

法規名稱(Title):	Regulations of Permission and Inspection on Genetically Modified Feed or Feed Additives
公發布日(Date):	2016.01.04
法規沿革(Legislative):	1.Promulgated on January 4, 2016
法規內文(Content):	<p><b>Article 1</b></p> <p>These Regulations are enacted pursuant to the provisions of Article 11-1 of the Feed Control Act (hereinafter referred to as “the Act” ).</p> <p><b>Article 2</b></p> <p>When applying for a permit with reference to Paragraph 1 of Article 11-1 of this Act or for a certificate of feed use approval with reference to Paragraph 2 of Article 11-1 of this Act, developers shall complete an application form and submit the following information prepared in an optical disk to the competent authority of the central government. Based on the notification of the competent authority of the central government, developers shall submit the payment receipt, samples, inspection methods, and other supplementation by the deadline:</p> <ol style="list-style-type: none"> <li>1. Identification documentation of developer. Corporate applicants shall submit the permit of establishment or certificate of registration and the identification documentation of the person-in-charge.</li> <li>2. Basic information of the genetically modified feed or feed additives.</li> <li>3. Description of bio-safety of the genetically modified feed or feed additives.</li> <li>4. Relevant research reports and literature and an index of them.</li> <li>5. When applying for a certificate of feed use approval specified in Paragraph 2 of Article 11-1 of this Act, applicants shall also submit the field test review of the genetically modified feed or feed additives completed by the law and the certificate of plantation or culture approval.</li> <li>6. For applications made on and for the behalf of a foreign developer, applicants shall also submit the power of attorney of this foreign developer.</li> </ol> <p><b>Article 3</b></p> <p>The competent authority of the central government may reject applications mentioned above or directly review existing information without further notice when applicants fail to make the payment, submit relevant information and samples, or make corrections thereof by the deadline advised by the competent authority of the central government.</p> <p><b>Article 4</b></p> <p>Applications made under Article 2 shall be disapproved under any of the following circumstances:</p> <ol style="list-style-type: none"> <li>1. Feed or feed additives that are not announced as feed and feed additives by the competent authority of the central government with</li> </ol>

reference to Paragraph 1 of Article 3 or Paragraph 1 or Article 3-1 of this Act; or feed or feed additives banned by the competent authority of the central government with reference to Paragraph 1 of Article 20 of this Act.

2. Genetically modified feed or feed additives failed in the bio-safety assessment.

3. Feed or feed additives with uncorrectable defects or errors or not corrected with reference to the regulations in the foregoing article.

#### **Article 5**

The longest review period of applications made under Article 2 may be 18 months. In addition, the competent authority of the central government may notify applicants of extension for another six months for applications requiring more complicated testing methods or bio-safety assessments, provided that only a one-time extension shall be allowed.

The competent authority of the central government may invite experts or scholars of relevant agencies, corporations, schools or groups to assist in the review of the abovementioned topics.

#### **Article 6**

Applicants applying for extension with reference to Paragraph 3 of Article 11-1 of this Act shall complete an application form and submit the following information to the competent authority of the central government. After approving the extension, the competent authority of the central government shall remark this in the certificate of feed use approval. When there is no suitable column for recording this, applicants shall make the payment to renew a certificate of feed use approval:

1. Original certificate of feed use approval.
2. Research reports or literature regarding the bio-safety of the genetically modified feed or feed additives within the past five years.
3. Other supplementation specified by the competent authority of the central government.

Applicants applying for the re-issue or renewal of a lost or damaged certificate of feed use approval specified in Paragraphs 1 and 2 of Article 11-1 of this Act shall specify the reasons for re-issue or renewal, make the payment, and apply to the original issuing agency.

After a change of the entries recorded in the certificate of feed use approval specified in Paragraphs 1 and 2 of Article 11-1 of this Act, certificate holders shall complete an application form and submit the original certificate of feed use approval and the certificate of changed entries to apply for a certificate change to the competent authority of the central government within two months after the change. After approving the change, the competent authority of the central government may record such change in the certificate of feed use approval. When there is no suitable column for recording such change, applicants shall make the

payment and submit the original certificate of feed use approval to renew the certificate of feed use approval.

#### **Article 7**

With the approval of the competent authority of the central government, applicants may be exempted from the bio-safety assessments under any of the following circumstances when applying for genetically modified feed or feed additives in accordance with Article 2.

1. Holders of the certificate of use approval of genetically modified foods issued by the health competent authority of the central government with reference to Paragraph 2 of Article 21 of the Act Governing Food Safety and Sanitation and relevant regulations prior to the implementation of the Regulations.
2. Applicants registering genetically modified foods registered for review to the health competent authority of the central government with reference to Paragraph 2 of Article 21 of the Act Governing Food Safety and Sanitation and obtaining the certificate of use approval for genetically modified foods after the implementation of the Regulations.

#### **Article 8**

A Chinese or English translation shall be provided for submittals or information not prepared in Chinese or English.

Submittals or information specified in the Regulations issued by a foreign government shall be certified by a ROC embassy or consulate, representative office, office, or other organizations authorized by the Ministry of Foreign Affairs. Documents issued by the competent authority of Hong Kong, Macau, or mainland China shall be certified by the organization established or appointed by the Executive Yuan or civilian groups it assigns.

#### **Article 9**

The Regulations shall be implemented as of the date of proclamation.