



USDA Foreign Agricultural Service

GAIN Report

Global Agriculture Information Network

Template Version 2.09

Voluntary Report - public distribution

Date: 9/26/2006

GAIN Report Number: CH6080

China, Peoples Republic of

FAIRS Product Specific

Feed and Feed Additives Registration Update

2006

Approved by:

Mark Petry
U.S. Embassy

Prepared by:

Marcela Rondon

Report Highlights:

In 2006, the Chinese Ministry of Agriculture (MOA) released several documents to clarify the application and registration process for new imported feed and feed additives for animal use in China. The Ministry of Agriculture issued the main document, Announcement 611, to elaborate on the application and registration process for new feed and feed additives for export to China. Announcements 658 and 517 are crucial supporting documents and are also provided. This report contains UNOFFICIAL English translations of these regulatory documents. Exporters should carefully discuss all relevant regulations with Chinese importers to ensure that their interpretation is accurate.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Beijing [CH1]
[CH]

| | |
|---|-----------|
| Executive Summary | 3 |
| Announcement 611 | 4 |
| Annex 1: Requirements on the Registration Materials of the Import Feed and Feedstuff Additives..... | 4 |
| I. Registration Scope..... | 4 |
| II. Requirements on the Format of the Registration Materials | 4 |
| III. Filling out the "Application Form" | 5 |
| IV. Content (List) of Application Materials | 5 |
| V. Requirement for sample for re-checking and quality inspection | 8 |
| Table 1: Application Form for Registration of Imported Feed and Feedstuff Additives..... | 9 |
| Table 2: List of Application Materials for Imported Feed and Feed Stuff Additives..... | 9 |
| Annex 2: Requirements for Re-Registration of Imported feed and feedstuff additives..... | 11 |
| I. Scope of the Re-registration | 11 |
| II. Requirements on the Format of the Application Materials | 11 |
| III. Filling out the "Application Form" | 11 |
| IV. Content of Application Materials | 11 |
| Table 3: Application Form for Re-registration of Import Feed or Feedstuff additives..... | 13 |
| Annex 3: Requirements for Altering Existing Registrations of Imported Feed and Feedstuff Additives..... | 14 |
| I. Registration Scope..... | 14 |
| II. Requirements on the format of the registration material. | 14 |
| III. Filling out the "Application form" | 14 |
| IV. Content of Application Materials | 14 |
| Table 4: Application Form for Altering Existing Registrations of Imported Feed or Feedstuff Additives..... | 15 |
| Announcement 517 | 16 |
| Registration of imported feed and feedstuff additives..... | 16 |
| Flowchart 1: Registration of imported feed and feedstuff additives | 18 |
| Re-registration materials for imported feed and feedstuff additives | 18 |
| Flowchart 2: Re-registration of imported feed and feedstuff additives | 20 |
| Registration of imported feed and feedstuff additives - Alterations | 20 |
| Flowchart 3: Registration alteration process for imported feed and feedstuff additives..... | 22 |
| Checking and issuing licenses for new feed and feedstuff additives | 22 |
| Flowchart 3: Checking and issuing the licenses for new feed and feedstuff additives..... | 24 |
| License for (domestic) production of feedstuff additives and feed pre-mixed with additives | 25 |
| Flowchart 4: License for (domestic) production of feedstuff additives and feed pre-mixed with additives | 27 |
| Announcement 658 | 28 |
| The Approved Feed Additives 2006 | 28 |

Executive Summary

In 2006, the Chinese Ministry of Agriculture (MOA) released Announcements 611 and 658 to clarify the application and registration process for new imported feed and feed additives for animal use in China. On February 20, 2006, the Chinese Ministry of Agriculture (MOA) issued Announcement 611, which specifically elaborates on the application documentation and process of registration for new feed and feed additives for export to China. Announcement 611 is not a new administrative regulation but a set of implementation guidelines for following MOA Announcement 517, entitled "Additional Chinese Product Registration Requirements," of June 30, 2005.

Announcement 611 was developed in order to address industry complaints about the transparency of the registration process and to update labeling requirements to increase the amount of information provided to the consumer. This document provides additional detail about the documents that companies must submit to register feed and feed additive products in China.

Announcement 517 describes the examination, registration, approval, and re-registration procedures for the importation of feed and feed additives into China. It provides a flow-chart to explain the approvals that are needed from various parts of MOA and expert committees. Announcement 517 provides only a rough outline of the documentation requirements, which prompted the clarification provided in Announcement 611.

MOA Announcement 658 is a list of feed additives that are already approved for use in China. Announcement 611 notes that several steps of the registration process can be omitted if all of the feed additives in the product are already registered (see Table 2).

Exporters should carefully discuss regulations with Chinese importers to ensure that their interpretation is accurate.

These three Announcements have not been notified to the World Trade Organization (WTO).

Additional Reference Regulations and Announcements:

MOA Regulation "Imported Feed and Feed Additive Registration Regulation." (GAIN Report CH1057)

MOA Decree 38 "Administrative Procedures for the Registration of Imported Feed and Feed Additives."

MOA Decree 37 "Managing New Feed and New Feedstuff Additives."

MOA Announcement 517 "Additional Chinese Product Registration Requirements." (GAIN 6081)

MOA Announcement 658 "List of all feedstuff allowed for use in China." (GAIN 6081)

GB/T 10647: General Terminology of the Feed Industry

GB/10648: Labeling requirements (GAIN Report CH2040)

BEGIN TRANSLATION

Announcement 611
Animal Feed and Feed Additives Registration Requirements

Ministry of Agriculture, People's Republic of China
February 28th 2006

Annex 1: Requirements on the Registration Materials of the Import Feed and Feedstuff Additives

I. Registration Scope

The feed and feedstuff additives manufactured by foreign corporations which are sold and used for the first time inside People's Republic of China. The feed and feedstuff additives manufactured in Hong Kong SAR, Macao SAR and Taiwan province shall be registered in reference to the Requirements.

The feed referred to in "Regulations on Managing the Feed and Feedstuff Additives" means feed for animals that has been processed and manufactured through industrial procedures, including single feed, feed premixed with additives, concentrated feed, compound feed and fine fodder supplemented feed.

The feedstuff additives referred in "Regulations on Managing the Feed and Feedstuff Additives" means the small or tiny quantity of materials added during processing, manufacturing and using the feed, including the nourishing feedstuff additives and the general feedstuff additives.

II. Requirements on the Format of the Registration Materials

(1) The registration materials shall include the "The Application Form for Registration of the Import Feed and Feedstuff additives" (See Table 1, hereinafter referred to as the "Application Form") and the application materials (for details, please refer to the "List of Application Materials for the Import Feed and Feed Stuff Additives", hereinafter referred to as "List of Application Materials"). If the product to be registered is feed or feedstuff additives not yet allowed to be used in People's Republic of China, the registration can only be made with approval of the National Feed Evaluation Committee.

(2) The registration materials shall be in both Chinese and English, with the English version after the Chinese version. If the producing country is not an English-speaking country, the registration materials in the language of the producing country shall also be attached. All the registration materials shall be in duplicate, with one original and one copy.

(3) The original registration materials in foreign languages shall be issued on the paper with the letterhead of the manufacturing facility, signed by the director or stamped with the common seal.

(4) The registration materials in Chinese shall be printed on A4 paper (in Size 4 minus Song Ti).

(5) The registration materials shall not include any information irrelevant to the declared product.

(6) The registration materials shall be bound in a book according to the order prescribed in the "List of Application Materials" marked by page numbers. The "Application Form" shall be placed at the first page of the registration materials.

III. Filling out the "Application Form"

The "Application Form" shall be filled out in both Chinese and English.

- (1) Common Name: the true attributes of the feed and feedstuff additives shall be reflected.
- (2) Trade Name: the name to be used when selling and using the product in China. The trade name shall not be represented entirely by letters of foreign languages, symbols, Chinese spellings or numbers.
- (3) Product Classification: it shall comply with the product classification approved in the producing country, and the requirements in the "General Terminology of Feed Industry"(GB/T 10647) of China (GB/T 10647).
- (4) Appearance: the color, odor, shape (powder, particle, crystal, and massive) and state (solid state, liquid state) shall be described.
- (5) Content of Main Ingredients: name and list of effective ingredients shall be consistent with the Product Quality Standard in the application materials.
- (6) Other Ingredients and Content: sanitation index, carrier name, and content.
- (7) Manufactory: the name and address of the facility of manufacture of the product, which cannot be substituted by the name and address of the head office and the dealer. Physical address, rather than P.O. box, number is required.
- (8) Applicant Company: shall be identical to the name and address of the manufacturing facility in general, while the name and address of the head office are also allowed. As for fish meal, if it is processed on a processing ship, the name and address of the head office shall be provided and the product shall be marked as "Made at Sea".
- (9) Agent: the name, contact number, fax, P.O. box and correspondence address of the company or individual deputized to apply for the import registration.
- (10) Signature: shall be signed by the applicant.

IV. Content (List) of Application Materials

(1) Certificate of approval to manufacture and sell the product in the producing country, and registration materials in other countries.

Mainly include:

1. The documentary evidence certifying that the registered product and its main components are permitted to be manufactured and used as feed and feedstuff additives in the producing country. As for the product generated from microorganisms and their metabolites, the generic name, specific name and strain number of the fungus shall be provided.
2. The documentary evidence issued by the official authority of the producing country to permit manufacture of these products in pursuant to local laws and regulations.
3. The certificate of free sale issued by the official authority of the producing country, displaying the product name, as well as the name and address of the manufacturing facility, proving that there are no restrictions limiting the manufacture, sales and utilization in the producing country.
4. If the product has acquired the import license in other countries, relevant documentary evidence or the copy of the registration license shall be provided.
5. The official documentary evidence shall be confirmed by an Embassy or Consulate of the People's Republic in the producing country.

(2) Letter of authorization

The agent shall submit proof that the manufacturer has authorized him to go through the import registration procedures for the product.

(3) Product description and physical and chemical properties

If the registered product is feed or feedstuff additives not yet allowed to be used in People's Republic of China, the effective components, physical and chemical properties, functions, manufacturing techniques and conditions, manufacturing methods, and range of applicability shall be illustrated briefly. Meanwhile, the safety, effectiveness, and stability of the product shall be elaborated. The physical and chemical properties therein shall include the sensory properties (color, order and state of existence, etc.) and physical and chemical parameters (e.g., the boiling point, melting point, specific gravity, refractive index, the solubility in common menstruum, and the stability towards the light or heat, etc.).

(4) Origin and components of the product

1. Origin of the Product: The animal and vegetal origin of the product or all the primary materials used for the chemical composition shall be described. As for the micro-organic fungus, the generic name, specific name and strain number shall be provided. Furthermore, the name and origin of the fungus and the component of the culture medium shall be provided for the zymolytic product.

2. Components: the components or effective ingredients of the material. The material name shall be as detailed as possible, and the chemical constitutional formula shall be provided for those materials with chemical constitutions. If the registered product is the feed or feedstuff not yet allowed to be used in People's Republic of China, a test report of the chemical constitution of the effective ingredients as well as the classification and determination report of the animal, plant and microorganism in the product shall be provided.

(5) The test report of the chemical constitution of the effective ingredients or the classification and determination report of the animal, plant and microorganism. If the registered product is the feed or feedstuff not yet allowed to be used in People's Republic of China, test report of the chemical constitution of the effective ingredient as well as the classification and determination report of the animal, plant and microorganism of the product shall be provided.

1. The effective ingredients shall be chemically defined: instruments and method of inspections employed in the experiment shall be described and determined, e.g., the spectrum charts of the infrared and ultraviolet spectrum, the mass spectrum or the nuclear magnetic resonance, and the characteristic reaction of the chemical functional group, etc., attached by the normative and real test report issued by a third party.

2. The effective ingredients shall be divided in to the animal, plant, microorganism and their products: classification and determination shall be made. The classification and determination shall be made to the genus and species level, and to the subspecies or individual plant level when necessary. The classification and determination of the animal and plant shall be carried out by relevant authorities, while the determination of the microorganism shall be carried out by the organization specified by the Ministry of Agriculture, with normative and real survey report provided.

3. Transgenic product: shall be handled in accordance to relevant regulations of the country.

(6) The manufacturing method

The manufacturing process flow chart and type matter of the product. The process chart shall display the critical steps in the manufacturing process. The type matter shall describe the technical conditions and methods in the process, and briefly illustrate the materials and equipment used in the production, as well as each step of the manufacturing process.

(7) The quality standard, method of inspection, quality inspection report and the certificate of sanitation and safety

1. The quality standard: the quality standard of the product shall be consistent with the quality specification and method of inspections approved and recognized by the relevant administrative authorities of the producing country. The quality standard shall include the content of each kind of effective ingredient, as well as a description of each kind of harmful substance in the product.

2. Method of inspection: for those adopting international standards such as the International Standardization Organization / International Electrotechnical Committee (ISO/IEC), Association of Official Agricultural Chemists (AOAC), etc., the standard code shall be noted; for those adopting other methods of inspection, the detailed operational process for the inspection shall be provided. The applicant shall help to provide the standard materials and special instrument accessories required by the inspection as necessary.

3. Quality inspection report: the quality inspection report for samples of three different batch numbers shall be provided for each product.

4. Certificate of sanitation and health: feed containing ingredients generated from animals shall be provided with the certificate of sanitation and health issued by the veterinarian or the inspection and quarantine department of the producing country; products with a high dioxin risk shall be provided with the certificate of health and safety issued by official authorities or the third party organizations.

(8) Pattern of the label, product description and trademark

1. Pattern of the label: the original label and the Chinese label shall be included. The original label shall be the sample or photo of the label of the product used in the producing country. The Chinese label shall comply with the "Label for the Feed" standard (GB 10648).

2. Product description: the application method and items shall be described briefly.

3. Trademark: the product, with a registered trademark, shall be provided with the pattern of the trademark.

(9) Range of applicability and method of application or the quantity to be added

The range of animals suited to apply the product; the quantity to be added in different animal feeds, as well as the items to be noted when using the product shall be described in detail.

(10) Packing specifications, notes in storage and storage life

1. Packing specifications: the packing materials and unit net weight of the product shall be described.

2. Notes in storage: the place, conditions and methods of the storage shall be included.
3. Storage life: the production date and storage life of the product shall be clearly marked.

(11) Stability test report and safety evaluation report

When importing the feed and feedstuff additives not yet allowed to be used in People's Republic of China which have been approved to be manufactured and used in the producing country, the safety evaluation report and stability test report of the producing country shall be provided. As for the product required to go through the supplementary safety evaluation test inside People's Republic of China, the organization to do the test shall be recognized by the Ministry of Agriculture, and the test plan shall be examined and checked by the Ministry of Agriculture. The test expenses shall be borne by the applicant.

(12) The information on the product's effectiveness test and the situation of promotion and application

The effectiveness test information of the product: When importing the feed and feedstuff additives not yet allowed to be used in People's Republic of China, which have been approved to be manufactured and used in the producing country, an effectiveness test shall be carried out inside People's Republic of China. The organization to do the test shall be recognized by the Ministry of Agriculture, and the test plan shall be examined and checked by the Ministry of Agriculture. The test expenses shall be borne by the applicant.

Situation of promotion and application: the situation of usage and application of the product in the producing country and other countries shall be provided.

(13) Main references

Literature references on the development, research and manufacture of the product shall be provided.

V. Requirement for sample for re-checking and quality inspection

Upon receiving the Notification of Acceptance, the applicant shall submit the sample of the applied product and Notification of Acceptance to the inspection organization specified by Ministry of Agriculture for rechecking and inspecting of the quality of the product. Three samples of different batch numbers shall be provided for each product for rechecking and quality inspection. Each batch number of the solid sample shall be no less than 500 ml. The inspection expenses shall be borne by the applicant.

Table 1: Application Form for Registration of Imported Feed and Feedstuff Additives

| | |
|-------------------------------------|---------------------------------------|
| Common Name: | Trade Name: |
| Product Classification: | Appearance: |
| Content of Main Ingredients: | Other Ingredients and Content: |
| Manufacturing Facility: | |
| Applicant Company: | |
| Agent: | Signature: |

Table 2: List of Application Materials for Imported Feed and Feed Stuff Additives

| No. | Application materials | Product requires no assessment | Product requires assessment |
|-----|---|--------------------------------|-----------------------------|
| 1 | Certificate of approval to manufacture and sell the product in the producing country, and registration materials in other countries | v | v |
| 2 | Letter of authorization | v | v |
| 3 | Product description and physics and chemistry properties | | v |

| | | | |
|----|--|---|---|
| 4 | Origin and components of the product | v | v |
| 5 | The test report of the chemical constitution of the effective ingredient or the classification and determination report of the animal, plant and microorganism | | v |
| 6 | The manufacturing method | v | v |
| 7 | The quality standard, method of inspection, quality inspection report and the certificate of sanitation and safety | v | v |
| 8 | Pattern of the label, product description and trademark | v | v |
| 9 | Range of applicability and method of application or the quantity to be added | v | v |
| 10 | Packing specifications, notes in storage and storage life | v | v |
| 11 | Stability test report | | v |
| 12 | Safety evaluation report | | v |
| 13 | The effectiveness test report and the situation of promotion and application | | v |
| 14 | Main references | | v |

Note: "v" denotes the required application materials.

Annex 2: Requirements for Re-Registration of Imported feed and feedstuff additives

I. Scope of the Re-registration

When the imported feed and feedstuff additives are to be sold and used inside China after the expiration of the import registration license, the registrant shall apply for re-registration six months before the import registration license has expired.

II. Requirements on the Format of the Application Materials

The material needed is identical to the "Requirements on the Registration Materials of the Import Feed and Feedstuff Additives".

III. Filling out the "Application Form"

The "Application Form" shall be filled out in both Chinese and English.

- (1) Product Name: the common name and trade name of the product shall be included.
- (2) Manufactory: the name and address of the manufacturing facility of the product, which cannot be substituted by the name and address of the head office and the dealer. Detailed address rather than mail box number only is required to be provided.
- (3) Applicant Company: shall be identical to the name and address of the manufacturing facility in general, while the name and address of the head office are also allowed. As for the fish meal, if it is processed on a processing ship, the name and address of the head office shall be provided and the product shall be marked as "Made at Sea".
- (4) The Number of Former License and the Date Issued: shall be filled out in accordance to the import registration license.
- (5) Supplementary Material: tick "v" in front of the respective items changed.
- (6) Applicant or Agent: name, contact number, fax, postcode and correspondence address of the company or individual applied or deputized to apply for the import registration.
- (7) Signature: shall be signed by the applicant.

IV. Content of Application Materials

- (1) Import registration license: The original Import Registration License or its copy.
- (2) Product quality standard: The current and effective quality standard of the product. The quality standard of the product shall be consistent with the quality specification and method of inspection approved and recognized by the relevant administrative authorities in the producing country. The quality standard shall include the content of each kind of effective ingredient, as well as the notation of each kind of harmful substance in the product. The certificate of sanitation and safety issued by the veterinarian or the inspection and quarantine department of the producing country shall be provided when necessary.
- (3) Latest product description: The latest version of the product shall be described, illustrating the product information including the origin, component, quality standard, range of applicability, method of application or quantity to be added, packing specification, items to be noted, and storage life.
- (4) The latest approval documents issued by the producing country should include:
 1. The documentary evidence certifying that the registered product and its main components are permitted to be manufactured and used as the feed and feedstuff additives in the producing country.
 2. The documentary evidence issued by the official authority of the producing country to permit the manufacturing facility to make the products in pursuant to domestic laws and regulations.

3. The certificate of free sale issued by the official authority of the producing country, displaying the product name, as well as the name and address of the manufacturing facility, proving that there are no restrictions limiting the manufacture, sales and utilization in the producing country.

4. If the product has acquired an import license in other countries, relevant documentary evidence or the copy of the registration license shall be provided.

5. The official documents shall be confirmed by the Chinese consulate in the producing country.

(5) Letter of authorization

The agent shall submit proof that the manufacturing facility has authorized him to go through the import re-registration procedures for the product.

(6) Requirement on the materials for the altered items

If the Chinese or English trade name of the product and the name of the applicant or manufacturing facility have been altered, relevant materials shall be provided in accordance to the "Requirements on the re-registration materials of the import feed and feedstuff additives".

If the address of manufacturing facility, the product quality, the composition and component of the product or the range of applicability has been altered, the registration procedures shall be the same as the "Requirement on the registration materials of the import feed and feedstuff additives".

V. Requirement on Samples for Re-checking and Quality Inspection.

For imported feed and feedstuff additives that have failed to re-register in the prescribed time limit or disqualified due to a spot test, the sample product shall be submitted for re-checking and quality inspection. The requirements on samples are identical to the "Requirements on the Registration Material of the Import Feed and Feedstuff Additives".

Table 3: Application Form for Re-registration of Import Feed or Feedstuff additives

| |
|--|
| Product Name |
| Manufacturing Facility |
| Applicant Company |
| Number of Former License and the Date Issued |
| Supplementary Material Product Name: Name of Applicant Company: Name of Manufacturing Facility: |
| Applicant or Agent |
| Signature |

Annex 3: Requirements for Altering Existing Registrations of Imported Feed and Feedstuff Additives

I. Registration Scope

If following any of the contents have been changed during the effective period of the import registration license of the imported feed and feedstuff additives, alteration of the registration shall is required:

- (1) Trade name of the product in Chinese and English;
- (2) Name of the applicant company;
- (3) Name of the manufacturing facility.

II. Requirements on the format of the registration material.

Identical to the "Requirements on the Registration Materials of the Import Feed and Feedstuff Additives".

III. Filling out the "Application form"

"The "Application form" shall be filled out in both Chinese and English.

- (1) Product Name: the common name and trade name of the product shall be included.
- (2) Altered Content: the trade name of the product in Chinese or English, the name of the applicant, and manufacturing facility shall be included.
- (3) Former Name: the respective name in the original import registration license.
- (4) Present Name: name after the change.
- (5) Manufactory: the detailed address of the manufacturing facility of the product.
- (6) The Number of the Former License and the Date Issued: shall be filled out in accordance to the former import registration license.
- (7) Applicant or Agent: name, contact number, fax, postcode and correspondence address of the company or individual applied or deputized to apply for the alter registration.
- (8) Signature: shall be signed by the applicant.

IV. Content of Application Materials

- (1) The former import registration license: The original of the former import registration license.
- (2) Explanation for the alteration: Reasons provided by the manufacturing facility for altering the relevant content.
- (3) Documentary evidence of the producing country: The documents issued by the official authorities of the producing country to permit the alteration of relevant content. The documentary evidence shall be confirmed in the Chinese consulate in the producing country. If the copy of the documentary evidence has been provided, it shall be notarized by the third party.
- (4) Letter of authorization: The agent shall submit the proof that the manufacturing facility has authorized him to go alter the registration of the product.

Table 4: Application Form for Altering Existing Registrations of Imported Feed or Feedstuff Additives

| |
|---|
| Product Name |
| Altered Content (Change Made) |
| Former Name |
| Present Name |
| Manufacturing facility |
| Number of Former License and the Date Issued |
| Applicant or Agent |
| Signature |

Announcement 517**Additional Chinese Product Registration Requirements**

Ministry of Agriculture, People's Republic of China
February 30th 2005

Project Name:**Registration of imported feed and feedstuff additives**

Project Type: Examination before approval

Content of Examination and Approval

1. Whether the product complies with the Regulations on our country (China) to use the feed and feedstuff additives
2. Whether the product is safe, effective, of stable quality and without environmental pollution
3. Whether the test data and relevant documents are real and credible
4. Whether the results of quality recheck and inspection comply with the standard

Legal Basis:

1. "Regulations on managing the feed and feedstuff additives"
2. "Regulations on the registration of the imported feed and feedstuff additives" (Issued on 2000 by Ministry of Agriculture, Decree 38, modified on 2004 by Ministry of Agriculture, Decree 38 revision)
3. Feedstuff additives catalogue issued by Ministry of Agriculture

Conditions:

Please submit following application documents (Chinese and English versions, one original and one copy if not specially required, among which the English original shall be the true copy provided by the manufacturer) and product samples:

1. "The application form for registering the imported feed and feedstuff additives"
2. The proof that the producing country (region) has approved the production and sales in the country and the registration information in other countries (with notarization and validation)
3. Letter of authorization issued by the manufacturer to the agent
4. Material composition, effective constituent and description of physical and chemical properties
5. Description of processing flow diagram and manufacturing method
6. Quality standard, inspection method, product samples with three batch numbers, as well as the inspection report
7. Description of the scope of application
8. Description of the label, packing specification, notes on storage, and service life
9. For products not registered in the producing country (region) or permitted to be produced in the exporting country (region), while not yet allowed to be used in our country, assessments shall be made by experts at registration while following information shall be submitted (one original, one copy):
 1. Official proof (copy) that the producing country (region) has been approved to use the product or the effective components as the feedstuff additives
 2. Product summary
 3. Test report on the chemical constitution of the effective components of the product as well as the authentication report classified by the animal, plant and microorganism

4. Samples of specification sheet
5. Report on testing the stability of the product
6. Feeding test report and report on application of the product
7. Report on the safety assessment of the product
8. Main reference documents

Procedures:

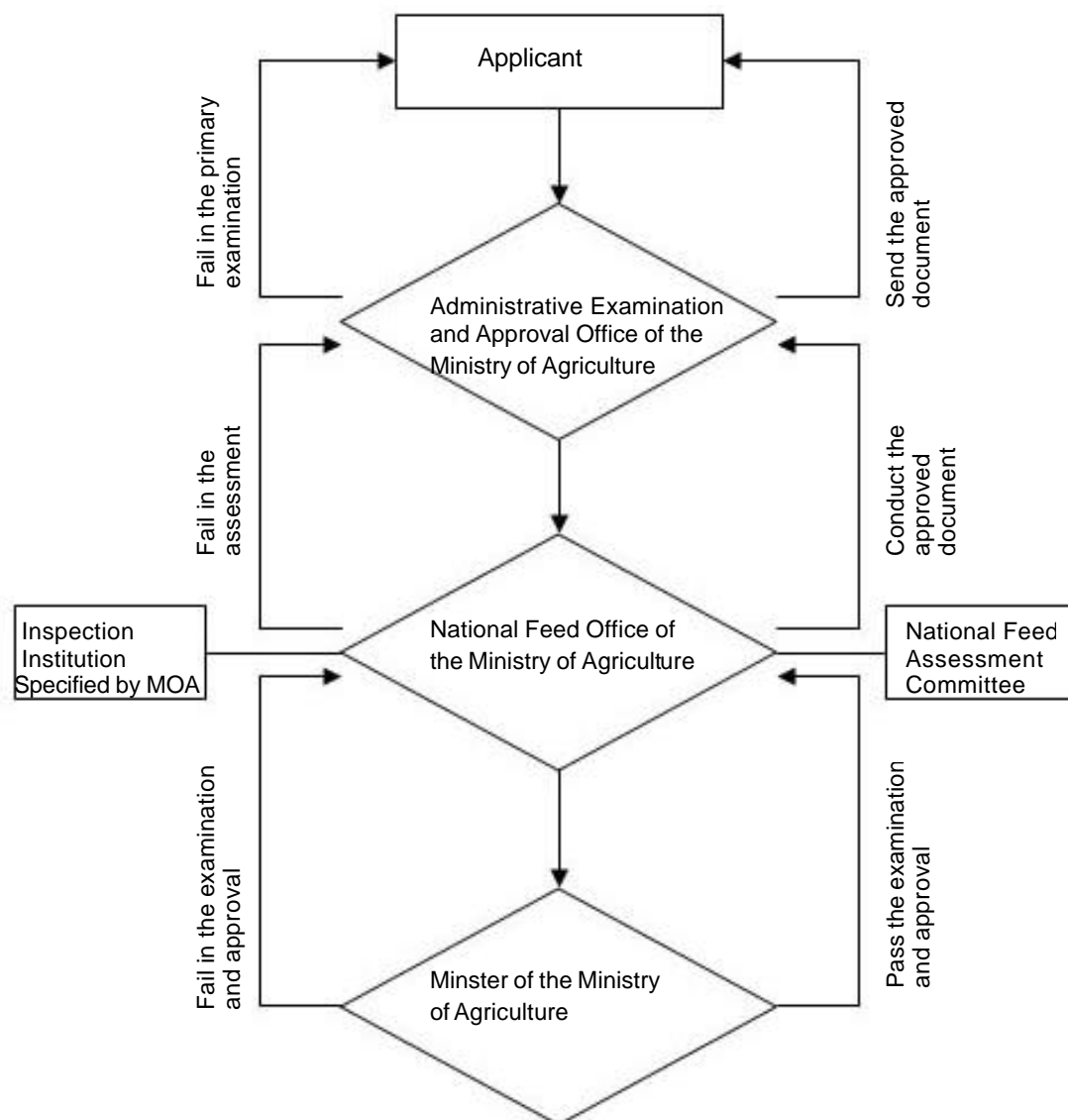
1. Accept the material. The Administration of Examination and Approval of Ministry of Agriculture accepts the "The application form for registering the imported feed and feedstuff additives" and relevant documents submitted by the applicant and starts pre-examination.
2. Project examination. The National Feed Administration Office of Ministry of Agriculture examines the application materials according to relevant Regulations of the exporting nation.
3. Quality recheck and inspection. The applicant submits product samples with three batch numbers to the inspection institutions specified by Ministry of Agriculture for the quality recheck and inspection.
4. Feeding test and safety assessment test. For the product not registered in the producing country (region), the applicant shall submit the product sample to the institution authorized by Ministry of Agriculture for the feeding test and safety assessment test.
5. Expert assessment. The National Feed Assessment Committee will assess the application materials of the two above-mentioned materials according to the results of the feeding test and the safety assessment test.
6. Issue the approved document. The National Feed Administration Office of the Ministry of Agriculture will propose the examination and approval solution according to the quality recheck and inspection and the result of expert assessment. The approved document shall be issued after the examination and approval of the Minister.

Promised (response) period: 20 working days (time for the expert assessment will be no more than 6 months; time for the quality recheck and inspection will be no more than 3 months)

Fee: RMB 8300/Product

- "Notification on adjusting the charging standard for registering the feedstuff issued by National Planning Committee and the Ministry of Finance

(Ji Jia Fei [1997] 41)

Flowchart 1: Registration of imported feed and feedstuff additives

Project Name:

Re-registration materials for imported feed and feedstuff additives

Project Type: Examination before approval

Content of examination and approval:

1. Whether the product complies with relevant (Chinese) Regulations
2. Whether the standards of the product have any changes

Legal basis:

1. "Regulations on managing the feed and feedstuff additives"

2. "Regulations on the registration of the imported feed and feedstuff additives" (Issued on 2000 by Ministry of Agriculture, Decree 38, modified on 2004 by Ministry of Agriculture, Decree 38 revision)
3. Feedstuff additives catalogue issued by Ministry of Agriculture

Conditions:

Please submit following application documents (Chinese and English version, one original and one copy, among which the English original shall be the true copy provided by the manufacturer) and product samples:

1. "Application form for re-registration of import feed or feedstuff additives"
2. The former registration license (Copy)
3. The quality standard document of the product
4. The latest specification of the product
5. The latest approval documents of the producing country (region)
6. The Letter of registration authorization issued by the manufacturer to the agent
7. For the imported feed and feedstuff additives that have failed in the selective examination, product samples with three batch numbers shall be submitted for the quality recheck and inspection.

Procedures:

1. Accept the material. The Administration of Examination and Approval of Ministry of Agriculture accepts the "Application Form for Re-registration of Import Feed or Feedstuff additives" and relevant documents submitted by the applicant and starts the primary examination.
2. Project examination. The National Feed Administration Office of Ministry of Agriculture examines the application materials according to relevant Regulations of China.
3. Quality recheck and inspection. For the product required to be rechecked, the applicant shall submit product samples with three batch numbers to the inspection institutions specified by Ministry of Agriculture for quality recheck and inspection.
4. Issue the approved document. The National Feed Administration Office of Ministry of Agriculture will propose the examination and approval solution according to results of the assessment and the quality recheck and inspection. The approved document shall be issued after the examination and approval of the Minister.

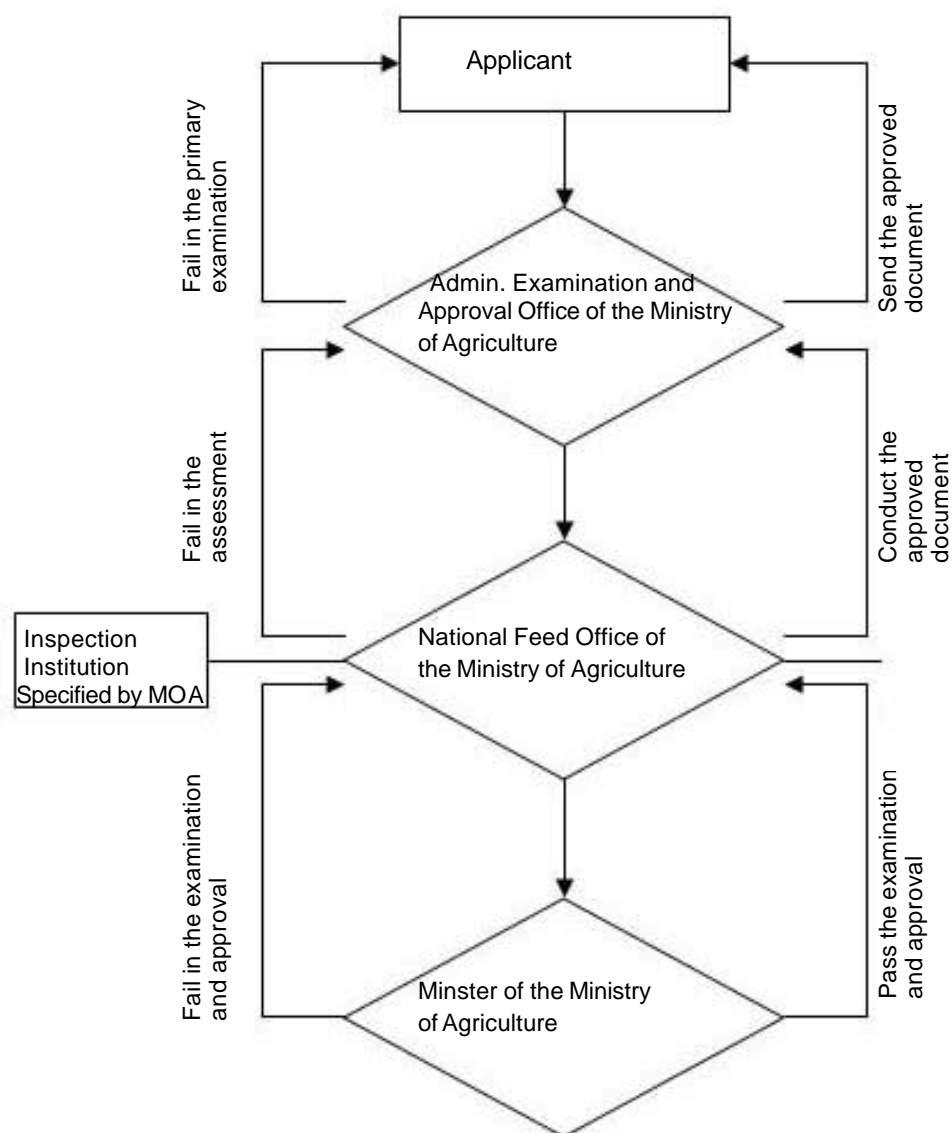
Promised (response) period: 20 working days (time for the quality recheck and inspection will be no more than 3 months)

Fee: RMB 4150/Product

- "Notification on adjusting the charging standard for registering the feedstuff issued by National Planning Committee and the Ministry of Finance

(Ji Jia Fei [1997] 41)

Flowchart 2: Re-registration of imported feed and feedstuff additives



Project Name:

Registration of imported feed and feedstuff additives - Alterations

Project Type: Examination before approval

Content of Examination and Approval

1. Whether the altered item is in the permitted range (of alteration of the product) within the existing registration
2. Whether the product is safe, effective, of stable quality and without environmental pollution
3. Whether the registration license is within the validity period

Legal Basis:

1. "Regulations on managing the feed and feedstuff additives"
2. "Regulations on the registration of the imported feed and feedstuff additives" (Issued on 2000 by Ministry of Agriculture, Decree 38, modified on 2004 by Ministry of Agriculture, Decree 38 revision)
3. Feedstuff additives catalogue issued by Ministry of Agriculture

Conditions:

Please submit following application documents (Chinese and English version, among which the English original shall be the true copy provided by the manufacturer) and product samples:

1. "Application Form for Alter Registration of Import Feed or Feedstuff additives"
2. The former registration license (Copy)
3. Description of the company name, etc., issued by the manufacturer
4. The documents proving that the feed and feedstuff additives administration in the producing country (region) has permitted the alteration (notarized copy)
5. The Letter of Authorization issued by the manufacturer to the agent

Procedures:

1. Accept the material. The Administration of Examination and Approval of Ministry of Agriculture accepts the "Application Form for Altered Registration for Import Feed or Feedstuff Additives" and relevant documents submitted by the applicant, and start the primary examination.
2. Project examination. The National Feed Administration Office of Ministry of Agriculture examines the application materials according to relevant regulations of China.
3. Issue the approved document. The National Feed Administration Office of Ministry of Agriculture will propose the examination and approval solution according to results of the assessment. The approved document shall be issued after the examination and approval of the Minister.

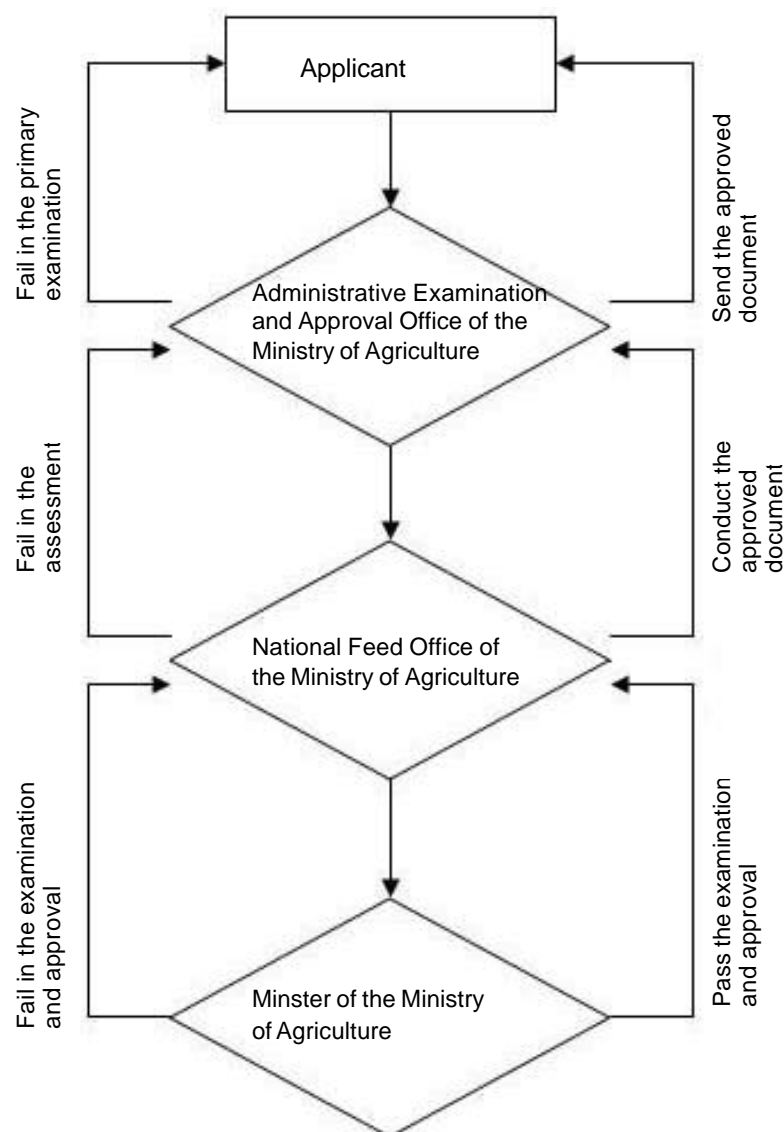
Promised (response) period: 20 working days

Fee: RMB 4150/Product

- "Notification on adjusting the charging standard for registering the feedstuff issued by National Planning Committee and the Ministry of Finance

(Ji Jia Fei [1997] No. 41)

Flowchart 3: Registration alteration process for imported feed and feedstuff additives



Project Name:

Checking and issuing licenses for new feed and feedstuff additives

Project Type: Examination before approval

Content of Examination and Approval

1. Whether the product is a new feed or new feedstuff additive
2. Whether the product is safe, effective, of stable quality and without environmental pollution
3. Whether the test data and relevant documents are real and credible

4. Whether the quality standard is scientific
5. Whether the results of the re-check and inspection of quality comply with the standard

Legal Basis:

1. "Regulations on managing the feed and feedstuff additives"
2. "Regulations on managing the new feed and new feedstuff additives" (Issued on 2000 by Ministry of Agriculture, Decree 37, modified on 2004 by Ministry of Agriculture, Decree 38 revision)
3. Feedstuff additives catalogue issued by Ministry of Agriculture

Conditions:

Please submit following application documents (one original and two copies) and product samples:

1. The application form for "registering new feed and new feedstuff additives"
2. Product name (general name and trade name) and description
3. The description about the basis of the product
4. Product summary
5. Effective constituent ingredients and description of physical and chemical properties
6. Test report on the chemical constitution of the effective components of the product as well as the authentication report classified by the animal, plant and microorganism
7. Quality standard and its compilation description, inspection method, product samples with three batch numbers, as well as the inspection report
8. Description about the manufacturing technique and methods (Type of the fungus and specification of the culture medium shall be provided for micro-organic additives)
9. Stability test report of the product
10. Validity test report of the product
11. Safety assessment test (including the toxicology test and fungus type identification) and report of the product
12. Summary of mid-term production and report on treating the "three types of wastes"
13. Description of the usage, the scope of application, methods of application, and amount of addition of the product
14. Description of the label, packing specification, notes on storage, and service life
15. Main reference documents

Procedures:

1. Accept the material. The Administration of Examination and Approval of Ministry of Agriculture accepts the "The application form for registering the new feed and new feedstuff additives" and relevant documents submitted by the applicant and starts pre-examination.
2. Project examination. The National Feed Administration Office of Ministry of Agriculture examines the application materials according to relevant Regulations on the nation.
3. Quality recheck and inspection. The applicant submits product samples with three batch numbers to the inspection institutions specified by Ministry of Agriculture for the quality recheck and inspection.
4. Feeding test and safety assessment test. The applicant shall, as required, submit the product samples with three successive batch numbers to the institution authorized by Ministry of Agriculture for the feeding test and safety assessment test.
5. Expert assessment. The National Feed Assessment Committee will assess the application materials of the product that has passed the quality recheck and inspection and has completed the feeding test and safety assessment test.
6. Issue the approved document. The National Feed Administration Office of Ministry of Agriculture will propose the examination and approval solution according to the result of assessment. The approved document shall be issued after the examination and approval of the Minister.

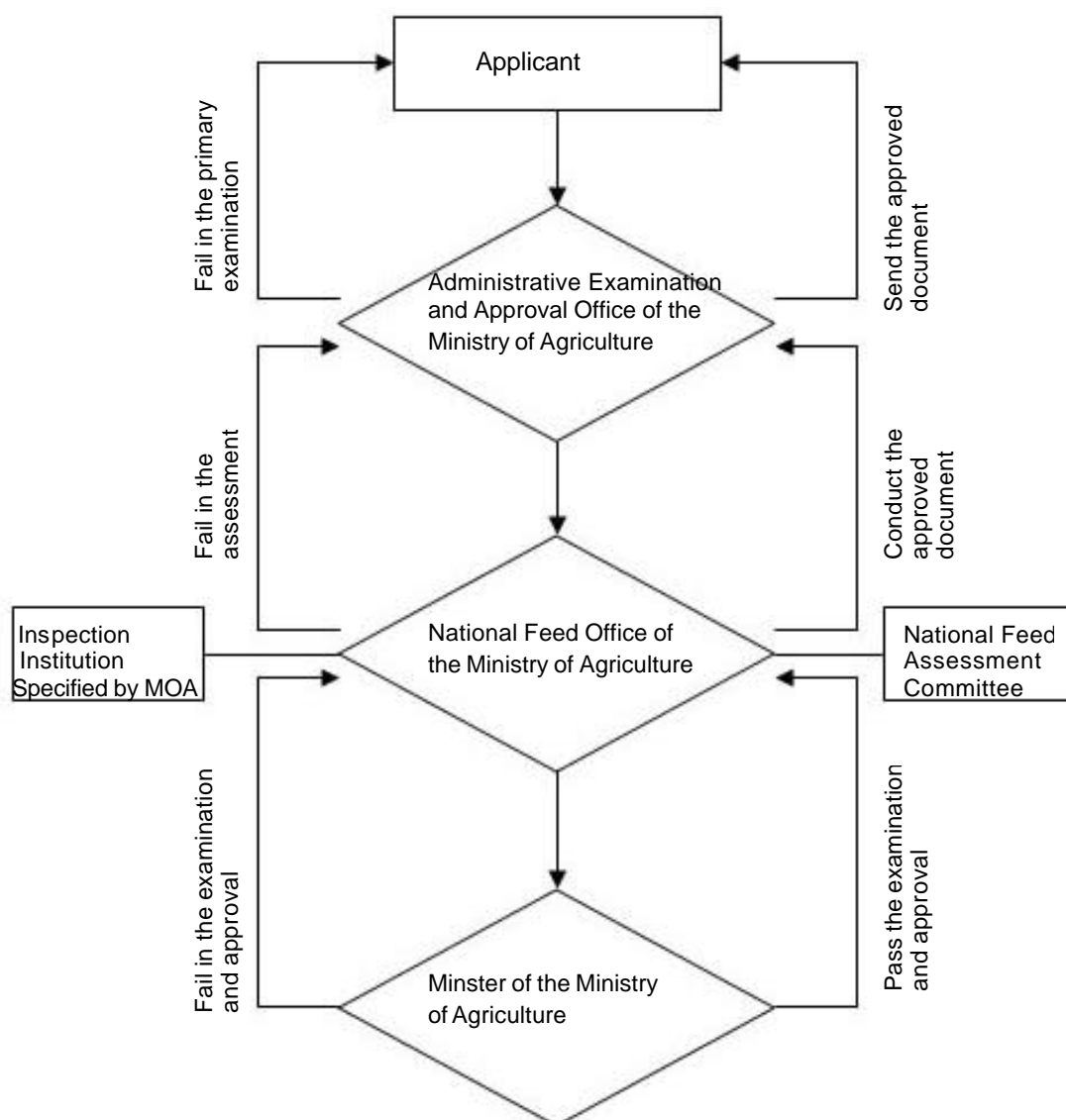
Promised (response) period: 20 working days (time for the expert assessment will be no more than 6 months; time for the quality re-check and inspection will be no more than 3 months)

Fee: RMB 8300/Product

- "Notification on issuing the administrative charging items and standards in the agriculture system"

([1992] Jia Fei Zi No. 452)

Flowchart 3: Checking and issuing the licenses for new feed and feedstuff additives



Project Name:**License for (domestic) production of feedstuff additives and feed pre-mixed with additives**

Project Type: Examination before approval

Content of Examination and Approval

1. Whether there are workshops, equipment, techniques and storage facilities are appropriate for production of the product
2. Whether there are specialized technicians appropriate for production of the product
3. Whether there are necessary quality inspection institutions, inspectors, and inspection facilities
4. Whether the production environment complies with safety and sanitation requirements
5. Whether the anti-pollution measures comply with environmental protection requirements

Legal Basis:

1. "Regulations on managing the feed and feedstuff additives"
2. "Regulations on managing the license for producing the feedstuff additives and the feed pre-mixed with additives" (Issued on 2000 by Ministry of Agriculture, Decree 24, modified on 2003 by Ministry of Agriculture, Decree 26 revision, and on 2004 by Ministry of Agriculture, Decree 38 revision)
3. Feedstuff additives catalogue issued by Ministry of Agriculture

Conditions:

1. "Integrated assessment form for the enterprise producing the feed additives and feed pre-mixed with additives" approved and issued by the provincial feed administration authority
2. Please submit the application documents separately according to following types (copies of the evidencing documents are applicable);
 1. Production license of the feedstuff additives (Type I) newly issued:
 - a. "Enterprise application form of the license of producing the feedstuff additives and the feed premixed with additives"
 - b. "Application of the license of producing the feedstuff additives and the feed premixed with additives"
 - c. Company name pre-approval (New company)
 - d. Manufacturing technique flowchart
 - e. Factory plane layout
 - f. Standard or standard draft of filing the company
 - g. Environmental protection proof
 - h. Those who produce feedstuff micro-organic additives and feedstuff enzyme preparation products shall provide the proof of the source of the fungus
 - i. Those who produce the feedstuff additives, which are dangerous chemical products, shall provide the license of producing dangerous chemical products
 - j. Those whose products have combustible and explosive materials in their raw materials or finished products shall provide the production safety certificate issued by the production safety administrative authorities
 - k. Those who has consigned the inspection shall provide the Test authorization agreement
 - l. All kinds of quality certification (voluntarily)
 2. Production license of the feedstuff additives (Type II) newly issued:
 - a. "Enterprise application form of the license of producing the feedstuff additives and the feed premixed with additives"

- b. "Application of the license of producing the feedstuff additives and the feed premixed with additives"
 - c. Company name pre-approval (New company)
 - d. Manufacturing technique flowchart
 - e. Factory layout
 - f. Filing certificate of company standards
 - g. Those who reprocess new feedstuff additives and imported feedstuff additives shall provide the authorization issued by the original manufacturer (agent)
 - h. Those who produce the feedstuff additives that are dangerous chemical products shall provide the license of producing dangerous chemical products
 - i. Those who have contracted out the inspection shall provide the test authorization agreement
 - j. All kinds of quality certification (voluntary)
3. Production license of the feed pre-mixed with additives
- a. "Enterprise application form of the license of producing the feedstuff additives and the feed premixed with additives"
 - b. "Application of the license of producing the feedstuff additives and the feed premixed with additives"
 - c. Company name pre-approval (New company)
 - d. Manufacturing flowchart
 - e. Factory plane layout
 - f. Filing certificate of company standards
 - g. Those who has consigned the inspection shall provide the Test authorization agreement
 - h. All kinds of quality certification (voluntarily)
4. Those who continue the production after the expiration of the production license shall renew the production license as required, providing above prescribed application materials as well as the former production license.
5. For those who set up branches, start production in other places, change the production location or add a production type out of the production range approved by the production license shall re-apply, providing the above prescribed application materials as well as the former production license.
6. Those who changed the company name, registered address or name of the production location shall submit the alter application report, the former production license and the valid "Company name pre-approval certificate"

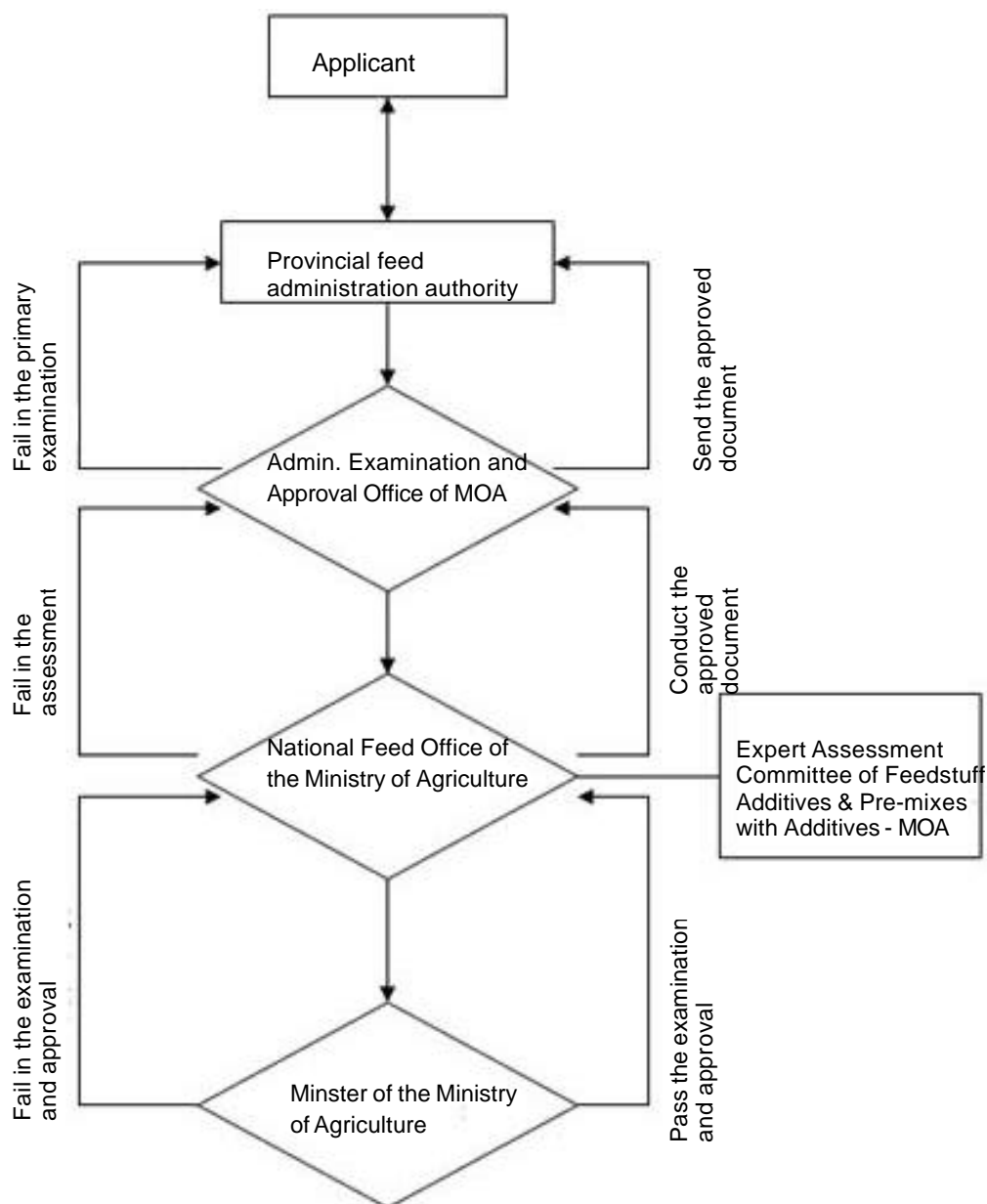
Procedures:

1. Accept the material. The Administration of Examination and Approval of Ministry of Agriculture accepts the "The application for the license of producing the feedstuff additives and the feed pre-mixed with additives" and "Integrated assessment form for the enterprise producing the feed additives and the feed pre-mixed with additives" and relevant documents submitted by the applicant and starts primary examination.
2. Expert assessment. The Expert Assessment Committee of Feedstuff Additives and the Feed Pre-mixed with Additives of the Ministry of Agriculture will assess the application materials and conduct a field re-check if necessary.
3. Issue the approved document. The National Feed Administration Office of Ministry of Agriculture will propose the examination and approval solution according to the result of expert assessment. The approved document shall be issued after the examination and approval of the Minister.

Promised (response) period: 20 working days (time for the expert assessment and the field recheck will be no more than 2 months)

Fee: No charge

Flowchart 4: License for (domestic) production of feedstuff additives and feed pre-mixed with additives



Announcement 658

Categories of Feedstuff Additives

Ministry of Agriculture of People's Republic of China
May 11, 2006

"Category of Feedstuff Additives (2006)" is hereby announced in accordance with the "Management Regulations of Feed and Feedstuffs", for the purpose of enhancing the management of the feedstuff additives. The "Category of Feedstuff Additives" (Announcement of Ministry of Agriculture, No. 318) issued by the Ministry of Agriculture on December 9th 2003 expires on this very day.

The Approved Feed Additives 2006

| Class | Common name of feed additive | Usage |
|--------------|--|--------------------------------------|
| Amino Acids | L-Lysine Monohydrochloride, L-Lysine Sulfate [*] , DL-Methionine, L-Threonine, L-Tryptophan | All species or categories of animals |
| | Methionine Hydroxy Analogue, Methionine Hydroxy Analogue Calcium | Pig, Chicken and Cattle |
| | N-Hydroxymethyl Methionine Calcium | Ruminant |
| Vitamins | Vitamin A, Vitamin A Acetate, Retinol Palmitate, Thiamin Hydrochloride (Vitamin B ₁), Thiamin Mononitrate (Vitamin B ₁), Riboflavin (Vitamin B ₂), Pyridoxine Hydrochloride (Vitamin B ₆), Vitamin B ₁₂ (Cyanocobalamin), L-Ascorbic Acid (Vitamin C), Calcium Ascorbate, L-Ascorbyl-2- Polyphosphate, Vitamin D ₃ , alpha-Tocopherol(Vitamin E), alpha-Tocopherol Acetate, Menadione Sodium Bisulfite (Vitamin K ₃), Menadione Dimethylpyrimidinol Bisulfite [*] , Menadione Nicotinamide Bisulfite [*] , Nicotinic Acid, Niacinamide, D-Calcium Pantothenate, DL-Calcium Pantothenate, Folic Acid, D-Biotin, Choline Chloride, Inositol, L-Carnitine Hydrochloride | All species or categories of animals |

| | | |
|-----------------------------|--|--------------------------------------|
| Minerals and Their chelates | Sodium Chloride, Sodium Sulfate, Sodium Dihydrogen Phosphate, Disodium Hydrogen Phosphate, Potassium Dihydrogen Phosphate, Dipotassium Hydrogen Phosphate, Light Calcium Carbonate, Calcium Chloride, Calcium Hydrogen Phosphate, Calcium Dihydrogen Phosphate, Tricalcium Phosphate, Calcium Lactate, Magnesium Sulfate Heptahydrate, Magnesium Sulfate Monohydrate, Magnesium Oxide, Magnesium Chloride, Ferrous Citrate Hexahydrate, Ferrous Fumarate, Ferrous Lactate Trihydrate, Ferrous Sulfate Heptahydrate, Ferrous Sulfate Monohydrate, Cupric Sulfate Monohydrate, Cupric Sulfate Pentahydrate, Zinc Oxide, Zinc Sulfate Heptahydrate, Zinc Sulfate Monohydrate, Zinc Sulfate Anhydride, Manganous Chloride, Manganous Oxide, Manganous Sulfate Monohydrate, Potassium Iodide, Potassium Iodate, Calcium Iodate, Cobaltous Chloride Hexahydrate, Cobaltous Chloride Monohydrate, Cobaltous Sulfate, Sodium Selenite, Cupric Methionine Chelate, Ferrous Glycine Chelate, Ferric Methionine Chelate, Zinc Methionine Chelate, Cupric Yeast Complex [*] , Ferrous Yeast Complex [*] , Manganous Yeast Complex [*] , Selenium Yeast Complex [*] | All species or categories of animals |
| | Chromium Nicotinate [#] , Chromium Yeast Complex [*] , Chromium Methionine Chelate [*] , Chromium Tripicolinate [#] | Growing-finishing pig |
| | Potassium Sulfate, Iron Oxide, Cobalt Carbonate, Copper Oxide | Ruminant |
| | Basic Copper Chloride [#] | Pig and Chicken |
| Enzymes | Amylase (Source : <i>Aspergillus niger</i> , <i>Bacillus amyloliquefaciens</i> , <i>Bacillus licheniformis</i> , <i>Bacillus subtilis</i>), Cellulase (Source: <i>Trichoderma longibrachiatum</i> , <i>Trichoderma reesei</i>), beta-Glucanase (Source : <i>Aspergillus niger</i> , <i>Bacillus subtilis</i> , <i>Trichoderma longibrachiatum</i>), Glucose Oxidase (Source : <i>Penicillium notatum</i>), Lipase (Source : <i>Aspergillus niger</i>), Maltase (Source : <i>Bacillus subtilis</i>), Mannanase (Source : <i>Bacillus lentus</i>), Pectase (Source : <i>Aspergillus niger</i>), Phytase (Source : <i>Aspergillus niger</i> , <i>Aspergillus oryzae</i>), Protease (Source : <i>Aspergillus niger</i> , <i>Aspergillus oryzae</i> , <i>Bacillus subtilis</i>), Pullulanase (Source : <i>Bacillus acidopullulyticus</i>), Xylanase (Source : <i>Aspergillus oryzae</i> , <i>Humicola insolens</i> , <i>Trichoderma longibrachiatum</i> , <i>Bacillus subtilis</i> [*] , <i>Trichoderma reesei</i> [*]), Galactomannase (Source: <i>Aspergillus niger</i> , <i>Aspergillus oryzae</i>) [*] | Following the directions for use |

| | | |
|--|--|--------------------------------------|
| Live Micro-organisms | <i>Bacillus licheniformis</i> [*] , <i>Bacillus subtilis</i> , <i>Bifidobacterium bifidum</i> [*] , <i>Enterococcus faecalis</i> , <i>Enterococcus faecium</i> , <i>Enterococcus lactis</i> , <i>Lactobacillus acidophilus</i> , <i>Lactobacillus casei</i> , <i>Lactobacillus lactis</i> [*] , <i>Lactobacillus plantarum</i> , <i>Pediococcus acidilacticii</i> , <i>Pediococcus pentasaceus</i> [*] , <i>Candida utilis</i> , <i>Saccharomyces cerevisiae</i> , <i>Rhodopseudomonas palustris</i> | Following the directions for use |
| | <i>Lactobacillus bulgaricus</i> [#] | Pig and Poultry |
| Non-protein Nitrogen | Urea, Ammonium Hydrogen Carbonate, Ammonium Sulfate, Liquid Ammonia, Ammonium Dihydrogen Phosphate, Diammonium Hydrogen Phosphate, Biuret, Isobutylidene Diurea, Urea Phosphate | Ruminant |
| Antioxidants | Ethoxyquin, Butylated Hydroxyanisole (BHA), Butylated Hydroxytoluene (BHT), Propyl Gallate | All species or categories of animals |
| Preservatives and Acidifier | Formic Acid, Ammonium Formate, Calcium Formate, Acetic Acid, Sodium Diacetate, Propionic Acid, Ammonium Propionate, Sodium Propionate, Calcium Propionate, Butyric Acid, Sodium Butyrate, Lactic Acid, Benzoic Acid, Sodium Benzoate, Sorbic Acid, Sodium Sorbate, Potassium Sorbate, Fumaric Acid, Citric Acid, Tartaric Acid, Malic Acid, Phosphoric Acid, Sodium Hydroxide, Sodium Hydrogen, Potassium Chloride, Sodium Carbonate | All species or categories of animals |
| Colouring Agents | beta-Carotene; Capsanthin; beta-Apo-8'-Carotenal; beta- Apo-8'-Carotenoic Acid Ethyl Ester; beta, beta- Carotene - 4,4-Diketone (Canthaxanthin); Xanthophyll [*] ; Natural Xanthophyll (Marigold Extract) | Poultry |
| | Astaxanthin | Aquatic animal |
| Seasonings and Flavoring Agents | Sodium Saccharin, Sodium Glutamate, Disodium 5'-Inosinate, Disodium 5'-Guanylate, Sanguinarine, Approved food additives | All species or categories of animals |
| Binders, Anticaking Agents and Stabilizers | alpha- Starch, Aluminum Oxide, Calcium Salt of Edible Fatty Acid [*] , Calcium Silicate, Calcium Stearate, Glycerine Fatty Acid Ester, Polyacrylic Resin II, Polyoxyethylene(20) Sorbitan Monooleate, Propylene Glycol, Silicon Dioxide, Sodium Alginate, Sodium Carboxymethylcellulose, Sodium Polyacrylate [*] , Sorbitol Esters of Fatty Acid, Sucrose Esters of Fatty Acid, Sodium Acid Pyrophosphate [*] , Glyceryl Monosterate [*] | All species or categories of animals |
| | Glycerine [*] | Pig, Chicken and Fish |
| Poly-saccharides | Xylo-oligosaccharides [#] | Laying hens |

| | | |
|-----------------------|--|--------------------------------------|
| and Oligo-saccharides | Low-molecular-weight Chitosan [#] | Growing-finishing pig and Chicken |
| | Galactomanno-oligosaccharides [#] | Pig, Broiler chick and Rabbit |
| | Fructo-oligosaccharides, Manno-oligosaccharides | All species or categories of animals |
| Others | Betaine, Betaine Hydrochloride, Natural Betaine, Garlicin (Allimin), Polyvinylpyrrolidone (PVP), Sorbitol, Soybean Lecithin, YUCCA (Yucca Schidigera Extract), Docosahexaenoic Acid (DHA) [*] , Cysteamine Hydrochloride [#] | All species or categories of animals |
| | Sacchariterpenin (Seed Cake of <i>Camellia L.</i>), Oregano Carvacrol (<i>Origanum aetheroleum</i>) [*] | Pig and Poultry |
| | Acetohydroxamic Acid | Ruminant |

Notes:

The feed additives with the asterisk '*' have obtained the registered licenses, but they can not be manufactured in China before their manufacturers apply for new feed additive certificates.

The feed additives with the asterisk '#' were authorized after Oct. 2000

END OF TRANSLATION