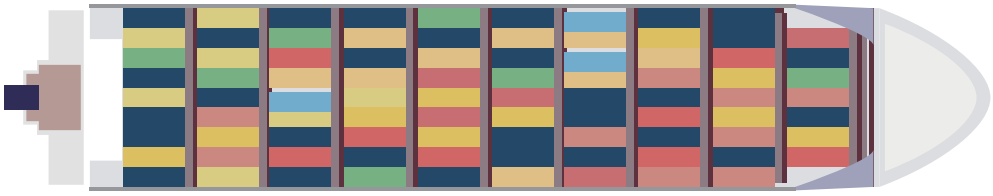

IMPORTED COSMETICS REGULATIONS

Q & A

衛生福利部食品藥物管理署
Taiwan Food and Drug Administration
2021.12 PUBLISHING

Contents

01 Imported Cosmetics Regulations FAQ

02 Existing Regulations

03 Relevant link

Q&A

What is Cosmetic Product?

Q:What is the definition of cosmetics?

1. "Cosmetics" means products applied externally to the human body, teeth, or oral cavity mucous membranes, and used to moisturize hair and skin, stimulate the sense of smell, improve body odors, change appearance, or cleanse the body. However, this is not applicable to those that are regarded as drugs in accordance with other laws or regulations.
2. The regulations regarding the scopes and categories of cosmetics can be found on the website of TDFA (Website: http://www.fda.gov.tw/ENG/) Homepage→Cosmetics→Laws and Regulations.

Q:How to distinguish my products belongs to cosmetic or not?

To make sure the suitable category of a product, the description of full ingredient names and individual content, usage method and dosage, purpose/function/efficacy, and product packages from the market (includes outer box, label, instruction) are necessary information. If there is any question as regards the category of the product, the cosmetics businesses may submit an application to TFDA for review. The review fee for the regulatory determination of cosmetic products shall be paid with the application.

Q&A

Legal requirement of cosmetics import

Q:Shall all imported cosmetics apply for approval licenses issued by TFDA?

Cosmetics are categorized as general cosmetics and specific purpose cosmetics.

If categorized as specific purpose cosmetics, an application for approval license shall be submitted to TFDA for registration before import (invalid from 2024.7.1).

If categorized as general cosmetics, the ingredients of the product shall comply with the regulations regarding cosmetic ingredients in Taiwan (R.O.C), ensuring safety and stability, and complete cosmetic notification and required labelling items before the products go to the market. Also, cosmetic notification shall be completed. Moreover, product information file shall be established, according to the announced schedule,and the Cosmetics Good Manufacturing Practice Regulations shall be enforced at the manufacturing premises.

Q:Shall foreign manufacturers who manufacture imported specific purpose cosmetics be regulated by GMP regulations?

From July 1st, 2024, the cosmetics categories listed and publicly announced by the central competent authority, their manufacturing factories in both domestic and foreign countries shall comply with regulations of Cosmetics GMP. The central competent authority may enforce on-site inspection and examination.

The categories of cosmetics and the enforcement date for which manufacturers or importers shall comply with Good Manufacturing Practice Regulations(GMP):

1. Specific purpose cosmetics: 2024.7.1
2. Non-specific purpose cosmetics for infants, lip, or eye : 2025.7.1
3. Non-specific purpose cosmetics (except specific purpose cosmetics, non-specific purpose cosmetics for infants, lip, or eye) : 2026.7.1

Q:Is acquiring the approval documents of ISO 22716 Good Manufacturing Practices for Cosmetics identical to comply with Cosmetics Good Manufacturing Practices Regulations (GMP) in Taiwan?

The establishment of Cosmetics Good Manufacturing Practice Regulations (GMP) in Taiwan is based on the contents of ISO 22716 Good Manufacturing Practices for Cosmetics. Cosmetics businesses shall review and check if their operation area is complying with the requirement of GMP, and the acquisition of the approval documents may be supporting documents of complying with GMP in Taiwan. Moreover, TFDA will review and evaluate the necessity of on-site inspection according to the risk management principles.

Q&A

Product Hygiene and Safety Standards

Q:Are there any restrictions or ban on cosmetic ingredients? How to find those regulations?

1. Regarding prohibited used ingredients, there is List of Ingredients Prohibited in Cosmetic Products announced; regarding the restricted used ingredients, there are List of Ingredients Restricted in Cosmetic Products, List of Preservatives in Cosmetic Products, List of Colorants in Cosmetic Products, List of Specific Purpose Ingredients in Cosmetic Products.
2. These regulations can be found on the TFDA website (http://www.fda.gov.tw/ENG/ law.aspx?cid=5062&cr=283153549)

Q:Is there any microorganisms limits to cosmetics?

There is List of Microorganisms Limits in Cosmetic Products, including total plate count and other restrictions, the full regulations can be found on the TFDA website (http://www.fda.gov.tw/ENG/law.aspx?cid=5062&cr=283153549)

Q:What is the regulation for the ingredients not listed in the public announcement from the Ministry of Health and Welfare?

The Ministry of Health and Welfare has established regulations for the use of raw materials of cosmetics including banned ingredients, the use limitation of preservatives, antiseptics, etc. All cosmetics shall comply with the health standards listed above, not contain false and exaggerated information, and not claim medical efficacy. This information can be found on the website of TDFA (Website: http://www.fda.gov.tw/ENG/) Homepage→Cosmetics→Laws and Regulations. If the additives in the cosmetics need further evidence to prove safety by science, international regulations and standards related to cosmetics ingredients safety assessment.

Q&A

Regulations for the Registration of Specific Purpose Cosmetics (invalid from 2024.7.1)

Q:What is the definition of specific purpose cosmetics?

Specific purpose cosmetics refers to the List of Specific Purpose Ingredients in Cosmetic Products regarding the use for sunscreen, hair-dyeing, permanent waving, antiperspirant, deodorant, tooth-whitening, or other purposes.

Q:What are the required documents for the application of importing specific purpose cosmetics registration?

According to Paragraph 1, Article 5 of Regulations for Issuance of License of Specific Purpose Cosmetics, an applicant applies for the registration of the license for importing specific purpose cosmetics shall submit an application with following documents, information, and pay the fee to the central competent authority:

1. A copy of company registration or business registration certificate.
2. Drafts of product labels, leaflets, and packaging.
3. The authorization letter issued within the past two years.
4. The MFSC issued within the past two years.
5. An ingredient list issued within the past two years.
6. The certificate of analysis.
7. For the contract manufacturer, a certificate identifies the relationship between the hiring firm and the contract manufacturer.

Q:If the cosmetics businesses do not have any offices or agents in Taiwan, can the businesses apply for registration or cosmetic notification overseas directly?

Specific purpose cosmetics importation registration shall be applied by cosmetic importers. In addition, referred to Article 4 of Cosmetic Hygiene and Safety Act, cosmetic importers shall complete cosmetic notification prior to the supply, sale, giveaway, public display, or consumer trial offer of cosmetics.

Q:How to apply for importing a small number of specific purpose cosmetics for testing purposes? If the ingredients do not comply with the existing regulations, can the product be imported as special cases?

1. If you intend to import a small number of specific purpose cosmetics for the use of applying for registration, according to Article 3 of Regulation for Authorizing the Applications of Import of Non-licensed Specific Purpose Cosmetics, authorization documents, product information and a filled-out application form needs to be submitted to TFDA to apply for approval.
2. According to Article 7 of Regulation for Authorizing the Applications of Import of Non-licensed Specific Purpose Cosmetics, if the product has banned ingredients publicly announced by the central competent authority, import can not be allowed; In addition, if the product ingredients do not comply with the List of Ingredients Restricted in Cosmetic Products publicly announced by the central competent authority, except for research and testing, import is not approved.

Q&A

Notification of Cosmetic Products

Q:Which cosmetic categories need to do product notification?

1. Cosmetics categories publicly announced by the Ministry of Health and Welfare shall be registered on the Cosmetic Products Notification Platform System. The products can be sold on the market after notification on the platform, the full regulations can be found on the TFDA website (http://www.fda.gov.tw/ENG/lawContent.aspx?cid=5062&id=3183).
2. Cosmetics manufacturers or importers except the handmade soap entities which are exempt from industry registration, for general cosmetics begins on July 1st, 2021, for specific purpose cosmetics begins on July 1st, 2024, shall complete cosmetic product notification prior to the supply, sale, giveaway, public display, or consumer trial offer of cosmetics; the same shall apply to any modifications.

Q:Who needs to do product notification?

According to Article 2 of Regulations Governing Notification of Cosmetic Products, the cosmetics manufacturers or importers of a certain scale under Paragraph 1 of Article 4 of the Act (the "Cosmetics Manufacturers or Importers") shall refer to below entities in the business of manufacturing or importing cosmetics products:

1. A corporate or a firm to be established and registered pursuant to Company Act and/or Business Registration Act.
2. A factory to be registered pursuant to Paragraph 1 of Article 8 of the Act.
3. The groups and corporations which engage in cosmetics manufacturing or importing, except the handmade soap entities which are exempt from industry registration, excluding the entities mentioned in preceding two subparagraphs.

Q:How to notify my product?

According to Article 3 of Regulations Governing Notification of Cosmetic Products, cosmetics manufacturers or importers shall, while manufacturing or importing cosmetics under Paragraph 1 of Article 4 of the Act, complete data notification via the platform provided by the central competent authorities.

The cosmetic product notification plateform: http://cos.fda.gov.tw/TCAL/main/ap/index_out.jsp

Q:What is the required data for notification of cosmetic products?

According to Article 4 of Regulations Governing Notification of Cosmetic Products, data notification specified in the preceding Article shall include:

1. Notification number of products.
2. Chinese and English names of products provided that no need to notify the English name of domestic products.
3. Category and usage of products.
4. Type of products. Model number and color code for series products.
5. Dosage of products.
6. Precautions of products.
7. Names, addresses and telephone numbers of manufacturers or importers of products.
8. Names, addresses nationalities of the premises where products manufactured and other criteria conforming to cosmetics Good Manufacturing Practice (GMP).
9. Full components of products. Weight or capacity percentage identifying its content inclusion if limitation of usage set forth by the central competent authorities.
10. Other relevant descriptions.

The aforesaid data notify shall be made in Chinese, English, numbers or international symbols.

Q:Will Cosmetic Products Notification Platform System be opened to the public for inquiries?

Cosmetic Products Notification Platform System has been opened to the public for inquiries since July 1st, 2021. Refer to the link below: http://cos.fda.gov.tw/TCAL/cospq/cospq0101f.jsp
The content related to commercial confidentiality does not go public.

Q&A

Cosmetic Product Information File (PIF)

Q:What is Cosmetic Product Information File (PIF)?

According to Article 3 of Cosmetic Hygiene and Safety Act, "Product information file" means a number of documents containing data about the quality, safety, and functions of cosmetics.

Q:When will the regulation of Product Information File regulation be enforced?

The categories of cosmetics and the enforcement date for which manufacturers or importers shall establish product information file:

1. Specific purpose cosmetics: 2024.7.1
2. Non-specific purpose cosmetics for infants, lip, or eye : 2025.7.1
3. Non-specific purpose cosmetics (except specific purpose cosmetics, Non-specific purpose cosmetics for infants, lip, or eye) : 2026.7.1

Q:What is the content for cosmetic product information file?

According to Article 3 of Regulations for Cosmetic Product Information File Management, cosmetic product information file shall establish the following information in Chinese or English:

1. Basic information of the product: the name of the product, the category of the product, dosage form, purpose, the names and addresses of manufacturing facilities, information of product manufacturers or importers.
2. Evidentiary documents of completing product notification.
3. Full ingredient names and the individual content.
4. The outer packaging of the products, containers, labels or leaflets.
5. GMP compliance certificates or self-declarations which the manufacturing facilities comply with cosmetic Good Manufacturing Practice Regulations.
6. Manufacturing methods and procedures.
7. Usage methods, body parts, dosage, frequencies and the targeted population.
8. Adverse effects of the product application.
9. Physical and chemical characteristics of the products and individual ingredients.
10. Toxicological data of the ingredients.
11. The product stability test reports.
12. The microbiological test reports.
13. The antimicrobial effectiveness test reports.
14. Supporting information of the functional assessments.
15. Information about the packaging materials which have contact with the products.
16. Product safety information:
    (1) Safety evaluation conclusion and suggestion which has the signature of the signatory for the safety report and the date.
    (2) Qualification certificates which the signatory for the safety report complies with Article 4, 5 and 6.

If the original information of the file in the preceding paragraph is established in the language other than Chinese or English, the Chinese or English translation shall be attached Cosmetic products which are manufactured in separate processes, the names and addresses of manufacturing facilities mentioned in the Subparagraph 1 of the previous paragraph shall include all of the manufacturing facilities in the processes and their operation procedures.

Cosmetic product information file shall be renewed in accordance with Paragraph 1 when it changes.

The information mentioned Subparagraph 11 to 13 of Paragraph 1, when the signatory for the safety report evaluates the characteristics or specialty of the product and makes reasoning in Subparagraph 16 of the same Paragraph, may be exempt from establishment.

Q:Are there test methods could be followed for product stability test and antimicrobial effectiveness test? Is there any qualification requirement for the laboratory?

1. There are many test guidelines announced by ISO and other country, published in Journal, which are acceptable. our recommendation is following all of the conditions within the test guideline to ensure the effectiveness of testing report.
2. To make sure the quality of the test, we recommend the laboratory complying with GLP or other quality control measures.

Q:Who can be the safety assessor? Can foreign companies use safety assessor from the country where the product is manufactured?

The qualification of the signatory for the safety report (also known as safety assessor) is regulated in Article 4, 5 and 6 of Regulations for Cosmetic Product Information File Management, people who comply with the requirement of, is allowed to be signatory for the safety report, while there is no nationality limitation of the signatory for the safety report.

Others

Q:If businesses intend to import raw materials to Taiwan for manufacturing cosmetics, do they need to apply to TFDA in advance?

Please check Import and Export Regulations of Classification of Commodities and Regulations from the Bureau of Foreign Trade, Ministry of Economic Affairs. If importing industrial oils and fat, the information about importing goods purpose approval is available on Chinese version website of Industrial Development Bureau, Ministry of Economic Affairs（Homepage/ Applications and Forms/Application for General Industrial Oils and Fat Import Approval） offers; In addition, if businesses intend to import food raw material for the purpose of manufacturing cosmetics, please go to the Chinese version website of TFDA(Homepage/ Services/Border Inspection/Download/Food/Application for exemption of import inspection for food and related product) to check information about the application for exemption of import inspection for non-edible food and related products.

Q:Can glass ampoules be imported?

According to the public announcement of Executive Yuan, the Department of Health Order Wei-Shu-Yao No. 840308, cosmetics are used by general consumers, if a glass ampoule is used as a container, it may cause injury during operation and it may also cause confusion with the ampoule for injection. Based on safety considerations of product use, glass ampoules may not be used as a cosmetic container. However, considering the need of some people for personal use, passengers who bring their own or send from abroad (parcels or express delivery) cosmetics with glass ampoules as containers may fill out the form of application for cosmetic import certificate, attached relevant information then submit to TFDA for application of import as special cases. These cosmetics are restricted to personal use only, while other purposes are not allowed.

> Regarding all the regulations mentioned above, the newest version announced by central competent authority shall prevail.

Existing Regulations

Cosmetic Hygiene and Safety Act

Chapter 1 General Provisions

Article 1

This Act is enacted to maintain the hygiene and safety of cosmetics in order to safeguard national health.

Article 2

For purposes of this Act, the term "competent authority" 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 used in this Act are defined as follows:

1. "Cosmetics" means products applied externally to the human body, teeth, or oral cavity mucous membranes, and used to moisturize hair and skin, stimulate the sense of smell, improve body odors, change appearance, or cleanse the body. However, this is not applicable to those that are regarded as drugs in accordance with other laws or regulations.
2. "Cosmetics business" means a business engaged in the manufacture, import, or sale of cosmetics.
3. "Product information file" means a number of documents containing data about the quality, safety, and functions of cosmetics.
4. "Cosmetics ingredient" means a single chemical entity or mixture contained in cosmetics.
5. "Label" means a marking object used to bear words, graphics, or symbols for affixation on the container or package of a cosmetic.
6. "Leaflet" means an instruction sheet accompanying a cosmetic.

The scope and categories of cosmetics as defined in Subparagraph 1 of the preceding paragraph shall be publicly announced by the central competent authority.

Chapter 2 Manufacturing, Import, and Management of Factories

Article 4

Cosmetics categories and cosmetics manufacturers or importers of a certain scale that are specified by the central competent authority as per public announcement shall complete product notification and establish product information file prior to the supply, sale, giveaway, public display, or consumer trial offer of cosmetics. The same shall apply to modifications.

Regulations governing the certain scale, the items, contents, procedures, modifications, validity term, revocation, and rescission of product notification, and other matters to be observed with regard to the preceding paragraph shall be prescribed by the central competent authority.

Regulations governing the certain scale, the items, contents, modifications, methods for

the safety report of product information file, and other matters to be observed with regard to Paragraph 1 shall be prescribed by the central competent authority.

Article 5

For the manufacturing or import of specific purpose cosmetics designated by the public announcement of central competent authority, an application for registration shall be filed with the central competent authority. No manufacturing or import shall be allowed until a license is approved and issued.

Licensed cosmetics of the preceding paragraph shall not modify any of the originally registered particulars without approval of the central competent authority. However, this restriction does not apply to particulars that may be voluntarily modified per public announcement by the central competent authority.

The import of specific purpose cosmetics shall be exempted from application for registration of Paragraph 1 if one of the following conditions applies. Furthermore, the supply, sale, public display, consumer trial offer, or transfer to other uses of said cosmetics shall be forbidden:

1. Import for personal use, the quantity of which complies with public announcement of the central competent authority;
2. Import for the application for registration of Paragraph 1 or for use in research and trial, through special permission of the central competent authority.

For the import of specific purpose cosmetics for personal use of the preceding Subparagraph 1 that exceed the quantity specified in public announcement, their excess portion shall be ordered a return or destruction within a specified time limit by the customs.

Prior to the enforcement of this Act as amended on April 10, 2018, for the manufacturing or import with a license of cosmetics containing medical or poisonous drugs whose license validity term expires within five years following the enforcement of this Act as amended on April 10, 2018, and where it is necessary to continue the manufacturing or import, an application for extension may be filed within three months before the expiration of validity term and an application for registration in accordance with Paragraph 1 may be exempted.

Regulations governing the issuance, modifications, revocation, and rescission of licenses with regard to Paragraph 1 and Paragraph 2, the application procedure for special permission with regard to Subparagraph 2 of Paragraph 3, the license extension with regard to Paragraph 5, and other matters to be observed shall be prescribed by the central competent authority.

The provisions of Paragraph 1 and Paragraph 2 shall cease to apply starting five years after the date of enforcement of this Act as amended on April 10, 2018.

Article 6

Cosmetics shall not contain mercury, lead, or other ingredients banned for use as per public announcement of the central competent authority. However, this restriction does not apply to residual traces contained therein that are inevitable due to contemporary technical or professional standards, provided that such traces pose no hazard to human health.

The central competent authority may restrict the use of cosmetics ingredients to prevent and avoid causing allergies, irritations, depigmentation, and conditions that pose a hazard to human health.

For the banned use and residual traces in Paragraph 1, and the restriction for use of ingredients or other conditions that pose an impact to the hygiene and safety of the preceding paragraph, their composition, content, applied body part, usage method, and other matters to be observed shall be publicly announced by the central competent authority.

Cosmetics businesses shall not subject animals to testing when conducting safety evaluation of cosmetics or cosmetic ingredients, unless one of the following conditions applies and has been approved by the central competent authority:

1. The ingredient is widely used, and its function cannot be replaced by other ingredients;
2. Those that require animal testing to be conducted, having evaluation data that demonstrate the potential for harming human health.

Cosmetics in violation of the provisions in the preceding Paragraph shall not be provided for sale.

Regulations governing the application procedure for using animals as test subjects and other matters to be observed with regard to Paragraph 4 shall be prescribed by the central competent authority.

Article 7

The outer packaging or containers of cosmetics shall conspicuously label the following information:

1. Product name;
2. Function;
3. Usage and storage instructions;
4. Net weight, volume, or amount;
5. Full ingredient names. For specific purpose cosmetics, the content of specific purpose ingredients contained therein shall be labeled separately;
6. Precautions for use;
7. Name, address, and telephone number of manufacturer or importer; country of origin of imported product;
8. Manufacturing date and shelf life, or manufacturing date and expiration date, or shelf life and expiration date;
9. Lot number;
10. Other information required to be labeled as per public announcement of the central competent authority.

The information to be labeled as specified in the preceding paragraph shall be provided in Chinese or internationally common symbols. However, the information of Subparagraph 5 may be labeled in English.

For the information of each subparagraph in Paragraph 1, if it cannot be labeled due to the surface area of outer packaging or container being too small or other special circumstances, said information shall be stated on the label, in the leaflet, or by other means.

The format and method of labeling and other matters to be observed with regard to the preceding three paragraphs shall be publicly announced by the central competent authority.

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

Article 8

Manufacturing facilities for cosmetics shall comply with the Establishment Standards for Cosmetics Manufactory. Except those specified jointly by the central competent authority and central competent industry authority as per public announcement, factory registration shall be completed.

For cosmetics categories that are specified by the central competent authority as per public announcement, their manufacturing facilities for cosmetics shall comply with cosmetic Good


Manufacturing Practice Regulations. The facilities are subject to on-site inspection by the central competent authority.

The provisions of the preceding paragraph may be applied mutatis mutandis to foreign manufacturing facilities.

The standards referred to in Paragraph 1 shall be formulated jointly by the central competent authority and central competent industry authority. The regulations referred to in Paragraph 2 shall be formulated by the central competent authority.

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, training, responsibilities of personnel with professional skills in the field of cosmetics, and other matters to be observed with regard to the preceding paragraph shall be prescribed by the central competent authority.

Chapter 3 Advertising and Logistics Management

Article 10

The contents of the labeling, promotion, and advertisement of cosmetics shall not be deceptive or exaggerated.

Cosmetics shall not be so labeled, promoted, or advertised as having medical efficacy.

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

Regulations for the determination criteria of deceptive or exaggerated contents referred to in Paragraph 1, medical efficacy referred to in Paragraph 2, promotion or advertisement contents and methods, and other matters to be observed shall be prescribed by the central competent authority.

Article 11

Cosmetics businesses shall establish and maintain data on direct supply sources and destinations of products. However, this provision shall not apply to data on products directly sold to consumers.

Regulations governing the scope, items, contents, methods for establishment and maintenance, retention period of data, and other matters to be observed with regard to the preceding paragraph shall be prescribed by the central competent authority.

Article 12

Cosmetics businesses shall report the serious adverse effects generated by cosmetics under conditions of normal or reasonable use, or the findings when product could possibly pose a hazard to hygiene and safety or a risk of harm, and handle them in accordance with the provisions of Article 10 of the Consumer Protection Act.

Serious adverse effects mentioned in the preceding paragraph shall refer to one of the following conditions:

1. Death;
2. Life-threatening;
3. Temporary or permanent disability/incapacity;
4. Congenital anomaly/birth defect of fetus/infant;
5. Resulting in hospitalization of users for treatment.

Regulations on reporting population, methods, contents, deadlines, and other matters to be observed with regard to Paragraph 1 shall be prescribed by the central competent authority.

Chapter 4 Sampling Check, Test, and Control

Article 13

Competent authorities may dispatch personnel to enter the premises of cosmetics businesses to conduct sampling checks of their facilities, product information files, data on product supply sources and destinations, relevant records and documents, or sampling tests of cosmetics or their raw materials used. Cosmetics businesses shall give their cooperation, and shall not evade, obstruct, or refuse.

In conducting sampling tests referred to in the preceding paragraph, the competent authorities shall sample amounts not to exceed quantities sufficient for conducting sampling tests and shall provide dockets to the cosmetics business.

In carrying out their official duties for conducting sampling checks or sampling tests, the personnel shall present evidentiary documents in relation to the performance of their duties.

Article 14

In order to enhance border control for cosmetics imports, the central competent authority may make public announcement about certain cosmetics categories or items that could possibly pose a hazard to hygiene and safety and may only be imported after sampling checks and sampling tests show compliance.

Regulations governing the methods, techniques, items, scope of sampling checks and sampling tests, and other matters to be observed with regard to the preceding paragraph shall be prescribed by the central competent authority.

Article 15

Competent authorities shall immediately initiate investigations and may order cosmetics businesses to suspend the manufacture, import, or sale, or order their products to be withdrawn from the market or to be sealed and stored if the cosmetics businesses are suspected to have violated the provisions of this Act or the cosmetics have one of the following conditions:

1. Expiration date exceeded;
2. Source unclear;
3. Other conditions sufficiently harmful to human health.

When competent authorities conduct investigations as specified in the preceding paragraph or other sampling checks or sampling tests referred to in this Act, they may order cosmetics businesses to provide testing specifications, testing methods, and testing reports of original manufacturers, as well as information, samples, reference standards, and relevant data necessary for testing. Cosmetics businesses shall give their cooperation, and shall not evade, obstruct, or refuse.

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

Article 16

Cosmetics businesses shall not supply, sell, give away, publicly display, or offer consumer trial cosmetics that are in violation of the provisions if one of the following conditions applies:

1. Violation of Paragraph 1 of Article 4;
2. Violation of the regulations prescribed pursuant to Paragraph 2 or Paragraph 3 of Article 4, pertaining to the provisions of items, contents, modifications, or methods for establishment and maintenance, retention period, and location of product notification or information file that could possibly pose a hazard to hygiene and safety as determined by competent authorities;
3. Violation of Paragraph 1 or Paragraph 2 of Article 5;
4. Violation of Paragraph 1 or the public announcement made pursuant to Paragraph 3 of Article 6;
5. Violation of Paragraph 1, Paragraph 2, Paragraph 3, or Paragraph 5, or the public announcement made pursuant to Paragraph 4 of Article 7;
6. Violation of Paragraph 1 of Article 8 in failing to apply for factory registration;
7. Violation of the Establishment Standards for Cosmetics Manufactory specified in Paragraph 1 or the Good Manufacturing Practice Regulations specified in Paragraph 2 of Article 8, and said violation could possibly pose a hazard to hygiene and safety as determined by competent authorities;
8. Violation of the labeling provisions specified in Paragraph 1 or Paragraph 2 of Article 10;
9. Product notification or product license revoked or rescinded by the central competent authority.

The same shall apply to cosmetics that have exceeded expiration date, are of unclear source, or pose other hazards to hygiene and safety as per public announcement of the central competent authority.

Article 17

Cosmetics manufacturers or importers shall immediately notify sellers and recall violating products from the market within a time period specified by competent authorities if one of the following conditions applies:

1. Violation of Paragraph 1 or the regulations prescribed pursuant to Paragraph 2 or Paragraph 3 of Article 4, pertaining to the provisions of items, contents, modifications, or methods for establishment and maintenance, retention period, and location of product notification or information file, and failure to make corrections within the time limit specified by competent authorities;
2. Violation of Paragraph 1, Paragraph 2, or Paragraph 3 of Article 5, and failure to make corrections within the time limit specified by competent authorities;
3. Violation of Paragraph 1 or the public announcement made pursuant to Paragraph 3 of Article 6;
4. Violation of Paragraph 1, Paragraph 2, Paragraph 3, or Paragraph 5, or the public announcement made pursuant to Paragraph 4 of Article 7;
5. Violation of Paragraph 1 of Article 8 in failing to apply for factory registration;
6. Violation of the Establishment Standards for Cosmetics Manufactory specified in Paragraph 1 of Article 8 or the Good Manufacturing Practice Regulations specified in Paragraph 2, and said violation could possibly pose a hazard to hygiene and safety as determined by competent authorities;


7. Violation of the labeling provisions specified in Paragraph 1 or Paragraph 2 of Article 10;
8. Product notification or product license revoked or rescinded by the central competent authority.

The same shall apply to cosmetics that are of unclear source or pose other hazards to hygiene and safety as per public announcement of the central competent authority.

Sellers shall cooperate with manufacturers and importers in the recall of cosmetics with regard to the preceding two paragraphs.

Regulations for cosmetics that shall be recalled, their classification, handling methods, implementation methods for recall operations, deadlines for completion, contents of protocol and report, record retention, and other matters to be observed with regard to Paragraph 1 and Paragraph 2 shall be prescribed by the central competent authority.

Article 18

Violating cosmetics shall be confiscated and destroyed if one of the following conditions applies:

1. Violation of Paragraph 1 or the regulations prescribed pursuant to Paragraph 2 or Paragraph 3 of Article 4, pertaining to the provisions of items, contents, modifications, or methods for establishment and maintenance, retention period, and location of product notification or information file, and said violation poses a hazard to hygiene and safety as determined by competent authorities;
2. Violation of Paragraph 1, Paragraph 2, or Paragraph 3 of Article 5, and said violation poses a hazard to hygiene and safety as determined by competent authorities;
3. Violation of Paragraph 1 or the public announcement made pursuant to Paragraph 3 of Article 6;
4. Violation of Paragraph 1, Paragraph 2, Paragraph 3, and Paragraph 5, or the public announcement made pursuant to Paragraph 4 of Article 7, and said violation poses a hazard to hygiene and safety as determined by competent authorities;
5. Violation of Paragraph 1 or Paragraph 2 of Article 8, and said violation poses a hazard to hygiene and safety as determined by competent authorities;
6. Violation of Paragraph 1 of Article 9, and said violation poses a hazard to hygiene and safety as determined by competent authorities;
7. Violation of Paragraph 1 or Paragraph 2 of Article 10, and said violation poses a hazard to hygiene and safety as determined by competent authorities;
8. Product notification or product license revoked or rescinded by the central competent authority.

The same shall apply to cosmetics that have exceeded expiration date, are of unclear source, or pose other hazards to hygiene and safety as per public announcement of the central competent authority.

Article 19

The competent authority shall keep strictly confidential the particulars of, and may at its discretion 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.

Regulations for the reward of informing with regard to the preceding paragraph shall be prescribed by the central competent authority.

Chapter 5 Penal Provisions

Article 20

Those in violation of Paragraph 1 or the regulations prescribed pursuant to Paragraph 4 of Article 10, pertaining to the provisions of promotion or advertisement contents and methods, shall be imposed a fine ranging from NT$40,000 to NT$200,000; violation of Paragraph 2 of the same article shall be imposed a fine ranging from NT$600,000 to NT$5,000,000. In case of severe violation, the business may be ordered to terminate business operations or revoke all or part of the items listed in the registration of its company, business, or factory.

Violators of cosmetics promotion or advertisement specified in Paragraph 1 or Paragraph 2, or the regulations prescribed pursuant to Paragraph 4 of Article 10, pertaining to the provisions of contents and methods, shall be fined successively until the violation is corrected or the publication or broadcast is terminated.

Severe violation of the provisions pertaining to promotion or advertisement specified in Paragraph 1 or Paragraph 2 of Article 10 shall not only be penalized in accordance with the preceding two paragraphs, the competent authorities shall also order the termination of supply, sale, giveaway, public display, or consumer trial offer of the advertised products.

Violators of the provisions pertaining to advertisement specified in the preceding paragraph shall publish or broadcast a corrective advertisement of the same length and in the same space and 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 two provisions who continue to supply, sell, give away, publicly display, or offer consumer trial, or fail to publish or broadcast a corrective advertisement shall be imposed a fine ranging from NT$120,000 to NT$2,000,000.

Article 21

Media businesses in violation of Paragraph 3 of Article 10 shall be imposed a fine ranging from NT$60,000 to NT$300,000 and may be fined successively.

Article 22

Cosmetics businesses shall be imposed a fine ranging from NT$20,000 to NT$5,000,000 and may be fined successively if one of the following conditions applies. In case of severe violation, the businesses may be subject to a suspension of business operations for not less than one month nor greater than one year, or ordered to revoke all or part of the items listed in the registration of their company, business, or factory, or to revoke or rescind notifications or licenses for the said cosmetics.

1. Violation of Paragraph 1 or the public announcement made pursuant to Paragraph 3 of Article 6;
2. Violation of Paragraph 1 of Article 8;
3. Violation of Paragraph 2 of Article 8, with corrections not made after being ordered to make corrections within a specified time limit.

In case of revocation of notifications or licenses for cosmetics of the preceding paragraph, re-notification or re-application for registration of said products shall not be permitted within one year.

Article 23

Cosmetics businesses shall be imposed a fine ranging from NT$10,000 to NT$1,000,000 and


may be fined successively if one of the following conditions applies. In case of severe violation, the businesses may be subject to a suspension of business operations for not less than one month nor greater than one year, or ordered to revoke all or part of the items listed in the registration of their company, business, or factory, or to revoke or rescind notifications or licenses for the said cosmetics.

1. Violation of Paragraph 1 of Article 4;
2. Provision of false information in product notification or information file referred to in Paragraph 1 of Article 4;
3. Violation of the regulations pertaining to items, contents, modifications, or methods for establishment and maintenance, retention period, and location of product notification or information file prescribed pursuant to Paragraph 2 or Paragraph 3 of Article 4, with corrections not made after being ordered to to make corrections within a specified time limit;
4. Violation of Paragraph 1, Paragraph 2, or Paragraph 3 of Article 5;
5. Provision of false information during the application for registration specified in Paragraph 1 or Paragraph 2 of Article 5;
6. Violation of Paragraph 4 or Paragraph 5 of Article 6;
7. Violation of Paragraph 1, Paragraph 2, Paragraph 3, or Paragraph 5, or the public announcement made pursuant to Paragraph 4 of Article 7;
8. Violation of Paragraph 1 of Article 9;
9. Provision of false data on sources or destinations as specified in Paragraph 1 of Article 11;
10. Violation of Paragraph 1 of Article 13;
11. Violation of Paragraph 2 of Article 15;
12. Violation of Article 16 by supplying, selling, giving away, publicly displaying violating cosmetics or offering consumer trial.

In case of revocation of notifications or licenses for cosmetics of the preceding paragraph, re-notification or re-application for registration of said products shall not be permitted within one year.

Article 24

Cosmetics businesses shall be imposed a fine ranging from NT$10,000 to NT$1,000,000 and may be fined successively if one of the following conditions applies and failing to make corrections within a specified time limit after being ordered to do so. In case of severe violation, the businesses may be suspended from operating for not less than one month nor greater than one year, or ordered to revoke all or part of the items listed in the registration of their company, business, or factory, or to revoke or rescind notifications or licenses for the said cosmetics.

1. Violation of Paragraph 1 or the regulations pertaining to scope, items, contents, methods for establishment and maintenance, and retention period of data as prescribed pursuant to Paragraph 2 of Article 11;
2. Violation of Paragraph 1 or the regulations pertaining to reporting methods, contents, or deadlines as prescribed pursuant to Paragraph 3 of Article 12;
3. Violation of Paragraph 1 or Paragraph 2 for failing to notify sellers or recall within time limit, or violation of Paragraph 3 or the regulations pertaining to handling methods, implementation methods for recall operations, deadlines for completion, contents of protocol and report, or record retention as prescribed pursuant to Paragraph 4 of Article 17.

In case of revocation of notifications or licenses for cosmetics of the preceding paragraph, re-notification or re-application for registration of said products shall not be permitted within one year.

Article 25

In case of violation specified in the preceding five articles, the competent authorities may, based on the circumstances of the offense, the extent of harm, and the scope of impact, make public the names and addresses of businesses, products, and conditions of the violation.

Article 26

The penalties prescribed in this Act, with the exception of revocation or rescission of notifications or licenses for cosmetics that shall be imposed by the central competent authority, shall be imposed by municipal or county/city competent authorities for the remaining penalties. The central competent authority may impose the penalties if deemed necessary.

Article 27

The revocation of all or part of the items listed in the registration of company, business, or factory as specified in this Act shall be forwarded for execution by the competent industry or commerce authority or its competent government authority 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/organizations, corporations, or groups to carry out inspections, sampling checks or sampling tests of cosmetics and cosmetics businesses, or to issue manufacturing and sale certificates.

The central competent authority may carry out accreditation of the commissioned institutions/organizations, corporations, or groups in the preceding paragraph. The accreditation tasks may be authorized to subordinate agencies or commissioned to relevant institutions/organizations, corporations, or groups.

Regulations governing the qualifications and requirements for organizations, corporations, or groups to undertake commission or accreditation, the procedures of tasks for commission or accreditation, and other relevant matters of those commissioned with regard to the preceding two paragraphs shall be prescribed by the central competent authority.

Article 29

Cosmetics businesses may submit applications of manufacturing and sale certificate or GMP compliance certificate to the central competent authority for the cosmetics they have notified or acquired licenses, or for cosmetics manufacturing facilities that comply with the cosmetic Good Manufacturing Practice Regulations as determined by the central competent authority.

Regulations governing the application criteria, review procedures and standards, validity term, revocation, return, cancellation, and other matters to be observed with regard to the issuance of certificates in the preceding paragraph shall be prescribed by the central competent authority.

Article 30

Cosmetics businesses shall pay the fees for cosmetics notification, applications for registration, applications for inspection of compliance with the cosmetic Good Manufacturing Practice Regulations, applications for sampling checks and sampling tests on border importation of cosmetics, and applications for certificates that are made in accordance with this Act.

Article 31

The enforcement rules of this Act shall be prescribed by the central competent authority.

Article 32

The date for enforcement of this Act shall be set by the Executive Yuan, with the exception of Paragraph 4 through Paragraph 6 of Article 6, and Subparagraph 6 of Paragraph 1 of Article 23, which shall be enforced from November 9, 2019.

Existing Regulations

Enforcement Rules of Cosmetic Hygiene and Safety Act

Article 1
This rule (the “Rule”) is enacted per Article 31 of Cosmetic Hygiene and Safety Act (the “Act”).

Article 2
Cosmetics product notification and product information file stipulated under Paragraph 1 of Article 4 and the product recall as set forth under Paragraph 1 of Article 17 of the Act shall be completed by the cosmetics manufacturers or importers.

The contract manufacturers are not deemed as the cosmetics manufacturers or importers stipulated under the preceding Paragraph.

Article 3
Country of origin of imported products stipulated under Sub-paragraph 7 of Paragraph 1 of Article 7 of the Act shall refer to regions or countries final products manufactured or processed per the Regulations Governing the Determination of Country of Origin of an Import Goods.

Article 4
Manufacturing facilities stipulated under Paragraph 1 and 2 of Article 8 of the Act shall refer to the plants conducting cosmetics manufacturing or packaging operation.
The plants for the further combination of cosmetics products which have fulfilled the labeling requirements of Article 7 of the Act shall be excluded from the manufacturing facilities prescribed in the preceding Paragraph.

Article 5
The requirement of hiring and stationing licensed pharmacists or personnel with professional skills in the field of cosmetics at the factory to supervise the dispensation and manufacturing of cosmetics stipulated under Paragraph 1 of Article 9 of the Act shall not apply to the manufacturing facilities that factory registration is not necessary as specified jointly by the central competent authority and central competent industry authority per Paragraph 1 of Article 8 of the Act.

Article 6
Products sealed and stored per Article 15 of the Act shall be additionally sealed or labeled by the competent authority. Those products shall be taken photos or videotaped. A list of items and numbers of sealed and stored products shall be made and confirmed by the on-site business by signing or affixing its stamp.

Products sealed and stored per the preceding Paragraph may be designated to be adequately retained by the business. Business shall not, without authorization, replace, remove, conceal or dispose of the products.

Article 7
Unclear source cosmetics stipulated under Sub-paragraph 2 of Paragraph 1 of Article 15, Paragraph 2 of Article 16, Paragraph 2 of Article 17, and Paragraph 2 of Article 18 of the Act shall refer to one of the followings:

1. Proof of source failed to be provided.
2. Provided source or its proof confirmed to be false.
3. No indication of the name or address of the manufacturers or the importers stated on the outer packaging or containers and no product notification information to be verified.

Article 8

Severe violation stipulated under Paragraph 1 and 3 of Article 20 of the Act shall refer to one of the followings:

1. Failing to cease medical efficacy claims in its promotion or advertisements after punished consecutively by the competent authority.
2. Its promotion or advertisements mislead the public and cause harm to human health or cause death.
3. Other situations determined by the competent authority having impact equivalent to preceding two Sub-paragraphs.

Article 9

If cosmetics notification information or originally approved information is amended, and the original information labeled is inconsistent with amended information, the cosmetics with original labels manufactured or imported before the amendment date are allowed for sale within the product expiration date.

If the renewal application for the license of specific purpose cosmetics or cosmetics product notification is not filed or renewal is not granted, the cosmetics manufactured or imported before the due date of the license or notification are allowed for sale within the product expiration date.

Article 10

The Rules shall take effect on July 1, 2019, except for Article 3 and Paragraph 2 of Article 4 of the Rules shall take effect on July 1, 2021.

> Regarding all the regulations mentioned above, the newest version announced by central competent authority shall prevail.

Relevant link

- Laws & Regulations Database of The Republic of China
  http://law.moj.gov.tw/ENG/Index.aspx
- Taiwan Food and Drug Administration
  http://www.fda.gov.tw/ENG/index.aspx
- Cosmetic Hygiene and Safety Act and Relevant Laws
  http://www.fda.gov.tw/tc/includes/GetFile.ashx?id=f637758565630575634

衛生福利部食品藥物管理署
Taiwan Food and Drug Administration

ADD：No.161-2, Kunyang St, Nangang District,
Taipei City 11561, Taiwan (R.O.C.)

TEL：886-2-2787-8000

WEB：www.fda.gov.tw