

Regulations for the Inspection and Examination of Imported Cosmetics

These Regulations have been translated into English according to the original Chinese version. If there is any inconsistency or ambiguity between these two versions, the Chinese version shall prevail.

- Article 1 These regulations have been established according to Paragraph 2 of Article 14 of the Cosmetic Hygiene and Safety Act (the “Act”).
- Article 2 Definition: terms used in these regulations:
1. Inspections: This refers to border checks or examination before permitting the importation of cosmetics.
 2. Examination: This refers to conducting sensory, physical, chemical, or biological tests and experiments in a laboratory.
 3. Inspection authorities: This refers to inspection enforcement by the central competent authority or its appointed agencies (organizations), corporations, or groups.
 4. Obligatory inspection applicants: This refers to cosmetics importers.
- Article 3 For cosmetics required for inspection as promulgated by the competent authority in accordance with Paragraph 1 of Article 14 of the Act, the obligatory inspection applicants shall file an application for inspection and submit the following documents and information to the inspection authority at the port of entry within fifteen (15) days prior to the date of import:
1. A copy of the application for import declaration.
 2. Necessary documents required by the inspection authority.
- The application of the preceding Paragraph can be submitted electronically.
- If the representative files the application of Paragraph 1, a letter of Power of Attorney and the identification documents for the representative, corporation, or business shall be submitted.
- Article 4 Cosmetics pursuant to Paragraph 1 of the preceding Article that conform to one of the following situations may be exempted from inspection:
1. Products to be imported are issued with a certificate of

examination by the government of the country of origin who has signed an examination waiver reciprocity agreement with the government of the Republic of China.

2. Others with the special permit of the central competent authority.

Article 5 The central competent authority shall inspect the compliance of imported cosmetics; the inspection shall not include the situations mentioned in Article 7 and Paragraph 1 of Article 10 of the Act. Obligatory inspection applicant shall legalize the items of the preceding Paragraph before the products were supplied, sold, gifted, publicly displayed, or offered for consumer trial.

Article 6 In addition to documentation review (as prescribed in Paragraph 1 and Paragraph 3 of Article 3), inspection authority may carry out the inspection of imported cosmetics in one or some of the following measures:

1. On-site inspection: check items, inspect the appearance of the packaging, labels, and other related items on site.
2. Randomly-selected batch examination: perform based on a 2%-50% inspection rate.
3. Batch-by-batch examination: carry out for each submitted batch of imported cosmetics.

Article 7 The samples required for inspection shall be taken free-of-charge. The maximum number (amount) of sampling shall be limited to what is required for inspection purpose. After collecting the samples, the authority shall issue a receipt to the obligatory inspection applicant.

For the sampling mentioned in the preceding Paragraph, the obligatory inspection applicant shall not designate the sample.

Article 8 The inspection and sampling shall be conducted at the storage site of products. If the products shipped in full container load, the inspection and sampling shall be conducted at the centralized inspection area or the specified zone approved by Taiwan Food and Drug Administration of the Ministry of Health and Welfare (TFDA).

Article 9 The examination of imported cosmetics shall be conducted in the order of sampling. However, the original examination laboratory shall prioritize inspection on products applying for re-examination according to Paragraph 2 of Article 11.

Article 10 Due to the difficulty of sampling in a container yard, requiring five or more days for examination, or deterioration or lack of stability of cosmetics, the inspection authority may issue a notice of prior release for import for customs clearance after the obligatory inspection applicant signs an affidavit of custodial responsibility.

If the pledged storage location does not conform to the actual storage location, or for anyone who intentionally uses, moves, provides, sells or gifts cosmetics before issuing the import permit, the inspection authority may suspend the acceptance of an application for prior release of import by the obligatory inspection applicant within 180 days from the day of discovery.

Article 11 After imported cosmetics applied for inspection are found to conform to the regulations, the inspection authority shall issue an import permit to the obligatory inspection applicant. The obligatory inspection applicant may apply to the inspection authority for a written permit.

The obligatory inspection applicant shall claim the remaining samples by presenting the sampling receipt within 15 days after receiving the permission. However, if the sample is not claimed within the statutory period or has a short shelf life, the inspection authority may dispose of the samples directly.

Article 12 In the event the imported cosmetics fail to conform to regulations, the inspection authority shall issue a notification of noncompliance for cosmetics to the obligatory inspection applicant.

The obligatory inspection applicant may apply for re-examination to the original inspection authority within 15 days after receiving the preceding notification, and the application is limited to one-time only. The original inspection authority performs re-examination by using the remaining samples.

Remaining samples of imported cosmetics that do not conform to regulations shall be destroyed after the end of the period of application for re-examination or receiving the notification of noncompliance by the obligatory inspection applicant unless otherwise stated by law.

Article 13 The imported cosmetics fail to conform to regulations; the inspection authority shall conduct the following measures followed by the result of randomly-selected examination or inspection unless otherwise stated by law:

1. Violation of Paragraph 2 of Article 10 of the Act, the obligatory inspection applicant may apply for a correction which improves within a given period. The correction may be made after the products were imported if the inspection authority approves.
2. Fail to apply for the correction per the preceding Subparagraph, the application was not approved or other noncompliance matters, the obligatory inspection applicant shall conduct a return or destruction.

The products of the preceding Paragraph were prior released per

Paragraph 1 of Article 10 shall be conducted per preceding Paragraph.

Article 14 In the event the cosmetics applied for inspection correspond to one of the following situations, the inspection authority may require the obligatory inspection applicant to submit documents or information before a given date, to explain the reasons for non-compliance, and a proposed improvement plan with preventative measures. Before the approval is granted, the application of re-examination of products belong to the same cosmetics registration number or permit license shall not be accepted:

1. Products belong to the same registration number or cosmetics permit license of the same obligatory inspection applicant, and whose batch-by-batch examination results do not conform to regulations for two times.
2. Products belong to the same registration number or cosmetics permit license, and whose inspection results do not conform to regulations for three times within 180 days from the day of the failure of the inspection.

Article 15 In the event the cosmetics applied for inspection correspond to one of the following situations, the inspection authority may suspend the acceptance of an application for products inspection from the same manufacturer, same origin, or same exporting country:

1. Products mentioned in the preceding Article requiring documents and information are not provided before the given date.
2. Products mentioned in the preceding Article requiring documents and information provided are not approved upon review.

Article 16 The application fees for border checks and examination per Article 30 of the Act shall include the following:

1. Review fees: the fees for reviewing the application of inspection by inspection authority.
2. On-site inspection fees: the fees for sampling, checking items, examining the packaging, labels, and other related inspection measures by inspectors.
3. Extended operation fees: the fees for applying the extension of inspection by obligatory inspection applicant or representative.
4. Documentary operation fees: the fees for re-issuance, replacement, additional copy, or correction of the import permit.
5. Examination fees: the fees for products batch-by-batch examination or re-examination.

The fees in the Subparagraph 1 to Subparagraph 4 of the preceding Paragraph is described in Annex. The fees in Subparagraph 5 shall be

collected based on Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics.

Article 17 When conducting inspections according to these regulations, inspectors shall present the identification documents about the performance of their duties.

Article 18 These regulations shall take effect on July 1, 2019.

Annex :

Category	Fee-charging Standard (New Taiwan Dollars)
1. Review Fees	<p>The standard of review fee adopts duty-paid value, and the fee is charged in accordance with following rates:</p> <ol style="list-style-type: none"> 1. The rate of imported cosmetics is 2.5%. 2. The fee of NTD 500 for an application shall be collected when the review fee is less than NTD 500. The exceeding part shall be half collected if the fee is over NTD 100,000.
2. On-site Inspection Fees	<ol style="list-style-type: none"> 1. The on-site fee of NTD 500 for an inspector shall be collected if batches of products are stored at the same place and the on-site inspection is conducted at the same time 2. The on-site fee of NTD 300 for an inspector shall be collected if the inspection authority has offices stationed in the harbor storehouses or container yard, and the same obligatory inspection applicant stores the products at the same place and the on-site inspection is conducted at the same time. 3. Need to collect or inspect products at the pledged storage location: The on-site fee of NTD 1000 an inspector shall be collected if batches of products are stored at the same place and the on-site inspection is conducted at the same time. 4. If the inspector cannot commute to the place of inspection and back within the same day, the on-site fees shall be additionally collected in accordance with the costs and expenses set forth in the Operating Guidelines Governing Domestic Business Travel Expenses formulated by the Executive Yuan.
3. Extended Operation Fees	<ol style="list-style-type: none"> 1. The inspection authority may charge extended operation fees, according to the following periods: <ol style="list-style-type: none"> (1) On weekdays, from 6 a.m. to 8:30 a.m. or 5:30 p.m. to 10 p.m., NTD 400 per person; (2) On holidays, from 6 a.m. to 10 p.m., NTD1,000 per person; (3) Every day from 10 p.m. to 6 a.m. the next day, NTD2,000 per person. 2. The operation for the same obligatory inspection applicant crosses different period, the highest rate shall be applied.
4. Documentary Operation Fees	NTD 100 per document.

