
Translation for reference:

Announcement of the Certification and Accreditation Administration of the People's Republic of China about the Relevant Issues on the Registration Renewal of the Overseas Manufacturers of Imported Milk-Based Infants and Young Children Formula

Issued on March 14, 2018
No. 9 2018

In compliant with the *Food Safety Law of the People's Republic of China* and its implementation regulations, the *Administrative Measures on the Registration of Overseas Manufacturers of Imported Food* (AQSIQ Decree 145), among others, in order to effectively complete the registration renewal process and carry out the subsequent regulatory measures on overseas manufacturers of imported infants and young children milk-based formula, the relevant information has now been announced as follows.

1. Application format:

According to the *Food Safety Law of the People's Republic of China* and its implementation regulations, the *Administrative Measures on the Registration of Overseas Manufacturers of Imported Food* (AQSIQ Decree 145), the term of validity of the registration of overseas manufacturers of infant and young children milk-based formula is 4 years. All overseas manufacturers of infant and young children milk-based formula which intend to renew their registrations shall submit their application to registration renewal through the competent authorities of the country or region where they are located and submit relevant information and supporting documents, among others to the Certification and Accreditation Administration of China (CNCA). (Please refer to the attachment for the application format and related requirements).

2. Application time:

If a registered overseas manufacturer of infant and young children milk-based formula needs to renew its registration, it shall submit its application one year prior to the expiration of its registration, and provide relevant information and supporting documents to prove that the company continuously to comply with the registration requirements as requested. To smooth the transition, all overseas manufacturers of infant and young children milk-based formula who were registered by the end of 2014 shall submit applications to registration renewal to the competent authorities of the country or region where they are located by the end of 2018.

3. Follow up procedures:

The application to registration renewal as well as related information and supporting documents, among others, submitted by registered overseas infant formula manufacturers, will be reviewed by the CNCA in accordance with relevant working procedures. For those manufacturers that meet the registration requirements, their registration will be renewed at the end of the term of validity; for those manufacturers that can't meet the registration requirements continuously, their registration will be suspended; and for those manufacturers who fail to submit applications to registration renewal after the expiration of the registration, their registrations will be cancelled.

CNCA
13 March 2018

Attachment 1: Format for Application to Registration Renewal

Attachment 2: Requirements on Submission of Relevant Information and Supporting Documents.

Translation for reference

Attachment 1: Format for application to registration renewal

Format for Application to Registration Renewal

1. Format for application to registration renewal for manufacturers

The manufacturer hereby declares that it is aware of the *Regulations for Administration of the Registration of Overseas Manufacturers of Imported Food* (AQSIQ Decree 145) and other relevant Chinese laws, regulations and food safety standards, and the manufacture as well as its infant and young children milk-based formula products to be exported to China comply with relevant Chinese laws, regulations, and food safety standards.

The manufacturer hereby is applying for the registration renewal. The information and additional materials submitted are authentic and accurate.

Name and position of the legal representative

Signature of the legal representative, company seal, date

2. Reference format for statement of the competent authority of the country or region where the manufacturer is located

We hereby declare that the manufacturer is approved and regulated by <name of the competent authority of the country or region where the manufacturer is located>, that we continue to recommend the registration of the manufacturer in China, and that the manufacturer complies with the requirements of relevant Chinese and the laws, regulations and standards in the <name of the country or region where the manufacturer is located) or equivalently.

Name and title of the person in charge

Signature of the person in charge and Competent Authority Seal

Attachment 2: Requirements on Submission of Relevant Information and Supporting Documents

Requirements on Submission of Relevant Information and Supporting Documents

All overseas manufacturers of infant and young children milk-based formula who apply to renew their registrations shall submit following relevant information and documents to show they have been continuously complying with the registration requirements no later than 31st December, 2018:

1. The inspection conclusion and report of the latest audit conducted by the competent authority of the country or region where the manufacturer is located.
2. The statement by the competent authority of the country or region where the manufacturer is located that the competent authority continues to recommend the registration of the manufacturer in China and that the manufacturer is able to comply with the requirements of relevant Chinese laws, regulations and standards (see attachment 1).
3. The manufacturer submits application in written following the application format (see attachment 1), and log into the China Import Food Enterprise Registration (CIFER) System (<http://cifer.cnca.cn>) to update the relevant registration information of the manufacturer.
4. A written report on self-assessment about being compliant with Chinese relevant laws and regulations and standards by the manufacturer. The written report shall at least include following information:
 - a. The manufacturer shall describe that within the valid registration period, if any activities, such as re-construction or expansion of facilities, which might impact the sanitation conditions, have been conducted; or if any activities, such as adjustments of production operation or environment condition, which might impact the sanitation controls, have been conducted.
 - b. Does the manufacturer's pathogen control plan match with the products it manufactures? During the valid registration period, have any reports on positive results of pathogen been issued? If yes, please describe all corrective and preventive measures that have been taken.
 - c. Please briefly describe the notification mechanism for food safety incidence. How to ensure the competent authority and consumers receive effective information in a timely manner? During the valid registration period, has the manufacture report any food safety incidence to the competent authority or consumers? If yes, please describe the incidence, follow up actions, cause analysis, as well as corrective and preventive measures in detail.
5. The manufacturer submits supporting reports in written to show that the manufacturer is able to continuously comply with the relevant Chinese laws, regulations and standards. The report can be one or some of the following documents:
 - a. The audit record or audit conclusion issued by the competent authority or the institute authorized by the competent authority of the country or region where the manufacturer is located from last year. The audit shall be conducted according to the requirements of relevant Chinese laws, regulations and standards or in equivalent.
 - b. The manufacturer or the Chinese importer requests a third-party certification body which is qualified according to relevant Chinese accreditation and certification regulations to

issue audit record or audit conclusion. The audit shall be conducted according to the requirements of relevant Chinese laws, regulations and standards or in equivalent.

- c. The China Dairy HACCP Certificate and audit record issued by a third-party certification body which is qualified according to relevant Chinese accreditation and certification regulations to the manufacturer from last year, or other food safety hygiene control system certificate and audit record, which are recognized as the equivalent to the China Dairy HACCP certificate and audit record.
6. Description and supporting documents that show that the manufacture has established and effectively implemented a comprehensive traceability system for the products export to China that covers from the origin of raw materials to the reception of products at ports.
7. If the products exported to China have the Organic Product Certificate, please provide the specified product's certificate and other supporting documents of audit and certification.

Translation for reference