

Notice of the Ministry of Health on Issuing the Measures for the Archival Filing of the Enterprise Food Safety Standards

Promulgation date:	06-10-2009	Department:	Ministry of Health
Effective date:	06-10-2009	Subject:	Health and Sanitation

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(No. 54 [2009] of the Ministry of Health)

The health administrative departments and bureaus of all provinces, autonomous regions and municipalities directly under the Central Government, and the Health Administrative Bureau of Xinjiang Production and Construction Corps,

This Ministry has formulated the Measures for the Archival Filing of the Enterprise Food Safety Standards in accordance with the Food Safety Law of the People's Republic of China. They are hereby issued to you for your compliance.

June 10, 2009

Measures for the Archival Filing of the Enterprise Food Safety Standards

Article 1 These Measures are formulated in accordance with the Food Safety Law of the People's Republic of China for the purpose of regulating the archival filing of the enterprise food safety standards (hereinafter referred to as the "enterprise standards").

Article 2 When a food production enterprise has formulated the following enterprise standards, it shall, before organizing the production, report them to the health administrative department of the province, autonomous region or municipality directly under the Central Government (hereinafter referred to as the "provincial health administrative department") for archival purpose:

- (1) enterprise standards when there are no national food safety standards or local standards; and
- (2) enterprise standards which are stricter than the national food safety standards or the local standards.

Article 3 The content of the enterprise standards filed for archival purpose shall conform to Article 18 and Article 20 of the Food Safety Law of the People's Republic of China.

Article 4 Where the enterprises subordinate to a group company apply unified enterprise standards, the headquarters of the group company or any of its subordinate production enterprise may report the enterprise standards to the provincial health administrative department of the place where it is located for archival purpose. When such enterprise standards are filed for archival purpose, the names and addresses of all enterprises applying the standards shall be indicated.

Article 5 For the food processed on a commissioned basis or manufactured upon authorization, if the enterprise standards have been reported for archival purpose by the entrusting party or the authorizing party, the entrusted party or the authorized party need not go through the formalities of archival filing again, but the entrusting party or the authorizing party shall indicate the name and address of the entrusted party or the authorized party when making the archival filing. Where the entrusting party or the authorizing party has no relevant enterprise standards, or the entrusted party or the authorized party does not implement the standards of the entrusting party or the authorizing party, the entrusted party or the authorized party shall formulate enterprise standards and report them

for archival purpose in accordance with relevant provisions.

Article 6 The enterprise standards shall cover the raw materials of food (including major ingredients, ingredients and food additives used), production technology, and indicators, limits as well as technical requirements related to food safety.

The formulation of enterprise standards shall meet the requirements of Part I of the Guiding Rules of Standardization: Structure of the Standards and Rules on the Formulation (GB/T1.1).

The format of the serial number of the enterprise standards shall be: Q/ (code of the enterprise) (four-digit sequential number) S— (year).

Article 7 When an enterprise is reporting the enterprise standards for archival purpose, it shall submit the following materials:

- (1) enterprise standards archival-filing registration form;
- (2) text of the enterprise standards (in octuplicate) and the electronic version thereof;
- (3) explanations on the formulation of the enterprise standards; and
- (4) other materials prescribed by the provincial health administrative department.

Article 8 The explanations on the formulation of the enterprise standards shall explain the process of formulating the enterprise standards in detail and the comparison with the relevant national standards, local standards, international standards, and foreign standards.

The comparison between standards shall follow the following principles:

- (1) Where there are national standards or local standards, the enterprise standards shall be compared with the national standards or the local standards;
- (2) Where there are no national standards and local standards, the enterprise standards shall be compared with the international standards; and
- (3) Where there are no national standards, local standards and international standards, the enterprise standards shall be compared with the standards of two or more countries or regions.

Article 9 The enterprise standards filed for archival purpose shall be signed by the legal representative or person-in-charge of the enterprise.

The enterprise shall ensure that the filed enterprise standards are authentic and legal and the food produced under the filed enterprise standards are safe, and assume all legal liabilities for the results of implementing the standards.

Article 10 The provincial health administrative department shall determine an institution responsible for accepting the archival filing of enterprise standards and publish its name.

Article 11 The provincial health administrative department shall, when receiving the archival-filing materials of enterprise standards, check whether the submitted materials are complete, and handle them respectively under the following circumstances:

- (1) Where the enterprise standards need not to be filed for archival purpose according to law, it shall immediately notify the party concerned of such information;

(2) Where the submitted materials are not complete or fail to meet the prescribed requirements, it shall, immediately or within five working days, notify the party concerned to supplement or correct; or

(3) Where the submitted materials are complete and meet the prescribed requirements, it shall accept the archival filing.

Article 12 After accepting the archival filing of enterprise standards, the provincial health administrative department shall, within ten working days from the acceptance of the archival filing, mark the serial number of archival filing on the archival-filing registration form and attach a seal of archival filing to it. The marked serial number of archival filing and the seal of archival filing attached shall be taken as the certificate for the archival filing of enterprise standards.

The format for arranging the serial number of archival filing shall be: (the first two digits of the administrative division code of the province, autonomous region or municipality directly under the Central Government) (four-digit sequential number) S— (year). The sequential number shall be arranged by the provincial health administrative department on its own.

Article 13 The provincial health administrative departments shall not charge any fee in any name during the handling of archival filing.

Article 14 The provincial health administrative department shall, within 20 working days from the day when a certificate of archival filing is issued to the enterprise, announce the filed enterprise standards to the general public, and send the text of the filed enterprise standards to the agriculture administrative department, quality supervision department, industry and commerce administrative department, food and drug supervision and administration department at the same level.

Where an enterprise asks not to disclose such content of enterprise standards as involving trade secrets, it shall put forward a written opinion during the archival filing and provide the text of enterprise standards that may be published to the public at the same time.

Article 15 Under any of the following circumstances, an enterprise shall review the enterprise standards initiatively:

(1) the relevant laws, regulations, rules and national food safety standards as well as local standards are undergoing any change;

(2) the production technology of the enterprise or the raw materials (including major ingredients, ingredients and the food additives used) and the formula of the food are undergoing any change; or

(3) other circumstances under which a review is required.

Article 16 The archival filing of the enterprise standards shall be valid for three years. Where the archival filing needs to be renewed at the expiry of the valid period, the enterprise shall review the filed enterprise standards, fill out the enterprise standards archival filing renewal form, and go through the formalities of renewal of archival filing at the original health administrative department where the archival filing is made.

Article 17 Where an enterprise considers that it is necessary to revise the enterprise standards upon review, it shall go through the archive filing formalities again after the revision.

Where an enterprise fails to go through the formalities of renewal of archival filing at the expiry of the valid period of the archival filing of enterprise standards, the original health administrative

department where the archival filing is made shall notify the enterprise to handle the relevant formalities within a prescribed time limit. If the enterprise fails to handle the relevant formalities within the prescribed time limit, the original health administrative department where the archival filing is made shall cancel the archival filing.

The provincial health administrative department shall, within 20 workdays from the day when the archival filing of the enterprise standards are renewed or cancelled, release the information of the renewal or cancellation to the general public.

Article 18 When the provincial health administrative department receives a notification of the relevant supervisory department that an enterprise fails to organize the production in accordance with the filed enterprise standards, it shall handle it under the following circumstances:

(1) As for the enterprise standards which are subject to Article 2 (1) of these Measures and the relevant supervisory department suggests the cancellation of the archival filing, it shall cancel the archival filing thereof.

(2) As for the enterprise standards which are subject to Article 2 (2) of these Measures, it shall cancel the archival filing thereof.

Article 19 Where the provincial health administrative department finds any falsification in the filed enterprise standards, it shall cancel the archival filing of such enterprise standards.

Article 20 The provincial health administrative department shall, before cancelling the archival filing, notify the enterprise of its right to a hearing. Where an enterprise requires a hearing, the health administrative department shall organize the hearing under relevant provisions.

Article 21 The enterprise standards which have been reported to the quality supervision department for archival purpose prior to June 1, 2009 shall continue to be valid within the valid period of the archival filing and are not required to be reported again to the health administrative departments for archival purpose.

Article 22 The provincial health administrative department may formulate detailed rules for implementation in accordance with these Measures.

Article 23 These Measures shall come into force on the date of promulgation.