

**Proposed amendment of the Statute for Control of Cosmetic Hygiene  
(Law for Control of Cosmetic Hygiene)**

*This Draft has 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.*

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Chapter 1 General Provisions

- Article 1 This law has been formulated to maintain the hygiene and safety of cosmetics and safeguard national health.
- Article 2 For purposes of this Act, the term "competent authorities" shall mean the Ministry of Health and Welfare at the central government level, the municipal governments at the municipal level, and the county/city governments at the county/city level.
- Article 3 The terms and definitions used in this law are as follows:
1. Cosmetics: This term shall refer to products applied externally to the human body, teeth, or oral cavity mucous membrane for the purpose of cleansing, perfuming, changing appearances, improvement of body odors, protection of the body, or maintenance of a good condition of the body.
  2. Cosmetics business(es): This term shall refer to businesses engaged in the manufacture, import, or sale of cosmetics.
  3. Product information files: This term shall refer to documents containing data about the quality, safety, and functions of cosmetics.
  4. Cosmetics ingredient(s): This term shall refer to single chemical entity or mixture contained in cosmetics.
  5. Label: This term shall refer to the marking object bearing words, graphics and/or symbols for affixation on the container or package of any cosmetic.
  6. Leaflet: This term shall refer to the instruction sheet accompanying a cosmetic.

The scope and categories of cosmetics as defined in clause 1 of the preceding paragraph shall be defined as per public notice(s) to be published by the central competent health authorities.

Chapter 2 Manufacturing, Import, and Management of factories

- Article 4 Manufacturers and importers of cosmetics shall complete the following procedures prior to the sale, giveaway, or trial of cosmetics by consumers. The same shall apply to modifications:
1. Establishment of the product information file;
  2. Completion of product notification.

The central competent authority shall formulate guidelines specifying relevant items, procedures, modifications, revocation, and rescission, and other matters to be observed pertaining to the aforementioned product information file and product notification.

- Article 5 The manufacture or importation of hair dyes, perm products, sunscreen products, and other specific purpose cosmetics designated by the central competent authority as per public notice requires the submission of an application for registration. The cosmetic may be manufactured or imported only after approval and issue of a license. Prior approval is required for alteration of registered items.

The import of specific purpose cosmetics shall be exempt from application for registration if one of the following conditions applies. The sale, giveaway, trial by consumers, supply, or public display of said cosmetics shall be forbidden:

1. Import for personal use in small quantities in accordance with public notices by the central competent authority;
2. Import for the purpose of application for examination and testing or research and experimentation by special permission of the central competent authority.

The central competent authority shall formulate all regulations pertaining to application procedures for registration, issue, modifications, revocation, and rescission of licenses specified in Paragraph 1, and application procedures and other matters to be observed for special permissions specified in Paragraph 2.

The regulations specified in the preceding three paragraphs shall lose their applicability starting five years after the date of enforcement of the revised provisions of this law on \_\_\_\_\_(mm/dd/yyyy).

- Article 6 Cosmetics shall not contain mercury, lead, and other ingredients banned by the central competent authority as per public notice. This restriction shall not apply to traces of prohibited ingredients which are technically unavoidable caused by prevailing technological or professional standards provided that such traces pose no hazard to human health.

The central competent authority is authorized to restrict the use of certain ingredients in cosmetics to prevent allergies, irritation, and

depigmentation, and other conditions that pose a hazard to human health and safety.

The central competent authority shall determine as per public notice the composition, content, applied body part, usage methods, and other matters to be observed for specific purpose cosmetics as specified in Paragraph 1 of the preceding article, cosmetics containing banned ingredients and traces of prohibited ingredients as specified in Paragraph 1, cosmetics containing restricted substances, and other conditions that pose a hazard to hygiene and safety as specified in the preceding Paragraph.

Article 7 The outer packaging and containers of cosmetics shall state the following information:

1. Manufacturer and importer names, addresses, and telephone numbers, names and addresses of manufacturing factories, and the countries of origin of imported products;
2. Product name;
3. License number provided that a license is required;
4. Lot number;
5. Manufacturing date and shelf life, or manufacturing date and expiration date, or the shelf life and expiration date;
6. Listing of all ingredients. For specific purpose cosmetics, the content of specific purpose ingredients shall be indicated;
7. Purpose;
8. Usage and storage instruction;
9. Net weight, volume, or amount;
10. Precautions for use;
11. Other information required to be stated as per public notice by the central competent authority.

Information indicated on packaging and containers in accordance with the preceding clauses shall be provided in Chinese characters or internationally accepted symbols. Names and addresses of manufacturing factories of imported cosmetics referred to in Clause I and the information referred to in Clause VI may be provided in English.

If the size of the outer packaging and container is too small or other unique circumstances preclude the provision of essential information required in the preceding paragraph, said information shall be stated on labels, in leaflets, or by other methods.

The formats, methods, and other matters to be observed with regard to the preceding three paragraphs shall be specified in the enforcement rules pertaining to this law.

Sellers of cosmetics shall not alter or modify the labels, leaflets, outer packaging, or containers of said cosmetics for sale.

Article 8 Manufacturing factories for cosmetics shall comply with the Standards for Establishment of Cosmetics Factories and shall apply for factories registration. Factories that are exempt from registration pursuant to regulations specified in the Factory Management Act shall not be required to be registered.

Manufacturing factories for cosmetics shall also comply with cosmetic Good Manufacturing Practice Regulation. The central competent authority is authorized to conduct inspections of factories.

The abovementioned regulations may be applied mutatis mutandis to foreign manufacturing factories.

The standards referred to in Paragraph 1 shall be specified jointly by the central competent authority and central competent industrial authorities. The Regulations referred to in Paragraph 2 shall be formulated by the central competent authority. The date of enforcement and applied cosmetics categories shall be specified by the central competent authority as per public notice.

Article 9 Licensed pharmacists or personnel with professional skills in the field of cosmetics shall be hired and stationed at the factory to supervise the dispensation and manufacturing of cosmetics.

The qualifications of personnel with professional skills in the field of cosmetics referred to in the preceding paragraph shall be specified in enforcement rules pertaining to this law.

### Chapter 3 Advertising and logistics management

Article 10 Cosmetics labels and the content of promotional materials or advertisements shall not be deceptive or exaggerating.

Cosmetics labels and the content of promotional materials or advertisements shall not contain any reference to medical efficacy.

A mass media enterprise being commissioned by a principal to publish or broadcast an advertisement shall maintain the particulars of its principal, including its name, national identification card, company or business registration, factory registration, domicile or address, and telephone number, etc., for six months from the date of such advertisement, and shall not evade, obstruct or refuse any request by the competent authority for such particulars.

The central competent authority shall determine the identification for deceptive or exaggerating content referred to in Paragraph 1, medical efficacy, promotion and advertising methods referred to in Paragraph 2, and other matters to be observed.

Article 11 Cosmetics businesses shall create and preserve data on direct supply sources and destinations of products. This regulation shall not apply to data on products directly sold to consumers.

The central competent authority shall formulate regulations governing the data scope, creation and preservation methods, and other matters to be observed with regard to the provisions in the preceding paragraph.

Article 12 Cosmetics businesses shall notify the serious adverse effects generated by cosmetics under conditions of normal or reasonable use.

Serious adverse effects are defined as follows:

1. Death;
2. Life-threatening;
3. Temporary or permanent disabilities;
4. Mental or physical handicaps;
5. Congenital deformities of embryos and infants;
6. Hospitalization of users.

The central competent authority shall formulate regulations governing reporting methods, contents, and other matters to be observed.

#### Chapter 4 Test Check, Inspection, and Control

Article 13 Competent authorities may dispatch personnel, who shall show the actor an evidentiary document in relation to the performance of his duty or display a symbol for adequate identification, to conduct test checks of facilities, product information files, data on product supply sources and destinations as well as relevant records and documents at the premises of cosmetics businesses. The authorized personnel shall offer receipts for test checks and inspections of cosmetics and their raw materials. Said businesses shall not evade, obstruct, or refuse requests.

Sample amounts required for the items specified in the preceding paragraph shall not exceed the quantities necessary for the execution of test checks or inspections.

Article 14 In order to enhance border control for cosmetics imports, the central

competent authority is authorized to announce certain cosmetics categories or items that may be pose a hazard to hygiene and safety as per public notice requiring test checks and inspection at the time of importation, and that the cosmetics may only be imported after passing an inspection.

The central competent authority shall formulate the regulations governing test check and inspection methods, techniques, items, scopes, and other matters to be observed.

- Article 15 Competent authorities shall immediately initiate investigations and may order cosmetics businesses to suspend the manufacture, import, or sale of cosmetics or to withdraw product(s) from the market or seal up product(s) if one of the following conditions is suspected:
1. Violations of Paragraph 1 of Article 4 or regulations pertaining to items, procedures, deadlines, or other management of file and notification prescribed pursuant to Paragraph 2 of Article 4;
  2. Violations of Paragraph 1 or 2 of Article 5;
  3. Violations of Paragraph 1 of Article 6 or public announcement made pursuant to Paragraph 3 of Article 6;
  4. Violations of Paragraph 1 or 2 of Article 8;
  5. Product notification or license revoked or rescinded by the central competent authority;
  6. Exceeding expiration date;
  7. Source unclear;
  8. Other conditions harmful to physical health.

When competent authorities conduct investigations as specified in the preceding paragraph or other test checks or tests referred to in this law, they may order cosmetics businesses to provide testing specifications, methods, reports and information established by original manufacturers, samples, reference standards and relevant data required for tests. Cosmetics businesses shall not evade, obstruct, or refuse these orders.

Penalties shall be rescinded and products shall be unsealed in the absence of any of conditions specified in the paragraph 1 after investigations.

- Article 16 Cosmetics businesses may not sell, supply, or publicly display cosmetics of the following conditions:
1. Violations of Paragraph 1 of Article 4;
  2. Violations of regulations prescribed pursuant to Paragraph 2 of Article 4 that may be pose a hazard to hygiene and safety as determined by competent authorities;
  3. Violations of Paragraph 1 of Article 5;
  4. Violations of Paragraph 1 or public announcement made pursuant

- to Paragraph 3 of Article 6;
5. Violations of any of Paragraph 1 to 3 or 5 of Paragraph 7 or the regulations specified in the enforcement rules pertaining to this law prescribed pursuant to Paragraph 4 of Article 7;
  6. Failure to register factories as specified in Paragraph 1 of Article 8;
  7. Violations of the Standards for Establishment of Cosmetics Factory specified in Paragraph 1 of Article 8 or the Good Manufacturing Practice Regulation specified in Paragraph 2 of Article 8. And said violations may be pose a hazard to hygiene and safety as determined by competent authorities;
  8. Violations of the labeling regulations specified in Paragraph 1 or 2 of Article 10;
  9. Product notification or license revoked or rescinded by the central competent authority;
  10. Shelf life exceeded;
  11. Source unclear;
  12. Other hazards to hygiene and safety designated by the central competent authority in a public announcement.

Article 17 Cosmetics manufacturers and importers shall immediately notify sellers and recall products from the markets within a time period prescribed by competent authorities if one of the following conditions applies:

1. Violations of Paragraph 1 of Article 4, regulations prescribed pursuant to Paragraph 2 of Article 4, Paragraph 1 of Article 5 or Paragraph 2 of Article 5, and failure to make corrections within the time limit prescribed by competent authorities;
2. Violations of Paragraph 1 or public announcement made pursuant to Paragraph 3 of Article 6;
3. Violations of any of the Paragraph 1 to 3 or 5 of Article 7 or the regulations specified in the enforcement rules pertaining to this law prescribed pursuant to Paragraph 4 of Article 7;
4. Failure to register factories as specified in Paragraph 1 of Article 8;
5. Violations of the Standards for Establishment of Cosmetics Factories specified in Paragraph 1 of Article 8, or the Good Manufacturing Practice Regulation specified in Paragraph 2 of Article 8. And said violations may be pose a hazard to hygiene and safety as determined by competent authorities;
6. Product notification or license revoked or rescinded by the central competent authority;
7. Source unclear;
8. Other hazards to hygiene and safety as per public notice by the central competent authority.

Sellers shall cooperate with manufacturers and importers in the recall of cosmetics set forth in the preceding paragraph. The regulations

governing recalled cosmetics under the provision of Paragraph 1 including classification, method of handling, implementation of recall procedures and other matters to be observed shall be prescribed by the central competent authority.

Article 18 Competent authorities shall confiscate and destroy cosmetics if one of the following conditions applies:

1. Violation of Paragraph 1 or public announcement made pursuant to Paragraph 3 of Article 6;
2. Violations of Paragraph 1 of Article 4, regulations prescribed pursuant to Paragraph 2 of Article 4, Paragraph 1 or 2 of Article 5, Paragraph 1 to 3 or 5 of Article 7, the regulations specified in the enforcement rules pertaining to this law prescribed pursuant to Paragraph 4 of 7, Paragraph 1 or 2 of Article 8, Paragraph 1 of Article 9, Paragraph 1 or 2 of Article 10. And said violations pose a hazard to hygiene and safety as determined by competent authorities;
3. Product notification or license revoked or rescinded by the central competent authority;
4. Shelf life exceeded;
5. Source unclear;
6. Other hazards to hygiene and safety as per public notice by the central competent authority.

Article 19 The competent authority shall keep strictly confidential the particulars of, and may grant reward to, anyone informing against cosmetics, labels, promotional materials, advertisements or cosmetics businesses that are found to have violated the provisions of this Act.

The regulations governing the granting of the above reward shall be prescribed by the central competent authority.

#### Chapter 5 Penal provisions

Article 20 Violations of Paragraph 1 of Article 10 shall be punishable with a fine ranging from NT\$40,000 to NT\$200,000; Violations of Paragraph 2 of the same article shall be punishable with a fine ranging from NT\$600,000 to NT\$5,000,000. In case of severe violations, the business may be ordered to terminate business operations or revoke all or part of the items listed in the company registration, business registration or factory registration.

Violators of the preceding advertisement provisions shall be consecutively fined until the broadcast or publication is terminated.

Severe violations of the regulations pertaining to advertisements



specified in Paragraph 1 or 2 of Article 10, shall not only be penalized in accordance with the preceding two paragraphs, the competent authorities shall order the termination of the sale, supply, and public display of advertised products. Such violators shall also broadcast or publish a corrective advertisement of the same length and in the same time slot as the original advertisement at a specified frequency within 30 days after receipt of the sanction order. Said corrective advertisement shall state an official apology and correct false information.

Violators of the preceding provisions who continue to sell, supply, or publicly display advertised cosmetics or fail to broadcast or publish corrective advertisements shall be liable to a fine ranging from NT\$120,000 to NT\$600,000.

- Article 21 Media businesses in violation of Paragraph 3 of Article 10 shall be liable to a fine ranging from NT\$60,000 to NT\$300,000 and may be consecutively fined.
- Article 22 Cosmetics businesses shall be liable to a fine ranging from NT\$20,000 to NT\$5,000,000 and may be consecutively fined if one of the following conditions applies. In case of severe violations, the business may be order to suspend business operations for not less than one month nor greater than one year terminate business operations, or revoke all or part of the items listed in the company registration, business registration or factory registration as well as notifications or licenses for said cosmetics. In case of revocation of notifications or licenses for cosmetics, re-notification or re-application for registration of said products shall not be permitted within a period of one year:
1. Violations of Paragraph 1 or public announcement made pursuant to Paragraph 3 of Article 6;
  2. Violations of Paragraph 1 of Article 8;
  3. Violations of Paragraph 2 of Article 8 which is severe or failure to make corrections of violations within the time limit prescribed.
- Article 23 Cosmetics businesses shall be liable to a fine ranging from NT\$10,000 to NT\$1,000,000 and may be consecutively fined if one of the following conditions applies. In case of severe violations, the business may be order to suspend business operations for not less than one month nor greater than one year termination of business operations, or revoke all or part of the items listed in the company registration, business registration or factory registration as well as notifications or licenses for said cosmetics. In case of revocation of notifications or licenses, re-notification or re-application for registration and market approval of said products shall not be permitted within a period of one year:
1. Violations of Paragraph 1 of Article 4;

2. Provision of false information in file or notification referred to in Paragraph 1 of Article 4;
3. Violations of regulations pertaining to items, procedures, deadlines, or other management of file and notification prescribed pursuant to Paragraph 2 of Article 4 which is severe or failure to make corrections of violations of within the time limit prescribed;
4. Violations of Paragraph 1 or 2 of Article 5;
5. Provision of false information during the application for registration specified in Paragraph 1 of Article 5;
6. Violations of any of the Paragraph 1 to 3 or 5 of Article 7 or regulations pertaining to formats and methods or other matters specified in the enforcement rules to this law prescribed pursuant to Paragraph 4 of Article 7;
7. Violations of Paragraph 1 of Article 9;
8. Provision of false information regarding sources or destinations as specified Paragraph 1 of Article 11;
9. Violations of Paragraph 1 of Article 13;
10. Violations of Paragraph 2 of Article 15;
11. Violations of Article 16.

Article 24      Cosmetics businesses are liable to fines ranging from NT\$10,000 to NT\$1,000,000 and may be consecutively fined if one of the following conditions applies which failure to make corrections of violations within the time limit prescribed. In case of severe violations, the business may be order to suspend business operations for not less than one month nor greater than one year termination of business operations, or revoke all or part of the items listed in the company registration, business registration or factory registration as well as notifications or licenses for said cosmetics. In case of revocation of notifications or licenses, re-notification or re-application for registration of said products shall not be permitted within a period of one year:

1. Violations of Paragraph 1 of Article 11 or regulations pertaining to the data scope, creation and preservation methods, or other matters prescribed pursuant to Paragraph 2 of Article 11;
2. Violations of Paragraph 1 of Article 12 or regulations pertaining to the reporting methods, contents, and other matters prescribed pursuant to Paragraph 3 of Article 12;
3. Violations of Paragraph 1 or 2 of Article 17, or regulations pertaining to the method of handling, implantation of recall procedures, or other matters prescribed pursuant to Paragraph 3 of Article 17.

Article 25      In the case of violations specified in the preceding five articles, the competent authorities may make public the names and addresses of businesses, products, and violations based on the circumstances of the

offense, the level of damage caused, and the overall impact.

Article 26 Revocation or rescission of notifications or licenses for cosmetics prescribed in this law shall be imposed by the central competent authority, while the remaining penalties shall be imposed by municipal or county/city competent authorities. The central competent authority may impose the punishment if deemed necessary.

Article 27 As for the revocation of all or part of the items listed in the company registration, business registration or factory registration prescribed in this law, the competent industrial or commercial authorities or competent governmental business authority shall be in charge of execution after the termination of business operations has been ordered and confirmed by municipal or county/city competent authorities.

#### Chapter 6 Supplementary Provisions

Article 28 Competent authorities may authorize subordinate agencies or commission relevant institutions and organizations, corporations, or groups to carry out inspections, test checks, or tests of cosmetics and cosmetics businesses or issue production and sales certificates. The central competent authority shall formulate the regulations governing the commissioning process and related matters.

The central competent authority may carry out accreditation of institutions/organizations, corporations, or groups commissioned in accordance with the preceding paragraph. The central competent authority shall also formulate the relevant accreditation and management regulations.

The central competent authority may appoint subordinate agencies or commission relevant institutions and organizations, corporations, or groups to carry out said accreditation. The central competent authority shall formulate the regulations governing the appointment and management process.

Article 29 Cosmetics businesses may submit applications to the central competent authority for production and sales certificates or GMP compliance certificates for cosmetics they have notified or acquired licenses, or for cosmetics manufacturing factories that meet the Good Manufacture Practice Regulation for cosmetics as determined by the central competent authority.

The central competent authority shall formulate regulations governing the application criteria, review procedures, standards, validity terms,

revocation, return, cancelation, and other matters to be observed with regard to the issue of certificates in accordance with the preceding paragraph.

- Article 30    Cosmetics businesses shall be liable to pay the required fees for cosmetics notification, applications for registration, applications for inspections determining compliance with GMP Regulation, applications for border inspections and tests for imported cosmetics as well as applications for certificates specified in this law.
- Article 31    As for cosmetics which have been sold on the market or provided for giveaway or free trial by consumers before the enforcement of the revised law on \_\_\_\_\_ (MM/DD/YYYY) and products originally identified as non-cosmetics which are governed by the regulations specified in this law upon enforcement, businesses shall complete product notification within two years and create product information file within five years upon public announcement made pursuant to Paragraph 2 of Article 3.
- Article 32    The enforcement rules pertaining to this Act shall be prescribed by the central competent authority.
- Article 33    The date for enforcement of this Act shall be determined by the Executive Yuan.