

# Regulations Governing Monitoring Inspection

[Chronicle of Promulgation and Amendments]

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## **Chapter I      General**

### **Article    1**

These Regulations are established in accordance with Article 32 of the Commodity Inspection Act (the Act).

### **Article    2**

The inspection authority mentioned in these Regulations shall mean the Bureau of Standards, Metrology and Inspection (the BSMI) of the Ministry of Economic Affairs, its branches, or other commissioned government agencies, legal entities or organizations.

## **Chapter II     Registration for Monitoring Inspection**

### **Article    3**

For commodities subject to monitoring inspection and registration in advance, designated and made known to the public by the BSMI as per the quasi-provisions set out in Article 19, mentioned in Article 34 of the Act, an applicant shall complete the application form and submit the following documents to the local inspection authority for registration:

1. Photocopies of Certificate of Company Registration, Certificate of Business Registration, or other equivalent documents; except for those who have filled out the uniform serial number of the company or business.
2. Other related technical documents as stipulated by the inspection authority.

### **Article    4**

A monitoring inspection registration certificate shall be issued when an application for monitoring inspection registration has passed examination.

The BSMI may cancel a certificate if an applicant who has obtained a certificate closes or suspends business, has unknown whereabouts, or has no record of applying for inspection for more than 2 years.

### **Article    5**

An applicant shall place a monitoring inspection registration number on the body of commodities that require an application for monitoring inspection in advance, in accordance with the quasi-provisions set out in Article 19, mentioned in Article 34 of the Act. However, if the body of the commodity is too small to accommodate such marking, the number may be marked on the smallest package of the commodity. Where it is allowed for an applicant to imprint the inspection marks on the body or package of the commodity can not accommodate such marking, such marking is not required.

### **Article    6**

If the original certificate is lost or damaged, an application for a replacement of the monitoring inspection registration certificate may be submitted to the inspection authority that issued the original certificate. If the registered items change, an application shall be made to the inspection authority that issues the original certificate for such changes within 30 days from the date such changes occur.

The replacement registration certificate shall use the original monitoring inspection registration number, identified with the date and indicating the nature of replacement.

## **Chapter III    Application for Inspection**

**Article 7**

An applicant shall apply for inspection in accordance with the following rules:

1. An application shall be made to the inspection authority of the entry port upon arrival of the commodities.
2. An application shall be made to the inspection authority located at the manufacturing location before the commodities are exported; and
3. An application shall be made to the inspection authority located at the manufacturing location before domestically manufactured commodities are shipped out of the production premises.

An application for inspection can be made to an inspection authority that does not have jurisdiction over that application.

**Article 8**

An applicant shall apply to the inspection authority for inspection by completing an application form and providing the following documents and inspection fees:

1. Relevant testing records, production records, or other documents as required by related announcement; and
2. Other documents required for inspection.

For commodities for which an application for monitoring inspection registration is not required, an applicant shall attach the documents mentioned in Article 3 of these Regulations when applying for inspection for the first time.

Where the application for inspection is made by an agent, a power of attorney and the agent's documentation must also be attached. Agents for inspection applications may register with the inspection authority by providing a power of attorney and then handle application procedures on behalf of applicants.

In case any special circumstance needs to be approved by the BSMI, the inspection fees prescribed in the first paragraph shall be paid before the inspection prescribed in Article 14 is carried out.

**Article 9**

The name of commodities in an application for inspection must use the same names as used in announcements by BSMI, the names used in the inspection standards, or the names approved by the inspection authority.

**Article 10**

An applicant may apply for inspection through visit in person, mail, facsimile or the Internet.

**Article 11**

Under any of the following circumstances, the inspection authority shall reject an application for inspection:

1. Failure to apply for monitoring inspection registration in accordance with Article 3 of these Regulations;
2. Failure to apply for inspection in accordance with Article 8 of these Regulations; or
3. The application form has gross errors or omissions.

**Article 12**

(Deleted.)

**Article 13**

(Deleted.)

**Article 13-1**

The inspection application may be exempted when the commodity subject to random inspection.

The random inspection mentioned in the preceding paragraph includes the random inspection of a premises sampling and samples purchased on the market; such inspections shall be implemented by the BSMI according to respective

commodity characteristics.

## **Chapter IV Execution method**

### **Article 14**

Inspection of commodities subject to monitoring inspection shall be conducted in accordance with the following procedures:

1. Batch-by-batch examination: a monitoring inspection certificate shall be issued only if each batch of commodities has passed an on-site examination of the packaging, appearance and labels, and also found conformity to the inspection requirements after a sampling inspection;
2. Batch-by-batch verification: a monitoring inspection certificate shall be issued only if each batch of commodities has passed an on-site examination of the packaging, appearance and labels. However, if any sanitary or safety concerns arise, a sampling inspection may be conducted;
3. Random-selected batch inspection: the commodities shall be randomly selected for inspection. For batches that are selected, a monitoring inspection certificate shall be issued only if they have passed an on-site examination of the packaging, appearance and labels, and have found conformity after sampling inspection. For batches that are not selected, the procedure of release after document examination shall apply;
4. Release after document examination: a monitoring inspection certificate shall be issued when the commodities have been approved by document examination. However, if any sanitary or safety concerns arise, an on-site examination of the packaging, appearance and labels or a sampling inspection may be conducted; and
5. Specific monitoring programs: a monitoring plan shall be drafted by the BSMI to conduct inspection of specific commodities and items. For commodities that are covered in the monitoring plan, a monitoring inspection certificate shall be issued only if the selected batches have passed an on-site examination of the packaging, appearance and labels, and have found conformity after sampling inspection.

The inspection items as mentioned in subparagraphs 1 to 4 of the preceding paragraph shall be conducted in accordance with the announcements. The BSMI may conduct part of or major inspection items in the light of the characteristics of commodities or inspection results.

### **Article 15**

Under any of the following circumstances, the procedure of batch-by-batch examination may apply to commodities subject to monitoring inspection:

1. Where international/domestic safety information or scientific evidence shows that the commodity may substantially endanger human health;
2. Where the inspection results during the past do not comply with applicable requirements;
3. Where the monitoring results do not comply with applicable requirements;
4. Where the inspection results of commodities placed on the market do not comply with applicable requirements; and
5. Where there is any other non-compliance.

For commodities that are mentioned in subparagraphs 1 to 2 of the preceding paragraph and apply batch-by-batch examination, the procedure of random-selected batch inspection shall apply if the applicant has made applications for commodities of the same origin, same manufacturing site or brand, or same type or specification and these commodities comply with the requirements for a certain number of consecutive batches. If non-conformities are found during the procedure of random-selected batch inspection, batch-by-batch examination will be applied thereafter to commodities of that applicant.

For commodities that are mentioned in subparagraph 3 of the preceding paragraph and apply batch-by-batch examination, the procedure of specific monitoring program shall apply if the applicant has made applications for commodities of the same origin, same manufacturing site or brand, or same type or specification and these commodities comply with the requirements for a certain number of consecutive batches.

For commodities that are mentioned in subparagraph 4 to 5 of the preceding paragraph and apply batch-by-batch examination, the originally announced procedure shall apply if the applicant has made applications for commodities of the same origin, same manufacturing site or brand, or same type or specification and these commodities comply with the requirements for a certain number of consecutive batches.

## **Article 16**

Under any of the following circumstances, the procedure of batch-by-batch verification may apply to commodities subject to monitoring inspection:

1. Where the purpose of usage of the commodity has been changed and such change is likely to cause healthy, safety or sanitary concerns;
2. Where the verification results during the past do not comply with applicable requirements; and
3. Where there is any other non-compliance.

For commodities that are mentioned in the preceding paragraph and apply batch-by-batch verification, the procedure of batch-by-batch examination shall apply if the applicant has made applications for commodities of the same origin, same manufacturing site or brand, or same type or specification and these commodities do not comply with the requirements for a certain number of consecutive batches. The procedure of batch-by-batch verification shall apply if a certain number of consecutive batches of the commodities under the procedure of batch-by-batch examination comply with the requirements.

## **Article 17**

The procedure of random-selected batch inspection shall apply to commodities that are not covered by the procedures of batch-by-batch examination or batch-by-batch verification. If the batches that are selected do not comply with the applicable requirements, the procedure of batch-by-batch examination shall apply to the next batches of same commodities filed for inspection from the same applicant. The procedure of random-selected batch inspection shall apply if a certain number of consecutive batches of the same commodities comply with the requirements.

## **Article 18**

The procedure of release after document examination shall apply to batches of commodities that are not selected under random-selected batch inspection.

## **Article 19**

The BSMI may set up annual monitoring plans in accordance with categories of commodities to ensure and understand the sanitary and safety conditions of commodities.

## **Article 20**

The procedure of release after document examination shall apply if the applicant has a testing report, inspection certificate or other relevant inspection certificates mentioned in Article 15 of the Act.

## **Article 21**

If commodities that are selected under the procedure of batch-by-batch examination or random-selected batch inspection have the inspection certificates or testing reports, issued by designated testing laboratories recognized by the BSMI, a monitoring inspection certificate shall be issued when they have passed an on-site examination of the packaging, appearance and labels. If any sanitary or safety concern arises, a sampling inspection may be conducted.

### **Article 21-1**

For a commodity apply to random inspection of a premises sampling, the obligatory inspection applicant thereof shall fill in and submit an application form and attach the following documents to apply to the inspection authority for random inspection of a premises sampling:

1. Monitoring inspection commodity registration certificate.
2. The delivery quantity of all items of the specific production factory in the last calendar year within the due inspection scope; if the production of the last calendar year is not available, the estimated delivery quantity of the current year shall be attached.
3. Other documents designated by the BSMI.

Where the preceding application conforms to the examination of the inspection authority, random inspection agreement will be issued.

The obligatory inspection applicant that has acquired the preceding agreement shall submit the Registration Form for Domestic Goods Entry into the Domestic Market to the inspection authority before the end of January of every calendar year and fill in the delivery quantity and delivery amount of the last calendar year.

The inspection authority will carry out premises sampling and receive inspection fees according to the preceding information.

For a commodity apply to random inspection of a sample purchased on the market, the inspection authority shall set up an annual inspection plan for performing inspections on samples purchased on the market.

#### **Article 21-2**

Where an obligatory inspection applicant's commodity is applied to a random inspection on a premises sampling and has any one of the following circumstances, the inspection authority may inform such an applicant to change to batch by batch monitoring inspection for the inspection application; the random inspection on a premises sampling can only be recovered after such circumstances have disappeared.

1. Fails to submit the Registration Form for Domestic Goods Entry into the Domestic Market as required, and still fails to submit it upon the expiration of the submission deadline, or the record in the Registration Form for Domestic Goods Entry into the Domestic Market is false.
2. Fails to pay the inspection fees and still fails to pay upon the expiration of the payment deadline.
3. Fails to coordinate with the inspection authority for the performance of sampling inspection.
4. Fails to provide samples for inspection in due time after being informed to do so by the inspection authority.
5. Voluntarily applies to cease the random inspection on a premises sampling.
6. Cessation of business, with unknown whereabouts, or fails to report its delivery quantity for two consecutive years.

Provided any one of the circumstances prescribed from Paragraph 1 to Paragraph 4 above exists, after changing the inspection method, if such circumstances persist, the random inspection on premises sampling can only be recovered four months after such circumstances have disappeared.

### **Chapter IV Issuance of Inspection Certificates**

#### **Article 22**

A monitoring inspection certificate shall be issued after a commodity has passed inspection, except for cases where the applicant declares that no such certificate is required.

#### **Article 23**

(Deleted.)

#### **Article 24**

The term of the validity, if required, must be indicated in the monitoring inspection certificate beginning from the date of issuance.

#### **Article 25**

If required, an applicant may apply to the inspection authority that issued the certificate for an extension of the term by submitting the monitoring inspection certificate and relevant documents, if the commodities have not been exported or imported during the terms of the validity of the monitoring inspection certificate. The extension shall be limited to another term of the original validity period. The inspection authority that issues the certificate shall note on the original monitoring inspection certificate such extension.

#### **Article 26**

(Deleted.)

#### **Article 27**

If the original certificate is lost or damaged, an application for a replacement of the original monitoring inspection certificate may be submitted to the inspection authority that issues the original certificate. The missing event and the certificate number must be stated in the applicant's declaration that the original certificate is null and void.

An applicant may apply for replacements of monitoring inspection certificate if the commodities are to be divided into several batches. The application shall be made to the inspection authority located at the same place where the commodities are stored; the original certificate shall be returned.

The replacement certificate shall note the original certificate number, date of issuance and indicate the nature of replacement.

#### **Article 28**

If the items specified in the monitoring inspection certificate must be changed, an applicant shall apply for changes or a replacement of the certificate during the term of the validity of the certificate.

#### **Article 29**

Commodities for which a new application for inspection shall be made in accordance with Article 27 of the Act, the original monitoring inspection certificate shall be returned, except for cases where no monitoring inspection certificate is issued in accordance with Article 22 of these Regulations.

### **Chapter VI Other**

#### **Article 30**

The format for application form, registration certificate, monitoring inspection certificates, or power of attorney required by these Regulations shall be prescribed by the BSMI.

#### **Article 31**

These Regulations shall take effect from the date of promulgation.