

Attachment 2

Requirements on the submission of relevant information and certification documents

For foreign manufacturers of imported infant formula requesting the renewal of the registration, they shall provide information and demonstrative documents as follows before 31 December 2018, to prove their eligibility for continued registration:

1. The conclusion and the report of the most recent supervision audit by competent authorities in home countries (regions) of the enterprise.
2. A declaration letter from competent authorities in home countries (regions) of the enterprise (refer to attachment 1), in which the competent authority shall confirm its commitment to continuing to recommend this enterprise to register in China and confirm that the enterprise can comply with China's laws, regulations and standards.
3. The enterprise shall put forward the request in written form in the format provided in attachment 1 and log in on the website of registration for foreign manufacturers of imported food (<http://cifer.cnca.cn>) to update or supplement relevant registration information of the enterprise.

4. The enterprise shall include at least the following content when drafting the written self-evaluation report according to China's relevant laws, regulations and standards:

(1) During the period of validity of the registration, is there any activity such as changing or expanding the construction of production facilities in factories, which would impact on the health conditions, and is there any adjustment in the ways and methods regarding the production operation or environment conditions, which would impact on the health control?

(2) Is the pathogenic bacteria monitoring plan of the enterprise aligned with its products? Is there any positive case of pathogenic bacteria during the validity of the registration? If there are positive cases, please list cases and explain the rectification and prevention measures that were taken to address those cases.

(3) A brief introduction of the information notification mechanism that the enterprise has in place in case of food safety incidents. How to ensure that the competent authority and consumers can get effective information in a timely manner? Has the enterprise reported to the competent authority or made available to consumers food safety incidents during the validity of the registration? If so, please elaborate on incidents, follow-up actions, analysis of reasons, rectification and prevention measures, etc.

5. The enterprise shall submit the written demonstrative report to prove its ability to continue to comply with China's relevant laws, regulations and standards. The report can be in one or more than one of the following forms:

(1) The audit record and the conclusion of the audit of the enterprise over the previous year according to China's relevant laws, regulations and standards, or equivalent requirements, conducted by competent authorities in home countries (regions) of the enterprise, or agencies authorized by competent authorities in home countries (regions) of the enterprise.

(2) The audit record and the conclusion of the audit of the enterprise over the previous year according to China's relevant laws, regulations and standards, conducted by the third-party certification agency which is recognized under China's certification and accreditation regulations and authorized by the enterprise or the Chinese importer.

(3) The authentication certificate and the record of the audit issued for the enterprise by the third-party certification agency which is recognized under China's certification and accreditation regulations on China's dairy HACCP over the previous year or other authentication certificate and the record of the audit on the food safety health control system recognized as being equivalent after evaluation.

6. Illustration and demonstrative documents, proving that the enterprise has established and effectively ensured the traceability across the whole process from the origin of the raw materials to the port in China.

7. Please provide demonstrative documents such as the authentication certificate of specific products, if the intended export into China has got China Organic Certification.