

**Voluntary Report** – Voluntary - Public Distribution

**Date:** March 20,2020

**Report Number:** CH2020-0023

**Report Name:** The Notice on the Technical Review of Relevant Standards for Imported Foods Without Applicable National Food Safety Standards

**Country:** China - Peoples Republic of

**Post:** Beijing

**Report Category:** FAIRS Subject Report

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**Report Highlights:**

In June 2017, the National Center for Food Safety Risk Assessment (CFSA) released the Notice on the Technical Review of Relevant Standards for Imported Foods without Applicable National Food Safety Standards. The Notice specifies the scope of imported foods without national food safety standards and lists foods that do not fall in the scope, including foods containing mixed raw materials that have applicable food safety standards, as well as imported foods produced from new food materials, new varieties of imported food additives, and new varieties of food-related products. The Notice also provides the detailed requirements to apply for authorization to import foods that do not have national standards, and the application review procedure. This report provides an unofficial translation of the CFSA notice.

## Summary

Article 92 of the 2015 Food Safety Law provides that imported foods, food additives and food-related products shall comply with China's national food safety standards.

Article 93 of the Food Safety Law and Article 47 of the Implementing Regulations of the Food Safety Law provide that when there is no Chinese national food safety standard for an imported food, its exporter, producer, or Chinese importer may submit the relevant (foreign) national, regional, or international standard(s) for review by the National Health Commission (NHC). NHC will review the submitted standards and decide whether to temporarily apply such standards if they comply with the requirements for food safety in China. While temporarily adopting the foreign/international standards, NHC will develop the corresponding Chinese national food safety standards in a timely manner.

Pursuant to the [Notice for Regulating the Standard Review of Imported Foods without National Food Safety Standard](#) issued by the National Health and Family Planning Commission (NHFPC, now NHC) in April 2017, the National Center for Food Safety Risk Assessment (CFSA) is responsible for conducting technical reviews of imported foods without existing Chinese national food safety standards. The Notice states that the foreign exporter, producer, or the entrusted importer may submit applications (including the standard applicable in their country) to CFSA for technical review.

Following the NHFPC notice, in June 2017, CFSA released the Notice on the Technical Review of Relevant Standards for Imported Foods without Applicable National Food Safety Standards, which specifies the scope of imported foods without national food safety standards, the requirements to apply for authorization to import foods that do not have national standards, and the application review procedure. The following foods are not considered imported foods without applicable national food safety standards:

- 1) Imported foods that are covered by the existing Chinese national food safety standard (including general standards and product-specific standards);
- 2) Foods already approved and announced by relevant government authorities in China;
- 3) Foods containing mixed raw materials that have applicable food safety standards; and
- 4) Imported foods produced from new food materials, new varieties of imported food additives, and new varieties of food-related products.

The Notice also provides the detailed requirements for documents/materials to be included in the applications for authorization to import foods that do not have national standards, and the application review procedure. However, the length of time required to complete a review is not provided.

This report provides an unofficial translation of the CFDA notice. Inquiries about the application process can be sent to CFSA at [jinkou@cfsa.net.cn](mailto:jinkou@cfsa.net.cn).

## **BEGIN TRANSLATION**

### **Notice on the Technical Review of Relevant Standards for Imported Foods Without Applicable National Food Safety Standards**

Pursuant to related provisions of the Food Safety Law of the People's Republic of China and the Notice of the General Office of the National Health and Family Planning Commission (NHFPC) on Regulating the Technical Review of Imported Foods without Applicable National Food Safety Standards to regulate the technical review of standards for imported foods without applicable national food safety standards, yet (hereinafter referred to as imported foods without applicable national standards) the relevant issues are hereby notified as follows:

#### **I. Scope of Imported Foods without Applicable National Standards**

Imported foods without applicable national standards refers to the foods produced and traded (by enterprises) outside of China, which China has not released corresponding national food safety standards for; such foods do not include foods that are covered by the general standards or product standards among national food safety standards, or the foods announced or approved by relevant departments of the State Council, or the pre-mixed foods produced by mixing various raw materials that have applicable food safety standards, or scenario where a food is not categorized as food without applicable national food safety standards.

General standards refer to national food safety standards of Maximum Levels of Mycotoxins in Food (GB2761), Maximum Levels of Contaminants in Food (GB2762), Maximum Residue Limits for Pesticides in Food (GB2763), Limit of Pathogens in Food (GB29921), Standards for Uses of Food Additives (GB2760), Standards for the Use of Nutritional Fortification Substances in Foods (GB14880), General Rules for the Labelling of Prepackaged Foods (GB7718), General Rules for the Nutrition Labelling of Prepackaged Foods (GB 28050), and other general standards that apply to various food categories.

According to the provisions of Article 93 of the Food Safety Law, the following products do not fall in the scope of imported foods without applicable national standards: imported foods produced from new food materials, new varieties of imported food additives, and new varieties of food-related products.

Imported food additives and imported food-related products do not fall in the scope of imported foods without applicable national standards, either.

#### **II. Requirements for Application Materials to Import Foods without Applicable National Standards**

To apply for importing foods without applicable national standards, an overseas exporter, an overseas manufacturer or an entrusted importer (hereinafter referred to as the "applicant") shall submit an application form and required materials to China National Center for Food Safety Risk Assessment (CFSA).

The applicant shall truthfully submit relevant materials, reflect the real situation (to CFSA), and be accountable for authenticity of the application materials. The application materials should be arranged in the following order, with conspicuous labels:

(I) An application form for the technical review of relevant standards for importing foods without applicable national food safety standards;

(II) Documents certifying that the food production and trade are permitted overseas issued by a (foreign) government or by an institute authorized by government, such as a free sale certificate;

(III) The food safety-related standards and regulations adopted in relevant countries (regions), or international standards adopted;

(IV) The basis for the rationality of the relevant regulations and standards implemented, including: list of ingredients (arranged in order of usage from high to low and specifying the content of main ingredients); detailed and normative description of the production process and the flow chart of the production process; the relevant food safety risk assessment to which the implementation of the standards are based, or other basis that helps to prove that the adopted regulations and standards are science-based and reasonable.

(V) Clear pictures of the product (sample), label of the product in the importing country (region), and the label (if applicable) to be used in China.

(VI) Other materials conducive to the review, such as text of corresponding standards and administrative regulations issued by international organizations or other countries.

(VII) One unopened sample of the product in the minimum package for sale, or a product sample of 30 grams.

(The applicant) shall provide Chinese translation of the above materials. The applicant should mark contents in the submitted materials that should be released to the public, such as business proprietary information.

### **III. Review Procedures of Relevant Standards for Importing Food Without Applicable National Standards**

(I) Application. The applicant logs in the “National Food Safety Standard Management Information System” (website: bz.cfsa.net.cn; hereinafter referred to as the “system”); after completing the new user registration, the applicant shall fill in and submit the application form online, and upload the electronic copy or scanned copy of the application materials. The uploaded materials should be clear to read, and in either the Word or the PDF format; the uploaded documents shall be named as “material sequence number + applicant name + product name + material name”; if simplified names/abbreviation used are used, such names/abbreviations for the materials shall be consistent in all submitted documents.

If the uploaded materials comply with the requirements for format, the system will inform the applicant that the online submission is completed.

(II) Completeness review. CFSA shall conduct a completeness review of the materials and decide whether to accept the application. If the content of the application materials comply with the requirements, CFSA accepts the application; otherwise, CFSA will notify the applicant, through the system, the missing content to be supplemented.

Confirming the application is accepted, the applicant shall print the application form with the system-allocated code; the printed application form, signed by the representative of the applicant and stamped with the applicant's official seal, shall be scanned and uploaded into the system. The original signed and stamped application form and two original copies of the complete application materials should be mailed to the "Secretariat of National Food Safety Standard Review Committee, China National Center for Food Safety Risk Assessment" (address: Building 2, Yard 37, Guangqu Road, Chaoyang District, Beijing, 100022). When mailing, please mark on the envelope "Application Materials for the Review of Importing Foods without applicable national food safety standards".

(III) Preliminary review. CFSA shall conduct preliminary review for the application materials that have passed the completeness review. Deeming the product does not fall in the scope of imported products without applicable national food safety standards, CFSA will provide suggestion for next step to the applicant, which will be sent to the applicant as feedback through the system.

(IV) Soliciting comments. If the application falls in the scope of importing foods without applicable national food safety standards, CFSA will solicit public comments in its website ([www.cfsa.net.cn](http://www.cfsa.net.cn)) about whether relevant standards, regulations or international standards are applicable to the imported foods without applicable national standards; the commenting period is 30 days. CFSA is responsible for organizing and summarizing the received comments.

(V) Technical review. After soliciting comments, CFSA shall invite experts from the National Food Safety Standard Review Committee to conduct technical review of the application materials; the review is carried out following various requirements by the National Food Safety Standard Review Conference and will be conducted in form of meetings. Based on needs, experts from the National Expert Committee for Food Safety Risk Assessment and experts from relevant technical institutes under the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and the China Food and Drug Administration (CFDA) can be invited to participate in the review.

If needed, the applicant can be invited to the technical review meeting to answer relevant technical questions. If the technical review deems the application material need to be supplemented and improved, the applicant shall submit the required supplementary materials within 60 days. If the applicant fails to submit the required supplementary material, the application shall be deemed to be terminated.

(VI) Conclusions of review. If the technical review considers the submitted food standard materials comply with requirements, it shall propose the review opinion, which designate the temporarily applicable standards; deem it necessary to develop and revise corresponding national food safety standards, the technical review opinion shall also put forward the proposals thereof; if the technical review finds the submitted materials are not applicable, or do not fall in the scope of the review of importing foods without applicable national food safety standards, corresponding reasons shall be given.

CFSA shall submit the technical review opinions to the National Health and Family Planning Commission and inform the applicant online through the system.

(VII) Re-examination. If there is evidence that there may be problems with the safety of the imported foods without applicable national standards, or technical indicators of the implemented standard are change, CFSA shall organize a re-examination of the announced standards for the imported foods without applicable national standards.

#### **IV. Other issues**

The “Management Information System of National Food Safety Standard” provides progress of the review for importing foods without applicable national food safety standards; the applicant can follow the system for application progress.

All application materials submitted by the applicant will not be returned; they are documented by CFSA for reference.

Inquiries about application for imported foods without applicable national standards could be sent via email to: [jinkou@cfsa.net.cn](mailto:jinkou@cfsa.net.cn).

**END OF TRANSLATION**

#### **Attachments:**

No Attachments.