

**【Title】** Notice of the Ministry of Health on Issuing the Provisions on the Administration of Permits for Import Foods without Governing National Food Safety Standards [Effective]

**【法规标题】** 卫生部关于印发《进口无食品安全国家标准食品许可管理规定》的通知  
[现行有效]

**【法宝引证码】** CLI.4.136481(EN)

Date Issued: 08-09-2010

发布日期：2010-08-09

Effective date: 08-09-2010

生效日期：2010-08-09

Issuing authority: Ministry of Health

发布部门：卫生部

Area of law: Health and Sanitation

类别：卫生

Notice of the Ministry of Health on Issuing the Provisions on the Administration of Permits for Import Foods without Governing National Food Safety Standards

(No.79 [2010] of the Ministry of Health)

The health departments (bureaus) of all provinces, autonomous regions and municipalities directly under the Central Government, the Health Bureau of Xinjiang Production and Construction Corps, Chinese Center for Disease Control and Prevention, and the National Center for Health Inspection and Supervision under the Ministry of Health:

In order to carry out the Food Safety Law and the Regulation on the Implementation of the Food Safety Law, regulate the permits for import foods without any governing national food safety standards, the Ministry of Health formulated the Provisions on the Administration of Permits for Import Foods without Governing National Food Safety Standards, which are hereby issued to you for your compliance and implementation.

August 9, 2010

Annex:

## Provisions on the Administration of Permits for Import Foods without Governing National Food Safety Standards

Article 1 For purposes of regulating the safety evaluation and the licensing of import foods without governing national food safety standards, these Provisions are formulated pursuant to the Food Safety Law and the Regulation on the Implementation of the Food Safety Law.

Article 2 For the purpose of these Provisions, the term “import foods without governing national food safety standards” refers to foods which are produced outside China and have not been imported yet and for which the state has not made or promulgated governing national food safety standards, except for:

1. Foods for which the edible agricultural product quality safety standards, food hygiene standards, food quality standards and the relevant food service standards have been made;
2. Foods announced or listed in the catalogue of foods whose import is permitted by the relevant departments of the State Council;
3. Pre-mixed foods produced by mixing materials with governing standards; and
4. Other foods not in the category of import foods without governing national food safety standards.

Article 3 Import foods without governing national food safety standards shall conform to the food safety requirements and the provisions of the relevant departments of the State Council.

Article 4 The Ministry of Health shall be responsible for the permission for import foods without governing national food safety standards, make and promulgate the safety evaluation technical norms, and designate the Health Supervision Center of the Ministry of Health as the technical reviewing organ for import foods without governing national food safety standards, which shall be responsible for accepting applications for import foods without governing national food safety standards, organizing safety evaluations, making technical reviews, submitting to the higher authorities for approval, etc.

Article 5 To apply for a permit to import any food without governing national food safety standards, an importer shall apply to the reviewing organ by submitting:

1. An application form;
2. Formula or ingredients of the food;
3. Producing techniques;
4. Enterprise standards and inspection methods;
5. A labeled sample in the smallest sales package;
6. Evidentiary materials on the lawfulness of its production and trading in the foreign country concerned; and
7. Other materials necessary for review.

Article 6 An applicant shall submit documents that truthfully reflect the relevant situations and undertake the authenticity of the application materials.

Article 7 The reviewing organ shall, within 60 days after accepting an application, organize experts in medicine, food, nutrition, standards, etc. to make a technical review on the safety of the import food without governing national food safety standards and reach a technical review conclusion.

If necessary, the reviewing organ may ask the applicant to answer the relevant technical questions on the spot, in which case the applicant shall be cooperative.

Where it needs to supplement the relevant materials for technical review, the reviewing organ shall promptly notify the applicant. The applicant shall supplement the required materials as required.

Where it needs to verify the relevant materials or the inspection results, the reviewing organ shall notify the applicant of the characteristics to be inspected, the batch to be inspected, the inspection methods and other relevant requirements. Safety inspection shall be conducted by an inspection institution with the required qualification. If there are no national standards for a food safety inspection method, the reviewing organ must firstly validate the inspection method.

Article 8 The specific procedures for obtaining a permit to import food without governing national food safety standards shall be governed by the Administrative License Law, the Measures for the Administration of Sanitary Administrative Licenses and other relevant provisions.

Article 9 The Ministry of Health shall decide whether to grant a permit for the import of foods without governing national food safety standards based on the technical review conclusion.

No permit may be granted if the food safety requirements are not satisfied, in which case reasons shall be given in writing.

Article 10 The Ministry of Health shall make an announcement on the permitted import foods without governing national food safety standards and serve the relevant documents upon the applicant. Such an announcement shall contain the generic name of the food, reference standards, characteristics to be inspected, inspection method, etc.

For import food which meets the above-mentioned announcement requirements, it is not required to apply for a permit again.

Article 11 The Ministry of Health shall, based on the safety evaluation results of import foods without governing national food safety standards, make and promulgate the corresponding national food safety standards pursuant to the relevant provisions on the administration of national food safety standards.

Along with the promulgation of the national food safety standards for an import food, the original announcement about the food shall be automatically abolished.

Article 12 Importers and dealers of import foods without governing national food safety standards shall establish a system to keep records of the import and sale of such foods.

Article 13 Under any of the following circumstances, the Ministry of Health shall promptly organize a re-evaluation on an import food without governing national food safety standards for which a permit has been granted:

1. Evidence shows that the said import food has potential safety problems; or
2. With scientific and technological progress, doubt arises regarding the safety of the import food.

If the import food fails to reach the food safety requirements upon reevaluation, the Ministry of Health is entitled to annul the original announcement and forbid its trading and use.

Article 14 Import health foods and import foods produced with new food production materials shall be governed by the provisions on the administration of health foods and new-resource foods.

Article 15 These Provisions shall come into force on the date of promulgation.

Annexes:

1. Provisions on the Application for the Import of Foods without Governing National Food Safety Standards and the Acceptance thereof
2. Application Form for the Administrative Permit of Import Foods without Governing National Food Safety Standards

Annex 1

Provisions on the Application for the Import of Foods without Governing National Food Safety Standards and the Acceptance thereof

Article 1 To regulate the applications for a license to import foods without governing national food safety standards and the acceptance thereof, these Provisions are formulated pursuant to the Provisions on the Permit of Import Foods without Governing National Food Safety Standards.

Article 2 An entity or individual applying for a license to import a food without governing national food safety standards (hereinafter referred to as “applicant”) shall submit one original and four photocopies of the application materials together with one food sample to the reviewing body of the Ministry of Health:

The application materials shall be arranged in the following order, be clearly labeled for distinguishing, and be bound up into a volume.

1. An application form for an administrative permit to import foods without governing national food safety standards;
2. Formula or ingredients;
3. Producing techniques;
4. Enterprise standards and inspection methods;
5. Sales tags;
6. Evidentiary materials on the lawfulness of the production and trading of the food in the foreign country concerned;
7. Relevant standards of international organizations or other countries;
8. Safety evaluation materials or other materials helpful to review; and
9. A labeled sample in the smallest sales package.

Article 3 Except for certificates issued by the government, the original application documents shall be affixed with the official seal of the applicant on each page or across the pages.

Article 4 Application documents in foreign languages shall be translated into standard Chinese and the translation shall be placed before the corresponding foreign document, except for ingredient's name, personal name, foreign address, etc., that need to be specified in English or Latin under these Provisions.

Article 5 The formula or ingredients of a food shall contain the name of the food, the composition and proportion of ingredients, physical and chemical properties and chemical constitution of the major ingredients, source of raw materials, etc.

Article 6 Producing techniques shall contain: detailed and standard descriptions and process charts, technical parameters, and key technical requirements; name, specifications and quality requirements of raw materials or auxiliary agents; and level of clean air and geographic division of the producing environment.

Article 7 Enterprise standards and inspection methods include quantitative and qualitative inspection methods for sensory indicators, chemical indicators, microorganism indicators, content of major ingredients, and other indicators.

Article 8 A labeled food sample in the smallest sales package shall include a sales sample and a label. The label shall conform to the relevant provisions and, if necessary, indicate the method of use, range of use, amount of consumption, people it is unsuitable for, cautions, etc.

Article 9 Documentary evidence proving the lawfulness of the production and trading of a food in a foreign country shall meet the following requirements:

1. It shall be issued by the competent governmental department or industrial association of the country (region) of production or origin. Photocopies are permitted if originals are unavailable but shall be notarized by the local authorities, and then certified by the Chinese embassy (consulate) in the country (region) of production or origin or confirmed by the issuer.
2. It shall bear the product name, the name of producer, the name of issuer, the official seal of the applicant or signature of the legal representative of the applicant, and the date of issuance.
3. The product name and the name of producer as indicated in the evidence shall be identical with those indicated in the application.
4. If one piece of documentary evidence involves two or more products, if the original evidence has been provided for the application of the first product, it is allowed to provide a photocopy of the documentary evidence for the application of the other products but a written explanation shall be made.
5. It shall be translated into standard Chinese and notarized by the Chinese notary organ.

Article 10 Other materials helpful for review may contain:

1. The relevant standards and provisions of international organizations or other countries;
2. Hygienic reports, ingredient analysis and survey reports and toxicological documents issued by overseas labs with the required test conditions or domestic inspection institutions with the required qualification; and
3. Others.

Article 11 The reviewing organ of the Ministry of Health shall, after receiving the application materials, make a decision on whether to accept the application or not immediately or within 5 workdays. If the application materials meet the prescribed requirements, the reviewing organ shall accept them; if they are incomplete or not in the statutory forms, the reviewing organ shall notify the applicant of all contents that need to be supplemented or corrected in writing at one time.

Article 12 An applicant shall, according to the technical review results, submit one original of the supplementary materials within one year. The supplementary materials shall be dated. Any failure to submit supplementary materials within the prescribed time shall be deemed as termination of application. If the submission is delayed under special circumstances, a written application for extending the time limit shall be submitted.

Article 13 An applicant may apply for returning the evidentiary materials proving the lawfulness of the production and trading of the food concerned in a foreign country and the agency certificates that have been submitted if the application is terminated or rejected. Other application materials will be retained by the reviewing organ for future reference and will not be returned to the applicant.