

# **Regulations Governing Implementation of Hygiene and Safety Management System Certification of Food And Feed for Export**

17 Articles adopted and promulgated in full by Ministerial Order of No. 09104614150 on June 19, 2002.

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21 Articles amended and promulgated in full by Ministerial Order of No. 10004601810 on April 14, 2011.

## **Article 1**

The Regulations are established in accordance with paragraph 2 of Article 14 of the Commodity Inspection Act (the Act).

## **Article 2**

The inspection authority as referred in the Regulations shall mean the Bureau of Standards, Metrology and Inspection of Economic Affairs (hereinafter referred to as BSMI), its branches, or other commissioned government agencies, legal entities or organization.

## **Article 3**

The certification of hygiene and safety management system for food and feed for export (hereinafter referred to as certification) shall mean that inspection authority conduct impartial and independence conformity assessments to the hygiene and safety management system established by establishments and certifies that such management system comply with certification standards.

The certification standards shall be prescribed by BSMI by referring to principles of related international organizations and provisions of the import country or area.

## **Article 4**

The establishments as referred in the Regulations referring to the establishments throughout the food or feed supply chain providing unload, process, transport, storage and other production related services, or other business, legal entities, groups or institutes providing indirect services.

The establishments described above must employ personnel obtaining qualified certificates of food or feed safety management training.

## **Article 5**

Establishments apply for certification shall submit an application form with the following documents to BSMI:

1. The copies of the establishment registration, the business registration or other equivalent document of registration.
2. The copy of factory registration.
3. The written food or feed hygiene and safety management system (including GHP and HACCP)
4. The factory layout and processing diagram.
5. The personnel training certificates as described in paragraph 2 of the preceding article.
6. The other documents specified by BSMI.

## **Article 6**

BSMI shall conduct document review after establishments file application. BSMI shall notify the establishment in written to arrange on-site inspection whenever document review deemed to comply with the requirements.

BSMI could proceed the simplified certification procedure for the establishment acquired ISO 22000 certification under BSMI scheme, grant the registration and issue the certificates after completion of document review and deemed compliance.

## **Article 7**

Under any of the following circumstances, the application shall be rejected by BSMI before inspection :

1. The application document fails to comply with Article 5 and not able to submit corrected documents within one month after receipt of the notice.
2. The establishment fails to arrange on-site inspection after application is accepted. If a reasonable explanation is provided, the establishment could apply to the BSMI for single extension of no longer than six months.

#### **Article 8**

The establishments inspected and deemed comply with certification standards, BSMI shall grant certification based on certification type, product category, and the information stated in the application and issue manufacture number and certificate valid for three years.

#### **Article 9**

The establishment inspected and deemed noncompliant to the certification standards could apply for re-inspection within two months after receiving the noncompliance notice in written. The establishment shall cooperate with re-inspection arrangements within six month after the application date. BSMI shall reject the re-inspection application if the establishment fails to cooperate with re-inspected arrangements. If a reasonable explanation is provided, the establishment could apply to the BSMI for single extension of no longer than six months.

#### **Article 10**

The establishment, inspected and deemed not complying with the certification standards, fails to apply for re-inspection according to the preceding article or fails the re-inspection, shall re-submit application two months after receiving the written notice as according to Article 5.

#### **Article 11**

The registered establishment shall not have product label, advertisement and publicity misleading the third parties to product certification.

#### **Article 12**

Whenever BSMI amends or changes the certification standards, the registered establishment shall complete the corrective action within the transition period designated by BSMI. The inspection authority shall verify that all the registered establishments have completed the corrective actions within one month before the end of the transition period.

#### **Article 13**

The inspection authority shall conduct surveillance for registered establishment at least once a year. When necessary, inspection authority should increase the surveillance rate based on risk.

The registered establishment shall conduct all arrangements for surveillance conducted by inspection authority.

The registered establishment shall provide corrective action for correctable noncompliance within ten days after surveillance. Inspection authority should conduct re-surveillance after correction period is expired.

#### **Article 14**

Before the expiration of certificate, BSMI shall verify the results of surveillance and assessment for the last three years. New certificate will be issued if results deemed to comply with the requirements.

#### **Article 15**

The registered establishment, whose registered basic information or facts as granted in registration were altered or BSMI has determined facts affecting granted registration, shall apply for alterations with the original certificate and relevant documents to the inspection authority within one month.

The inspection authority shall conduct document review for application for the alteration described and conduct

surveillance if necessary. If the alteration was determined to comply to the requirements, BSMI shall approve the alteration and issue the new certificate in exchange of the previous certificate. If the alteration was determined not complying with the requirements, BSMI will proceed the paragraph 3 of Article 13.

The registered establishment should apply for issuance of certificate to the inspection authority if the registered certificate is lost or damage.

#### **Article 16**

The registered establishment shall file to the inspection authority regarding to its suspension of production or business for more than on month. The filing date shall be within one month after the suspension.

The filed suspension is limited to six months. The establishment shall apply for the single extension for production or business if there is a reasonable cause. Extension is limited to six months.

#### **Article 17**

If the registered establishment is relocated, it shall apply for alteration within 3 months of relocation. The establishment could use the original establishment code after inspection authority proceeds the surveillance.

If the establishment suspends the production or business or relocates, it shall file the inventory, which still in effective period, to the inspection authority, it should apply for export certificate as according to Article 18.

#### **Article 18**

The registered establishment should prepare relevant documents to apply for export certificate as required in the Regulation Governing Contracted Inspection to inspection authority.

#### **Article 19**

Under any of the following circumstances, the registration of establishment certification made shall be rescinded:

1. Where the establishment violates the Article 11 and did not make corrective action in time.
2. Where the establishment does not take the required correction within a given time as required in Article 12.
3. Where the establishment fails the surveillance and the corrective action would not be made according No.1 of Article 13.
4. Where the establishment does not conduct any arrangements for surveillance as required in paragraph 2 of Article 13.
5. Where the corrective action and re-surveillance not complying to the certification standards as required in paragraph 3 of Article 13.
6. Where the establishment does not apply the alteration in time, and did not take action within 15 days after receiving notice.
7. Where the establishment does not file to the inspection authority as according to Article 16, or did not file to inspection authority within 15 days after receiving the notice or resume production and business.
8. Where the establishment files to the inspection authority as required in Article 16 but did not resume the production or business before the expiration date.
9. Where the establishment does not apply for alteration in time as required in paragraph 1 of Article 17.
10. Where the registered establishment fails to make payments in accordance with related requirements and does not make the overdue payments in time days after receiving a notice.
11. Where the registration, business registration, establishment registration and other equivalent document which the competent authority take rescission, cancellation, revocation actions.
12. Where the establishment applies for rescinding the registration.
13. Where the certification standards, certification categories and product categories was rescinded.
14. Where the establishment goes out for business.

#### **Article 20**

The establishment shall return the certificate within 15 days after receiving the notice of registration revocation or rescission. The establishment could apply for certificate labeling with the rescinded mark and return. If the establishment did not return the certificate in time, BSMI shall announce the rescission.

The establishment registration which was rescinded or be rescinded according to paragraph 1-9 of proceeding article, shall re-submit the application 4 months after the rescinded date.

**Article 21**

This Regulations shall come into force from the date of promulgation.