

法規名稱(Title) : Regulations of Permission on Manufacture and Import of
Feed and Feed Additives

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法規內文(Content) : **Article 1**

These regulations are prescribed according to Sections 10.2 and 11.3 of the Feed Control Act (hereinafter “the Act”)

Article 2

2.1 For the license to manufacture and/or process feed/feed additives according to Section 10.1 of the Act, the application shall be submitted to the central competent authority along with the following information or objects and, upon subsequent notice of the central competent authority, provide the fee receipt, two copies of the list for lab tests, and four 300-gram samples of the feed/feed additives before the deadline.

2.1.1 Four photocopies of the applicant’ s Identity card (ID). Non-natural-person applicants shall submit four

photocopies of the certificate of incorporation or registration.

2.1.2 Four photocopies of registration certificate for the feed/ feed additives factory.

2.1.3 Two copies each of product description, ingredient specification, manufacture flowchart, testing method and the test report, formulation basis, and reference material or literature. Such documents are not required for feed/additive for which national standards already exist.

2.1.4 Two photos of the feed/ feed additives package or container, if any.

2.1.5 For reuse-entity applicants, four copies of the one-time or general-purpose permit, or the industrial waste disposal plan.

2.1.6 For applicants that are public/private waste clearance/disposal organization, four copies of the waste clearance/disposal permit, its attached list and appendices.

2.1.7 For feed in the animal-fat category, the proof of raw material source, and one color photo of the material.

2.1.8 For feed used as mineral supplements, two copies

of proof of raw material source.

2.1.9 For feed additives containing peptide, protein, or nucleic acid that are produced with genetically modified (GM) or molecular biotechnology, the characteristics of the GM additives, safety assessment, a list of relevant research papers and such papers.

2.1.10 For feed/ feed additives claiming special benefits, two copies of post-feeding test report about the benefit.

2.1.11 Four copies of the affidavit stating that the entity name and/or trademark are not a likeness, duplicate, counterfeit, or allusion of any existing entity name or trademark.

2.1.12 Other information or objects specified by the central competent authority.

2.2 For the license to repackage feed or feed additives according to Section 10.1 of the Act, applicants shall submit the application to the central competent authority along with the following information or objects and, upon subsequent notice of the central competent authority, provide the fee receipt, two copies of the list for lab tests, and four 300-gram samples of

the feed or feed additives.

2.2.1 Two photocopies of manufacture/import license registration for feed and additives.

2.2.2 Two copies of written consent by the holder of the registration described in Section 2.2.1.

2.2.3 Information or objects specified in Sections 2.1.1~2.1.4, 2.1.11, and 2.1.12. However, the formulation basis and reference material in Section 2.1.3 are not required.

2.2.4 Other information or objects specified by the central competent authority.

Article 3

For the license to import feed/feed additives according to Section 11.1 of the Act, the application shall be submitted to the central competent authority along with the following information or objects and, upon subsequent notice of the central competent authority, provide the fee receipt, two copies of the list for lab tests, and four 300-gram samples of the feed or additive before the deadline.

3.1 Four photocopies of the applicant' s ID paper.

Non-natural-person applicants shall submit four photocopies of the certificate of incorporation or registration.

3.2 Four photocopies of registration certificate for feed sale.

3.3 Two copies each of product description, ingredient specification, manufacture flowchart, inspection method and the inspection report, formulation basis, and reference literature. Such documents are not required for feed/feed additives for which national standards already exist.

3.4 Two photos of the feed/feed additives package or container, if any.

3.5 One original and three photocopies of notarized/certified Power of Attorney (POA) by the foreign supplier and manufacture/sales permit issued by the exporting country; if the foreign supplier is not the original manufacturer, additional documents are required: one original and two photocopies of notarized/certified POA by the original manufacturer to the supplier. No need to submit such a POA if the manufacturer has been verified by the central competent

authority to be officially recognized by the exporting country.

3.6 For feed in the animal-fat category, the proof of raw material source, and one color photo of the material.

3.7 For feed additives containing peptide, protein, or nucleic acid that are produced with genetically modified (GM) or molecular biotechnology, the characteristics of the GM additives, safety assessment, a list of relevant research papers and such papers listed.

3.8 For feed/additives claiming special benefits, two copies of post-feeding test report about the benefit.

3.9 Four copies of the affidavit stating that the entity name and/or trademark are not a likeness, duplicate, counterfeit, or imitation of any existing entity name or trademark.

3.10 Other information or objects specified by the central competent authority.

Article 4

Regarding the application for license (hereinafter “application”) described in Articles 2 and 3, if the applicant -- after being notified to pay the fee, and/or

provide complete and accurate information/ samples -- fails to fully rectify the issue before a deadline, the central competent author may disregard the application, or review the application simply based on currently available information.

Article 5

The application in Articles 2, 3, and 10 will be denied in any of the following situations:

5.1 The feed/feed additives listed in the application has not yet been declared by the central competent authority for use as feed/ feed additives according to Section 3.1 or Section 3-1.1 of the Act; or has been declared by the central competent authority according to Section 20.1 of the Act as a substance prohibited from use in feed or feed additives.

5.2 The factory making the feed/feed additives listed in the application is incompliant with the factory establishment standards in Section 9.2 of the Act, or has not been registered according to law.

5.3 Test results show that feed/feed additives listed in the application is incompliant with applicable national

standards, or in the absence of applicable national standards, incompliant with ingredient specifications approved by the central competent authority.

5.4 The label on the feed/additive package or container fails to comply with the requirements of Article 14 of the Act.

5.5 The applicant is not eligible for feed/feed additives manufacture license registration (hereinafter “manufacture registration”) or import license registration (hereinafter “import registration”) according to Section 25.2 of the Act.

5.6 For the mineral supplements described in Article 2, the raw material supplier has not obtained import registration, manufacture registration or the license is not for feed/food.

5.7 For additives containing peptide, protein, or nucleic acid that are produced with GM or molecular biotechnology, failure to pass the safety assessment test.

5.8 For feed/additives claiming special benefits, failure to deliver said benefits or necessity for animal growth after reviews.

5.9 The company name or trademark is found to be a likeness, duplicate, counterfeit or imitation of existing ones.

5.10 The application contains deficiency or mistakes that cannot be rectified, or failure to rectify according to Article 4.

Article 6

For applications described in Articles 2, 3, and 10, the central competent authority may invite experts or scholars from relevant authorities, legal entities, schools or organizations to assist in the review. When necessary, the authority may send officials to inspect the domestic/overseas site of feed/feed additives factory or supplier.

Article 7

6.2 For the application approved according to Article 2 or 3, a manufacture or import registration shall be issued by the central competent authority.

Article 8

A manufacture registration shall contain the following information:

8.1 The registration number,

8.2 Categories, descriptions, commercial names of the feed/feed additives, and scope of the license of registration,

8.3 Name and address of the feed manufacturer; non-natural-person manufacturer shall list its name, and the name of the person-in-charge, or the representative,

8.4 Name and address of the factory,

8.5 Ingredients and their content levels,

8.6 Target species, and

8.7 Description of feed appearance, and the package/container.

Article 9

An import registration shall contain the following information:

9.1 The registration number,

9.2 Categories, descriptions, commercial names of the feed/feed additives, and scope of the registration license,

9.3 Name and address of the feed vendor;

non-natural-person vendor shall list its name, the person-in-charge or representative, and the primary office or sales venue,

9.4 Name and address of foreign supplier or manufacturer,

9.5 Ingredients and their content levels,

9.6 Target species and life stages, and

9.7 Description of feed appearance, and the package/container.

Article 10

10.1 Application for extension of manufacture/import registration (license) according to Section 12.1 of the Act shall be submitted to the central competent authority one to four months before it expires, along with the following documents:

10.1.1 The original manufacture/import registration,

10.1.2 One photocopy of the applicant' s ID card.

Non-natural-person applicants shall submit one photocopy of the certificate of incorporation or registration.

10.1.3 For extension of import registration, one

photocopy of registration certificate for the feed or feed additives factory.

10.1.4 For extension of import registration, the original and one photocopy of notarized/certified Power of Attorney (POA) from the foreign supplier; if the foreign supplier is not the original manufacturer, additional documents are required: the original and one photocopy of notarized/certified POA by the original manufacturer to the supplier. No need to submit such a POA if the manufacturer has been verified by the central competent authority to be officially recognized by the exporting country.

10.1.5 For reuse-entity applicants, two copies of the one-time or general-purpose permit, or the industrial waste disposal plan.

10.1.6 For applicants that are public/private waste clearance and/or disposal organizations, two copies of the waste clearance/disposal permit, its attached list and appendices.

10.2 Once approved by the central competent authority, the license extension applied for in Article 9 shall last for no more than four years, and shall be noted as so on

the manufacture/import registration. When the registration license runs out of space for such notes, the applicant shall pay a fee and surrender the original license for a replacement manufacture/import registration.

Article 11

The categories, descriptions, ingredients, and target species of animals on the manufacture/import registration must not change; for changes to other items on the registration, the following procedure shall be followed:

11.1 Regarding the manufacture license, application for changes to name/address of the manufacturer, person-in-charge or representative, name or address of the factory shall be submitted within one month of the fact of change, along with relevant document proof.

11.2 Regarding the import registration, applications for changes to name/address of the foreign supplier/factory shall be submitted within three months after the fact of change, along with the document proofs described in Section 3.5. However, for a change of the country of

manufacturing factory, stipulations in Article 3 may be applicable.

11.3 Application for changes to commercial name, appearance, package/container of feed/feed additives shall be submitted before one month prior to the change, along with two photos of the package/container.

11.4 If the content of feed/additive listed on the manufacture/import registration is rendered incompliant with Section 4.2 of the Act due to a change of applicable national standards, the application shall be submitted upon notice of the central competent authority.

Article 12

If a manufacture/import registration is defaced, damaged or lost, application for a renewed/re-issued registration shall be submitted to the central competent authority, along with explanation and fee payment. In exchange for a re-issued registration, the original registration shall be surrendered and annulled.

Article 13

Entities delegating importation tasks to other feed

vendors according to Section 11.2 of the Act shall enter
- batch by batch - the name and tax ID of the delegated
party on the joint review and customs clearance platform
instituted by central competent authorities.

Article 14

14.1 Documents or information required under these
Regulations shall be submitted along with the Chinese or
English-language translation if originally prepared in
a third language.

14.2 Supporting documents or information required under
these Regulations - if issued by a foreign government
or a power of attorney (POA) produced in a foreign country
- shall be duly authenticated by the Republic of China's
embassy, consulate, representative office or other
institutions authorized by the Ministry of Foreign
Affairs. Documents issued by authorities in Hong Kong,
Macau or Mainland China, shall be certified by an
organization established or designated, or a private
organization entrusted, by Executive Yuan.

Article 15

These Regulations shall enter into force on the date of
its promulgation.