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Feed and Feed Additive Regulation (Draft)

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Report Highlights:

On February 20, 2010, the State Council's Legislative Office published a draft regulation on feed and feed additives for domestic comment. The deadline for comments is March 15. The draft regulation has not been notified to the WTO. This report contains an UNOFFICIAL translation of the draft regulation.

General Information:

Executive Summary

On February 20, 2010, the State Council's Legislative Office published a draft regulation on feed and feed additives for domestic comment. The deadline for comments is March 15. The draft regulation has not been notified to the WTO. This report contains an UNOFFICIAL translation of the regulation.

Changes to animal feed and feed additives regulations is the second large category of developments that happened the China's food and feed regulatory system in 2009. In addition to the change in quality standards for most grains and oilseeds, China published a host of feed quarantine regulations throughout 2009 and the draft regulation below appears to collect many of the various themes of the 2009 regulations and repackage them through the State Council. There appears to be little new in this draft.

For comparison purposes, the following text will describe the current situation with feed and feed additive standards. This text was taken from the 2009 China Export Certification Report. Based on this description and the supporting documents that can be found in various FAS GAIN reports, the new draft regulation can be compared with the current regulatory situation.

The two main changes in 2009 appeared in AQSIQ Feed Quarantine Regulation 118 (CH9071) and AQSIQ Feed Quarantine Implementing Announcement 372 (CH9074). Much of the information in Regulation 118 and Announcement 372 is itself not new; it is a consolidation of older measures and incorporates feed and feed additives within the general re-organization of measures resulting from the Food Safety Law. Exporters should read and evaluate the measures to understand how they might be affected. One point of clarification relates to the requirement for exporter registration that is set out in Regulation 118 Chapter III Import Inspection and Quarantine, Section 1 Registration, Articles 10 and 11. The statement in I Import Inspection and Quarantine, (1) Registration of Announcement 372 adds some clarity, "AQSIQ will publish a list of countries/regions which are eligible to export their feed products to China, as well as a list of the permitted products, and will carry out this registration of foreign feed producers in an orderly manner. For those countries/regions who have completed registration, the imported feeds shall only be sourced from the registered producers or processors." China has noted that this registration process is for quarantine, product safety and trace back reasons.

As of November 2009, there is a quarantine facility registration process for exporting of non-ruminant animal derived feed with China's AQSIQ, such as pet food. However, there currently is no mandatory registration requirement for other U.S. feed and feed additive exporters.

According to preliminary explanations provided by AQSIQ to USDA representatives, AQSIQ plans to complete feed registration as a multi-stage process. The first stage, as noted in the quote above, is a process that many countries go through to assess whether the general laws, regulations, and oversight of a supplier country are "equivalent" to their own. Thus, China intends to send a detailed questionnaire out to trading partners to gather information about the equivalency of an exporter's regulatory structure versus their own. Part of this examination will involve detailing how the supplier generally regulates feed and feed additives domestically and for export and how exports are handled in terms of regulation, monitoring, and certification. This questionnaire will be sent to the United States Government. Assuming that China agrees that an exporter has an equivalent system, it would request that the exporting country create and maintain a list of companies that are eligible and want to produce feed and feed additive products for export to China. This list of possible exporters would be submitted to AQSIQ authorities. China then intends to maintain some type of monitoring as described in Chapter III of Regulation 118. At the current time, AQSIQ has not submitted the questionnaire to the United States and has not stated when it is likely to do so. According to AQSIQ, registration for plant and chemical based feed and feed additives will not begin until the equivalency process has run its course and the two countries have negotiated an understanding of these new registration requirements.

As noted above, one class of feed and feed additives, non-ruminant derived animal feed, currently undergo a quarantine

registration process. For these products, they must request inclusion onto a potential exporter list by USDA's Animal and Plant Health Inspection Service (APHIS). Once these products gain APHIS's concurrence that they meet China's quarantine requirements, APHIS places them on a list that is submitted to AQSIQ. Generally speaking, AQSIQ accepts the list several times a year and updates their internal list for distribution to their provincial affiliate offices (CIQs) in a timely fashion. At this point, a product is eligible for a "Health Certificate/Export Certificate for Animal Products" for export to China issued by APHIS whose provisions are governed by the Protocol for Veterinary Health Requirements for Non-Ruminant Derived Animal Feed and Tallow to be Imported from the United States of American into the People's Republic of China. As of November 2009, 143 U.S. facilities producing non-ruminant derived animal feed are currently registered with AQSIQ for export to China. This document is listed below and can be found at the APHIS IRegs site: http://www.aphis.usda.gov/regulations/vs/iregs/products/downloads/ch_pf_fi.pdf.

Please see GAIN Reports CH9033 (2008 Catalogue of Feed Additives), CH9071 (AQSIQ Feed Quarantine Regulation 118), CH9074 (Implementation of Feed Quarantine Regulation 118), CH9075 (Risk Levels and Inspection and Quarantine Supervision Methods for Import and Export of Feed and Feed Additives), CH9057 (Corn Quality Standards), and CH9083 (Feed Labeling) for the recent history and breadth of this issue.

Additional attention has been paid to the existing registration for animal feed and feed additives currently conducted by China's Ministry of Agriculture. Basically speaking, all non-grain or non-traditional feed and feed additives need to be registered with the Ministry of Agriculture. This definition is not described clearly by MOA, but appears to mean any feed except grains/oilseeds and their most basic/standard processed derivatives (e.g. soybeans/soy meal/soy oil or corn/corn meal/starch). Details on feed registration process and history can be found in GAIN Reports CH6083, CH6084, CH6080, CH6099, CH6101, and CH6091. This process involves extensive submissions of information to MOA and the registration process can take a significant amount of time. Many in the U.S. export industry complain that the current MOA registration process requests product production information, which might be proprietary information to the company. They note that MOA's process does not provide additional value to Chinese regulators and that the proposed AQSIQ registration system makes it clearly duplicative and trade inhibiting.

Not surprising, the shifting situation and unclear understanding by many in the industry and Chinese officials outside the central government has caused a number of contradictions to persist in the system as it relates to imports. An example is the status of imported processed feed grains, which includes dried distillers grains with solubles (DDGS). China currently produces a limited amount of ethanol from corn and has DDGS as a by-product. This Chinese-produced DDGS is marketed, but is not recognized in MOA regulations in any feed component category and does not have a national quality standard. Imported DDGS have never been approved by MOA through its official feed registration process, though some facilities are currently making their way through the process. However, provincial CIQs regularly grant imported DDGS the official right to enter the country for Chinese domestic distribution. Moreover, DDGS officially appears in AQSIQ feed quarantine standards (risk classifications) for the United States. This contradictory situation persists despite the fact that the regulation of imported DDGS has not been subject to any of the regulatory changes mentioned in the paragraphs above. At this time, USDA China recommends that companies adhere to quarantine requirements necessary to obtain quarantine import permits and strive to complete the MOA feed registration process.

BEGIN TRANSLATION

Feed and Feed Additives Management Regulations (Revised and exposure draft)

Chapter I General Provisions

Article 1 These Regulations are formulated for the purpose of strengthening the administration of feed and feed additives, increasing the quality of feed and feed additives, promoting the development of feed industry and breeding industry, and safeguarding human health.

Article 2 “FEED” in this Regulation means material to be used as animal food after industrial manufacture, including single feeds, feed premixes, concentrate feeds, compound feeds and concentrate supplements; “FEED ADDITIVES” means material to be added in small or micro quantities during feed manufacture, including nutritive or common feed additives.

Article 3 The administrative department in charge of agriculture under the State Council is responsible for the national administration and supervision of feed and feed additives; the administrative departments for feed and feed additives of the local people’s governments at or above the county level (hereinafter referred to as the Feed Administrative Department) are responsible for local feed and feed additives administration within their respective administrative areas.

Article 4 Local people’s governments at or above the county level shall strengthen the organization and leading, supervision and check to the supervisory administration of feed and feed additives, establish and improve the mechanism for feed supervision within their respective administrative areas.

Article 5 An enterprise or operator for manufacturing or operating feed and feed additives shall establish and improve the quality safety system and shall be liable for the quality safety of the feed and feed additives manufactured or operated by itself.

Article 6 Any organization or person shall has the right to report any violation of the present Regulation in the course of manufacturing, operating and using feed and feed additives and have the right to give advice and make suggestions on the supervisory administration of feed and feed additives.

Chapter II Administration of Approval, Import and Export

Article 7 The government encourages research and the creation of new feeds and feed additives.

Research and the creation of new feeds and feed additives shall follow the principle of science, safety, efficiency and environment-protection, ensuring the quality safety of new feeds and feed additives.

Article 8 Before the manufacture of new feeds and feed additives, the researcher or manufacturer must put forward an application for evaluation of the new product to the administrative department in charge of agriculture under the State Council and provide the samples of new feeds and feed additives as well as the data as follows:

- Name, composition, and physical and chemical characteristics of such new feed or feed additive;
- Research method, production technology, quality standards and analytical procedure used for such new feed or feed additive;
- The feeding effect, the dynamic of residue degradation, the toxicological testing and the product inspection report of such new feed or feed additive issued by inspection and testing institutions assigned by the administrative department in charge of agriculture under the State Council;

- Report of the environmental impact and measures taken to prevent pollution.

Article 9 The administrative department in charge of agriculture under the State Council shall, within five working days from the acceptance of the application, deliver the application materials and samples of such new feed or feed additive to the National Feed Evaluation Council to evaluate the results of such new feed or feed additive, the safety, availability and impact on the environment. The administrative department in charge of agriculture under the State Council shall, within ten working days from the acceptance of the application, make a decision whether to issue the certificates of such new feed or feed additive; in the case of disapproval, a written notice with explanation shall be given to the researcher or manufacturer.

The National Feed Evaluation Council is made up by scientists in animal husbandry, feed manufacture, animal nutrition, toxicology, pharmacology, metabolism, hygiene, chemistry, biotechnology, quality standards, environmental protection and food safety risk assessment.

Article 10 The quality standard of the new feeds and feed additives issued by the administrative department in charge of agriculture under the State Council is the industrial standard. If a national standard is required, the procedure will be conducted according to the National Standard Law.

Article 11 With a view to ensuring the quality safety of animal products and to protecting the public health, the administrative department in charge of agriculture under the State Council shall set forth monitoring periods for new feeds and feed additives approved to be manufactured; within the monitoring period, no other application for the approval of the new feeds and feed additives shall be accepted. The maximum monitoring period shall not exceed five years.

Within the monitoring period, in accordance with the provisions of the administrative department in charge of agriculture under the State Council, the manufacturing enterprises shall collect and report the information with regard to the stability of product quality, the impact on the quality safety of animal products; the administrative department in charge of agriculture under the State Council shall organize tracking and monitoring of the quality and safety of new feeds and feed additives, when safety problems have been verified to exist, the certificates of such new feed or feed additive shall be revoked and publicly announced to disable the products.

Article 12 When feed or feed additives are imported for the first time, application for registration should be made to the administrative department in charge of agriculture under the State Council. In addition to samples of the feed or feed additives, the Exporter shall provide the following information:

- (1) Trademark, label and history of use in the producing country;
- (2) Certificate of registration of manufacture and sale in the producing country and registration documents from other countries;

(3) Information required in Article 8 of this regulation.

The administrative department in charge of agriculture under the State Council shall, within five working days from the acceptance of the application, examine and verify the application materials and deliver the samples of such new feed or feed additive to the designated organization for re-check. In case of being qualified, the administrative department in charge of agriculture under the State Council shall, within ten working days, issue the import registration certificate of such new feed or feed additive.

As for the importation of the feed and feed additive that have not been used in the People's Republic of China, but approved to produce and use by the country of export, the matter shall be handled in accordance with the provisions as stipulated in Article 8 and Article 9.

The certificate of registration for imported feeds and feed additives is normally valid for 5 years; where the registrant intends to continue to export the feeds and feed additives in China beyond the expiration of the period of validity, an application for renewal of the registration shall be made within six months before the said expiration.

Article 13 The State offers protection to the undisclosed test data and other data, accumulated by the applicant itself and submitted by it, which concern the feeds and feed additives that have been registered and approved and contains a new compound.

Where another entity, without consent of the applicant whose products have already been approved or registered, applies for the approval or registration of the feeds and feed additives by using the data specified in the preceding paragraph, the approval or registration department shall, within six years from the date of the approval or registration, refuse to have it registered, unless the data submitted by that entity are accumulated by itself.

The approval or registration department shall not disclose the data specified in the first paragraph of this Article, except under the following circumstances:

- (1) For the need of public interest; or
- (2) Where measures have been taken to ensure that the data are protected against illegitimate commercial use.

Article 14 An enterprise or person from abroad that intends to sell feeds and feed additives in China shall, in accordance with the law, establish a sales office within the territory of China or authorize an agency within the territory of China that meets the requirements.

The feed or feed additives for sales in China shall be packed and attached with the label in Chinese complying with the provisions as prescribed in Article 23 under this Regulation.

The entry and exit inspection and quarantine institution shall conduct inspection and quarantine on the imported feeds and feed additives and shall examine and verify the package and the labels in Chinese.

Article 15 Where a feed or a feed additive is to be exported abroad and the importer requires the provision of a document certifying exportation of the feeds and feed additives, the administrative department in charge of agriculture under the State Council or the administrative department for feeds and feed additives of the people's government of the province, autonomous region or municipality directly under the Central Government where the exporter is located may issue such a document.

Chapter III Administration of manufacture, operation and usage

Article 16 Besides complying with the development program for feed industry and industry policy, the following conditions are required for the establishment of feed or feed additives enterprises:

- Plant, equipment, technology and storage building for feed or feed additives manufacture;
- Full-time technicians for feed or feed additives manufacture;
- Necessary product quality test department, technician and equipment for quality control of produced feed or feed additives;
- Production conditions in accordance with the safety and sanitation requirements of the National Legislation;
- Measures for pollution prevention complying with environment-friendly requirements of the state;
- Other conditions as prescribed in the specifications with regard to the production quality and safety management formulated by the administrative department in charge of agriculture under the State Council.

Article 17 When applying for establishment of an enterprise for manufacturing feed and feed additives, the applicant shall file applications to the feed administration departments at the provincial, autonomous regional and municipal level for approval.

When applying for establishment of an enterprise for manufacturing feed additives or feed premixes, the feed administration departments at the provincial, autonomous regional and municipal level shall, within twenty working days from the acceptance of the application, examine and verify the application materials in writing and conduct spot-investigation and then submit relevant data and judgment suggestions to the administrative department in charge of agriculture under the State Council; when receiving such data and judgment suggestions, the administrative department in charge of agriculture under the State Council shall organize the National Feed Evaluation Council for evaluation; the administrative department in charge of agriculture under the State Council shall, within ten working days from the acceptance of the evaluation result, make a decision whether to issue the manufacturing license, and the outcome of the decision shall be sent to the feed administration departments at the provincial, autonomous regional and municipal level.

When applying for establishment of an enterprise for manufacturing other feed, the feed administration departments at the provincial, autonomous regional and municipal level shall, within ten working days from the acceptance of the

application, examine and verify the application materials in writing and conduct spot-investigation and then shall, within ten working days, make a decision whether to issue the manufacturing license based on the audit result.

The applicant shall complete the formalities for business registration on the basis of the manufacturing license.

The manufacturing license is normally valid for 5 years; where the manufacturer intends to continue manufacturing the feeds and feed additives beyond the expiration of the period of validity, an application for renewal of the production shall be made within six months before the said expiration.

Article 18 When an enterprise for manufacturing feed additives or feed premixes obtains the manufacturing license issued by the administrative department in charge of agriculture under the State Council, the feed administration departments at the provincial, autonomous regional and municipal level shall issue the registered number of approval for such products in accordance with the provisions of the administrative department in charge of agriculture under the State Council.

Article 19 An enterprise for manufacturing feed and feed additives shall inspect or test the purchased raw materials according to the provisions of the administrative department in charge of agriculture under the State Council and relevant standards, and shall examine the permit paper and the Product Qualification Certificate of the suppliers when purchasing single feeds, feed additives or feed premixes. It is prohibited to use the feed manufactured by any substance beyond the List of Feed Raw Materials and the List of Feed Additives Varieties released by the administrative department in charge of agriculture under the State Council.

An enterprise for manufacturing feed and feed additives shall truly record the name, producing area, quantity, quality guarantee period, serial number of the certificate of license, serial number of quality inspection certificate of the raw materials and the name of the manufacturing enterprise or supplier as well as the contact information and date of input and the records shall be kept for at least two years.

Article 20 An enterprise for manufacturing feed and feed additives shall organize the production, effectively control the production process and carry out production record and the system for keeping samples of products for observation according to the products quality standards and the management code for the quality safety of feed and feed additives.

When an enterprise manufacturing feed and feed additives, veterinary drugs or other prohibited drugs shall not be added directly to feed or feed additives; the permitted drugs can only be added after diluting with suitable materials in 'drug containing feed additives'. No hormone material shall be added to feed additives; adding to feed additives shall comply with the Safety Code constituted by the administrative department in charge of agriculture under the State Council.

Article 21 An enterprise for manufacturing feed and feed additives shall conduct the product quality inspection to the

feed and feed additives that the enterprise produces; qualified on the inspection, the quality inspection certificate of approval of the product shall be attached to such products. Feed or feed additives without being tested on the product quality, or disqualified upon inspection or without being attached with the quality inspection certificate of approval of the product are prohibited from sale.

An enterprise for manufacturing feed and feed additives shall truly record the name, quantity, production batch, serial number of quality inspection certificate of the feed and feed additives dispatched off site for sale and the name of the purchasers and the contact information as well as the date of sales and the records shall be kept for at least two years.

Article 22 The feed or feed additives dispatched off site for sale shall be packed and the packaging of feed or feed additives should comply with the National Regulations on safety and hygiene.

The flammable feed or feed additives, or those with special requirements, should carry the appropriate warning signs and instructions for storage or transport.

Article 23 The packaging of feed or feed additives shall carry a label. The label shall show the name, ingredients, composition, net weight, storage conditions, use instructions, matters need attention, date of production, expiry date, manufacturer's name and address, serial number of the certificate of license and the code number of the quality standard applied to the product etc.

Article 24 The following conditions are required for the operators of feed or feed additives:

- Site for business operation and storage facilities suitable for operation of feed or feed additives;
- Technical personnel with the knowledge of use or storage of feed or feed additives;
- Necessary management system for products quality.

The feed administration departments or the industry and commerce administration departments of the people's government at the county level shall strengthen the supervision and inspection of the operation of feed or feed additives within their respective jurisdictions and shall release the information on the supervision and management in time.

Article 25 When purchasing the goods, the operators of feed or feed additives shall examine the operation qualifications of the suppliers and shall check the product label, the quality inspection certificate of approval of the product and corresponding certificate of license.

The operators of feed or feed additives shall establish system of purchase and sale machine account and truly record the name of the products and serial number of the certificate of license, manufacturer's name, specification, quantity, quality guarantee period, suppliers and their contact information and the time of purchase or sales. The purchase and sale machine account shall be kept for at least two years.

The operators of feed or feed additives shall not unpack or pre-pack the feed and feed additives and shall not process or add any substance to the feed and feed additives.

Article 26 The culturist shall use the feed and feed additives according to the directions for use and matters for attention on the product label, during which no substance beyond the List of Feed Raw Materials and the List of Feed Additives Varieties is allowed to be added to.

It is prohibited to add animal origin composition to the feed and additives for ruminant, but except for milk and milk product.

Article 27 When self-preparing and using the feed, the breeding farms, breeding professional cooperatives and breeding plots shall comply with relevant requirements as set out by the administrative department in charge of agriculture under the State Council and shall record the services conditions of the self-prepared feeds, which shall accept supervision and inspection of the feed administration department of the local people's government at the county level.

Any of the breeding farms, breeding professional cooperatives and breeding plots shall not provide the self-prepared feeds to the public.

Article 28 When the feed or feed additives that an enterprise produces are proved harmful to animals, humans or have other safety quality potentials, the enterprise for manufacturing such feed and feed additives shall cease production at once and promptly notify the operators to stop sales, inform the users of no use of such products, issue recalls on their own products and report to the feed administration department, where the recalled feed and feed additives shall be treated harmlessly or .destroyed under the supervision of the feed administration department.

When finding out the products that they sell are provided with the cases as provided for in the preceding paragraph, the operators of the feed and feed additives shall cease sales at once, notify the manufacturers, suppliers and users and report to the feed administration department.

Article 29 As for the feed or feed additives which are proved harmful to animals, humans or the environment in the course of usage, evaluated by the National Feed Evaluation Council, the administrative department in charge of agriculture under the State Council shall publicly announce to disable the products and cancel corresponding certificate of license according to law.

Article 30 It is forbidden to produce, sell or use any of the following feed and feed additives:

- Feed or feed additives which have been stopped, forbidden, or not approved to release;
- Feed or feed additives without the quality standard, product labels, quality certification or corresponding certificate of license;

It is forbidden to produce, sell or use any of the feed manufactured by any substances beyond the List of Feed Raw Materials and the List of Feed Additives Varieties.

Article 31 It is prohibited to advertise feed or feed additives for the purpose of preventing or treating animal diseases; but feed or feed additives containing drug additives must carry their functional instructions.

Article 32 The following measures can be taken by the administrative department in charge of agriculture under the State Council and the feed administrations under local people's governments at and above the county level for supervision and management:

- Conduct spot-inspection on places of manufacturing, operating and using feed and feed additives;
- Look up and copy relevant contracts, bills, account books and other concerned data;
- Seal up and detain the raw materials, products, tools or facilities that have been proved to be used for illegal production, operation and usage of feed and feed additives;
- Seal up the places for illegal production and operation of feed and feed additives.

The feed administrations under local people's governments at and above the county level shall keep files the supervision and management of feed and feed additives to record the results of routine supervision and inspection and the circumstance of investigation for violations of legal procedures.

Article 33 The administrative department in charge of agriculture under the State Council and the feed administrations under local people's governments at and above the county level shall constitute and organize the implementation of supervised random checking program for feed and feed additives, which shall be undertaken by the institutions with corresponding technical conditions designated by the administrative department in charge of agriculture under the State Council and the feed administrations of the people's government of the province, autonomous region or municipality. No fees shall be charged for such supervised random checking program.

The administrative department in charge of agriculture under the State Council and the feed administrations of the people's government of the province, autonomous region or municipality can give publicity to the names of the manufacturing enterprises, operators of feed and feed additives that have records of improper activities as well as their principals.

Chapter IV Legal Liability

Article 34 Any feed administrative department or industry and commerce administration department of the people's government at or above county level or any of its staff members that commit one of the following acts, The persons who are directly in charge and the other persons who are directly responsible shall be given administrative sanctions in accordance with law, if crime is constituted, such persons shall be investigated for criminal liability in accordance with

the law:

(1) Not to make an administrative licensing decision or not issue the permit and the approval document according to law;

(2) Failing to perform his functions and duties of supervision and administration or failing to investigate into and deal with irregularities as found or upon receipt of report on acts in violation of the present Regulation;

(3) Performing any other functions and duties in an unlawful manner;

Article 35 If providing false materials or samples or acquiring the certificate of new feed and new feed additives or the manufacturing license of feed and feed additives by cheating means, relevant certificates shall be revoked by license-issuing authority; and the violator may be imposed upon a fine between 500,000 Yuan and 100,000 Yuan; if any loss is caused to other persons, the violator shall be liable therefore according to law; if crime is constituted, the violator shall be investigated for criminal liability in accordance with the law.

Article 36 In violation of the provisions of these Regulations, an enterprise manufacturing for feed and feed additives to produce feed and feed additives without a manufacturing license, or to produce new feed and feed additives without the certificate of new feed and new feed additives, shall be ordered to desist from production by the feed administrative department of the local people's government at or above county level, the illegally manufactured products and the raw materials used for illegal production, as well as the unlawful gains therefrom shall be confiscated and, in addition, a fine of not less than twice but not more than five times the value of the goods illegally produced shall be imposed; if the amount of the value cannot be investigated and verified, a fine of not less than 100,000 Yuan but not more than 200,000 Yuan shall be imposed; if the circumstances are serious, the manufacturing equipment shall be confiscated and the principal leading members the manufacturer and the persons in charge who are directly responsible shall not be allowed to engage in any production and operating activities with regard to feed and feed additives for their lifetime; if having the manufacturing licenses, the license-issuing authority shall revoke the manufacturing license, if crime is constituted, such persons shall be investigated for criminal liability in accordance with the law.

If an enterprise has the manufacturing license but no longer meets the requirements as set out in Article 16 of present Regulation and continues to produce feed and feed additives, the feed administrative department of the local people's government at or above county level shall issue an order for suspension of production and for making corrections within a fixed period of time and impose a fine of no less than RMB10, 000 Yuan and no more than RMB 50,000 Yuan; If failing to meet the requirements within the specified time limit, the manufacturing license shall be revoked by license-issuing authority.

Article 37 In any of the following cases, an enterprise manufacturing for feed and feed additives shall be ordered to make corrections by the feed administrative department of the local people's government at or above county level, the illegally manufactured products and the raw materials used for illegal production, as well as the unlawful gains therefrom shall be confiscated and, in addition, a fine of not less than five times but not more than ten times the value of

the goods illegally produced shall be imposed; if the amount of the value cannot be investigated and verified, a fine of not less than 100,000 Yuan but not more than 200,000 Yuan shall be imposed; if the circumstances are serious, the manufacturing license shall be revoked and the principal leading members the manufacturer and the persons in charge who are directly responsible shall not be allowed to engage in any production and operating activities with regard to feed and feed additives for their lifetime; if crime is constituted, such persons shall be investigated for criminal liability in accordance with the law:

- Using the raw materials without inspection or disqualified upon inspection;
- Using the feed manufactured by any substances beyond the List of Feed Raw Materials and the List of Feed Additives Varieties ;
- Producing the feed and feed additives which have been stopped, forbidden;
- Directly adding to veterinary drugs or other prohibited drugs;
- Adding any hormonal drug to medicated feed additives.

Article 38 The feed and feed additives sold by an enterprise manufacturing for feed and feed additives without passing qualification check or without production certificate of conformity being attached or with the packaging and labels inconsistent with the provisions shall be ordered to make corrections by the feed administrative department of the local people's government at or above county level; if the circumstances are serious, the illegally sold products as well as the unlawful gains therefrom shall be confiscated and, in addition, a fine of 30% of the value of the goods illegally sold shall be imposed.

Failure of recording or keeping the data of raw materials procurement and the products sales according to law of an enterprise manufacturing for feed and feed additives shall be ordered to make corrections by the feed administrative department of the local people's government at or above county level; if the circumstances are serious, a fine of more than 10,000 Yuan and less than 20,000 Yuan shall be imposed.

Article 39 In violation of the provisions as prescribed in Article 24 of this Regulation, the operation of feed and feed additives shall be ordered to make corrections within a time limit by the feed administrative department of the local people's government at or above county level; if it fails to comply at the expiration of the time limit, it shall be ordered to desist from operation and the illegally operated products as well as the unlawful gains therefrom shall be confiscated and shall, in addition, be fined not less than one times but not more than three times the value of the goods illegally operated; if the amount of the value cannot be investigated and verified, a fine of not less than 10,000 Yuan but not more than 50,000 Yuan shall be imposed.

Article 40 In any of the following cases, an operator of feed and feed additives shall be ordered to make corrections by the feed administrative department of the local people's government at or above county level, the illegally operated products and the unlawful gains therefrom shall be confiscated and, in addition, a fine of not less than five times but not more than ten times the value of the goods illegally operated shall be imposed; if the amount of the value cannot be

investigated and verified, a fine of not less than 50,000 Yuan but not more than 100,000 Yuan shall be imposed; if crime is constituted, such persons shall be investigated for criminal liability in accordance with the law:

- Operating the feed or feed additives which have been stopped, forbidden, or not approved to release;
- Operating the feed manufactured by any substances beyond the List of Feed Raw Materials and the List of Feed Additives Varieties ;
- Operating the feed or feed additives without the quality standard, product labels, quality certification or corresponding certificate of license;
- Processing or adding substances to the feed or feed additives.

Failure of recording or keeping the data of procurement and sales of the products according to law, or unpacking or pre-packing the feed and feed additives of an operator of feed and feed additives shall be ordered to make corrections by the feed administrative department of the local people's government at or above county level; if the circumstances are serious, a fine of more than 10,000 Yuan and less than 20,000 Yuan shall be imposed.

Article 41 Any operator who imports the feed and feed additives which have not obtained the import certificate of registration for feed and feed additives or the feed and feed additives with the packaging and label not complying with the provisions or any foreign enterprise or person that directly sells feed and feed additives in China shall be ordered to make corrections by the feed administrative department of the local people's government at or above county level, the illegally imported and sold products and the unlawful gains therefrom shall be confiscated, in addition, a fine of not less than five times but not more than ten times the value of the goods illegally imported shall be imposed; if the amount of the value cannot be investigated and verified, a fine of not less than 50,000 Yuan but not more than 100,000 Yuan shall be imposed.

Article 42 An enterprise or an operator manufacturing or operating feed and feed additives, which shall recall or cease the sales of the feed and additives but actually fails to recall or cease the sales of such products, shall be ordered to make corrections by local quality surveillance department and the competent department in charge of industry and commerce administration at or above county level according to separate authority; whoever refuses to make rectification shall be announced a well-publicized recall, where the expenses thus incurred shall be borne by the manufacturing enterprise or the operator; if the circumstances are serious, the illegal proceeds and the unlawful products shall be confiscated and the violator shall be imposed upon a fine of more than 100,000 Yuan and less than 200,000 Yuan.

Article 43 In any of the following cases, a culturist shall be ordered to make corrections by the feed administrative department of the local people's government at or above county level; the illegally used products and the unlawful addition of substances shall be confiscated; if the circumstances are serious, an illegal unit shall be imposed upon a fine of more than 10,000 Yuan and less than 50,000 Yuan while an individual who commits the illegal act may be imposed upon a fine of less than 5,000 Yuan:

- Using the feed and feed additives which have been stopped, forbidden or unapproved to release;
- Using the feed manufactured by any substances beyond the List of Feed Raw Materials and the List of

Feed Additives Varieties ;

- Using the feed or feed additives without the quality standard, product labels, quality certification or corresponding certificate of license;
- Adding any substances beyond the List of Feed Raw Materials and the List of Feed Additives Varieties to feed and feed additives;
- Illegally adding animal origin composition to the feed and additives for ruminant.

Article 44 Any of the breeding farms, breeding professional cooperatives and breeding plots which self-prepares feed, in violation of the provisions of relevant requirements as set out by the administrative department in charge of agriculture under the State Council, or provides the self-prepared feed for sales shall be ordered to make corrections by the feed administrative department of the local people's government at county level and shall be imposed upon a fine of more than 2,000 Yuan and less than 20,000 Yuan.

Article 45 The amount of the value of the goods as prescribed in this Regulation shall be calculated on the basis of the marked prices of the illegally manufactured or operated feed and feed additives or the illegally used raw materials; in case of no marked price, calculated based on the market prices of the feed and feed additives or the raw materials of the same kind.

Chapter V Supplementary provisions

Article 46 The meanings of the following terms used in these Regulations are:

- (1) "Nutritive feed additive" means the low volume substances or the micro-substances to supplement the nutritional ingredients to feed, including the amino acid for feed use, vitamins, mineral elements and microelements, enzymes preparations and non-protein nitrogen;
- (2) "Common feed additives" means the low volume substances or the micro-substances to be added in the feed to ensure or improve feed quality or to increase the feed efficiency;
- (3) "Medicated feed additives" means the premix containing veterinary drugs mixed into the carrier or the diluent agent used for prevention and treatment of animal diseases, including anticoccidial drugs, parasiticide, bacteriostat and growth-promoting drugs.

Article 47 Medicated feed additives shall be administered in accordance with the relevant provisions of Regulations on Administration of Veterinary Drugs.

Article 48 These Regulations shall be effective as of _____.

END TRANSLATION

