50,000~RMB100,000. If the circumstance is grave, the production shall be ordered to stop; the license certificate shall be revoked.

(1) Where an enterprise manufacturing feed or feed additive doesn't conduct inspection or test on purchased feed raw materials, single feed, feed additives, drug feed additives, premix and raw materials used to produce feed additive, according to regulations and relative standard published by the department of agriculture administration of the State Council;

(2) During production process, where an enterprise does not follow the administration regulations of quality and safety of feed & feed additives as well as the safety use regulations of feed additives published by the department of agriculture administration of the State Council;

(3) Where feed and feed additives produced have not undertaken the product quality test.

Article 41 Where an enterprise manufacturing feed or feed additive doesn't record the information of purchase, production and sales or save the samples for test according to this regulation, the feed administration department under the people's government at or above county level shall order it to make a correction, impose a fine of RMB10,000~RMB20,000, if correction is refused to make, the feed administration department shall confiscate the illegal gains, the illegally produced products, the feed raw materials, single feed, feed additives, drug feed additives, premix feed and raw materials that are used for illegal production of feed additives; and impose a fine of RMB20,000~RMB50,000. The license certificate shall be revoked.

Where the feed or feed additive sold by an enterprise manufacturing feed or feed additive is not attached with a certificate of product quality or its package or label doesn't conform to specification, the feed administration department under the people's government at or above county level shall order the enterprise to make a correction; if the circumstance is grave, the illegal gains and the illegally sold products shall be confiscated and a fine below 30% of the value of the goods shall be imposed.

Article 42 Where an enterprise operates feed or feed additive in violation of the conditions prescribed

in Article 22 hereof, the feed administration department under the people's government at county level shall order it to make a correction within a time limit; if the enterprise failed to make a correction within the time limit, the feed department shall order the enterprise to confiscate the illegal gains and the illegally operated products, impose a fine of RMB2,000~RMB20,000 if the value of the goods is less than RMB10,000; and impose a fine of 2~5 times of the value of the goods if the value of the goods is more than RMB10,000. If the circumstance is grave, the production shall be ordered to stop and the Industrial and Commercial Administration Department shall be informed to revoke the business license.

Article 43 Where an enterprise operating feed or feed additive commits one of the following acts, the feed administration department under the people's government at county level shall order it to make a correction, confiscate the illegal gains and the illegally operated products; impose a fine of RMB2,000~RMB20,000 if the value of the goods is less than RMB10,000; and impose a fine of 2~5 times of the value of the goods if the value of the goods is more than RMB10,000. If the circumstance is grave, the operation shall be ordered to stop and the Industrial and Commercial Administration Department shall be informed to revoke the business license. If a crime is constituted, the criminal responsibility shall be investigated according to law:

Reprocessing feed or feed additive or adding substances into it.

Operating feed or feed additive without product label, production license, or certificate of product quality;

Operating feed or feed additive that has no product authentication code;

Operating feed produced with any substances not in the list of feed raw materials and the list of feed additives or in the list of drug feed additives; Operating feed or feed additive that has no license certificate or import registration certificate or that is being restricted to operate.

Article 44 Where an enterprise operating feed or feed additive commits one of the following acts, the feed administration department under the people's government at county level shall order it to make a correction, confiscate the illegal gains and the illegally operated products; impose a fine of RMB2,000~RMB10,000:

(1) Opening or sub-packaging feed or feed additive;

(2) Not abiding by rules of purchases and sales record listed in this regulation;

(3) Operating feed or feed additive that lost efficacy, mildewed or expired.

Article 45 Where an enterprise manufacturing feed or feed additive listed in Article 28 doesn't recall the feed or feed additive, the feed administration department under the local government at or above county level shall order the enterprise to recall the feed or feed additive. The recalled feed or feed additive shall be treated or destroyed without generating any harm under the supervision of the feed administration department. If the circumstance is grave, the illegal gains and illegal products shall be confiscated. The manufacturer shall be imposed a fine equal to 1~3 times the value of recalled products. The related license certificates shall be revoked. If the enterprise refuses to treat or destroy the recalled products without generating harm, the feed administration department under the local government at county level shall do it for them. The cost arising thereof shall be borne by the manufacturer.

Where an enterprise operating feed or feed additive listed in Article 28 doesn't stop the sales, the feed administration department under the local government at or above county level shall order the enterprise to stop the sales. If the enterprise refuses to stop the sales, the illegal gains shall be confiscated and a fine of RMB1,000~RMB50,000 shall be imposed. If the circumstance is grave, the operation shall be ordered to stop and Industrial and Commercial Administration Department shall be informed to revoke the commercial instrument.

Article 46 Where an enterprise manufacturing or operating feed or feed additive commits one of the following acts, the feed administration department under the people's government at county level shall order it to stop production or operation, confiscate the illegal gains and the illegally produced or operated products; impose a fine of RMB2,000~RMB20,000 if the value of the goods is less than RMB10,000; and impose a fine of 2~5 times of the value of the goods if the value of the goods is more than RMB10,000. If a crime is constituted, the criminal responsibility shall be investigated according to law:

(1) During production or operation, where non-feed or non-feed additive is said to be feed or feed additive; or one kind of feed or feed additive is said to be another kind.

(2) Where feed or feed additive without or not conforming to product quality standard is being produced or operated.

(3) Where feed or feed additive being produced or operated is not in accordance with what is describe on the label.

A feed or feed additive manufacturer commits behaviours listed above, if the circumstance is grave, the related license certificate shall be revoked; A feed or feed additive operator commits behaviours listed above, if the circumstance is grave, the commercial instrument shall be revoked.

Article 47 Where a farmer commits one of the following acts, the feed administration department under the people's government at county level shall confiscate the illegally used products and the illegally added substance; the unit violated law shall be imposed a fine of RMB10,000~RMB50,000 and the person violated law shall be imposed a fine below RMB5,000; if the act constitutes a crime, the criminal responsibility shall be investigated according to law.

(1) Using the feed or feed additive that has no license certificate or import registration certificate;

(2) Using the feed or feed additive without product label, production license, standards for product quality, certificate of product quality or approval document;

(3) Using the feed additive or premix that has no product authentication code;

(4) Using feed additives mixed in feed or water without following safety use regulations published by the department of agriculture administration of the State Council ;

(5) Using own-making feed without following relative regulations published by the department of agriculture administration of the State Council;

(6) Using restricted substances to feed animals without following restriction regulations published by the department of agriculture administration under State Council;

(7) Illegally adding animal source ingredients into the feed or feed additive of ruminants other than milk or milk products.

Some units add forbidden substances published by the department of agriculture administration of the

State Council to feed or water and others which cause direct or potential damage to human health or feed those substances directly to animals. The feed administration department under the people's government at county level shall order these units to commit treatment to those animals fed illegal substance without causing damage; impose a fine of RMB30,000~RMB100,000; if the act constitutes a crime, the criminal responsibility shall be investigated according to law.

Article 48 Where a farm which makes its own feed sells it to the market, feed administration department under local government at county level shall order it to make a correction and impose a fine of RMB2,000~RMB20,000.

Chapter 5 Supplementary Provisions

Article 49 The meaning of the following terms in these Regulations is:

- (1) Raw material refers to substances which do not belong to feed additives and are used to produce feed, coming from animals, plants, microbes and minerals sources.
- (2) single feed refers to feed composed of ingredients coming from only one kind of animal, plant, microbe or mineral.
- (3) Premix refers to feed mainly composed of at least two nutritional feed additives which are mixed with carriers or diluents conforming to a certain ratio, including complex premix, mineral premix and vitamin premix.
- (4) Concentrated feed refers to feed composed of protein, minerals and feed additives mixed with a certain ratio.
- (5) Complete feed refers to that according to nutrition requirements of animals, feed raw materials and feed additives are mixed conforming to a certain ratio.
- (6) Complementary feed refers to that in order to improve herbivore's nutrition, feed raw materials and feed additives are mixed conforming to a certain ratio.
- (7) Nutritional feed additive refers to the small or minim amount of substances added for nutrition

purpose, including feed-grade amino acids, vitamins, minerals, enzyme, non-protein nitrogen (NPN), etc.

(8) Ordinary feed additive refers to the small or minim amount of substances blended in feed to ensure or improve feed quality and efficiency.

(9) Drug feed additive refers to the preblended substance of animal medicine intermingled into the carriers or diluents for prevention and control of animal diseases.

(10) A license certificate refers to import registration certificate of new feed or feed additive; production license of feed or feed additive; authentication code of feed additive or premix.

Article 50 The administration of drug feed additive shall be fulfilled according to the Regulations on Administration of Animal Medicine.

Article 51 These Regulations shall be implemented on May 1st, 2012.

END TRANSLATION