NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH
RE: RULES, PROCEDURES AND CONDITIONS
ON THE MANUFACTURE OR IMPORTATION OF COSMETICS,
B.E. 2561 (2018)*

By virtue of the provisions of section 5 paragraph one, section 6 (5) and (6) of the Cosmetics Act, B.E. 2558 (2015), the Minister of Public Health, upon recommendation of the Cosmetics Committee, hereby issues the Notification prescribing rules, procedures and conditions on the manufacture or importation of cosmetics as follows.

Clause 1. A person manufacturing a cosmetic for sale or a contract manufacturer of a cosmetic must comply with the specifications regarding the manufacturing facility, tools, instruments, equipment, containers and storage method of cosmetics prescribed in the Annex A attached to this Notification.

Clause 2. A person importing a cosmetic for sale must comply with the specifications regarding the import facility, importation procedure and storage method of cosmetics prescribed in the Annex B attached to this Notification.

Clause 3. A person manufacturing for sale, a person importing for sale or a contract manufacturer of a cosmetic whose notification on manufacturing or importation of cosmetics for sale has been accepted prior to the date on which this Notification comes into force, must comply with this Notification within two years from the date on which this Notification comes into force.

Clause 4. This Notification shall come into force as from the day following the date of its publication in the Government Gazette.

Announced on the 4th day of May B.E. 2561 (2018)
Piyasakol Sakolsatayadorn
Minister of Public Health

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* Published in the Government Gazette, Vol. 135, Special Issue, Part 117d, page 3, dated 23rd May B.E. 2561 (2018)

Annex A
Attached to the Notification of the Ministry of Public Health
Re: Rules, Procedures and Conditions on the Manufacture or Importation of Cosmetics, B.E. 2561 (2018)

Specifications regarding the manufacturing facility, tools, instruments, equipment, containers and storage method of cosmetics

Definitions

"Manufacturing process" means the part of manufacturing cycle starting from weighing of raw materials to obtaining a bulk product.

"Quality control" means all inspections and analyses carried out during manufacturing to ensure the cosmetic products manufactured in each lot possess the properties in conformity with the established specifications.

"Production" means all operations starting from the manufacturing process to packaging to obtain a finished product.

"Packaging" means a stage of manufacturing cycle applied to a bulk product to obtain the finished product.

"Manufacture" means all operations to manufacture a cosmetic product, comprising of production and quality control, starting from acquisition of raw materials through manufacturing process and packaging to obtain a finished product, and release of the finished product for distribution.

"Cosmetic product" means a cosmetic under the law on cosmetics.

"Bulk product" means a cosmetic product that passed through the manufacturing process and is prepared to undergo the packaging stage in order to become a finished product.

"Finished product" means a cosmetic product which has undergone all stages of manufacture.

"Clean area" means an area which is controlled to prevent contamination.

"Batch number or lot number" means a designation in numbers or letters or combination of both that identifies the complete history of the batch or lot.

"**Raw material**" means any substance or material which is an ingredient in the formulation for the manufacture of a cosmetic product.

"Packaging material" means materials used in the packaging of a bulk product to obtain the finished product.

"Manufacture site" means a place, a building or a part of a building, including the vicinity thereof, used for manufacture.

"Document" means written procedures, instructions and records involved in the manufacture and quality control of cosmetic products.

"Master formula" means a document containing details in relation to determination of quantity of raw materials, containers or packaging materials used in the manufacture of each formulation in accordance with the specified manufacturing procedures, including important precautions and recommendations in the manufacturing processes and in-process controls.

1. General Information

The person manufacturing a cosmetic product for sale or a contract manufacturer of a cosmetic product shall undertake to prepare a document providing general information on the manufacture site, information of finished products, raw materials, information on historical background or on organization's history and information on the notification of the cosmetic products.

2. Personnel

2.1 Every personnel working in the manufacturing process of a cosmetic product must have knowledge in relation to cosmetic good manufacturing practices, knowledge on hygiene and operational precautions.

2.2 Personnel involved in the notification must have knowledge on the relevant laws and regulations, such as notification and preparation of labels.

2.3 The personnel under 2.1 and 2.2 must undergo a training or self-education, and the record thereon shall be kept as evidence.

3. Manufacture Site

3.1 The location must not cause contamination.

3.2 The manufacture site must be structurally sound, have adequate areas for the installation of tools and equipment used in the manufacture. The floors, walls and ceilings of the manufacture site must be made from materials which are durable, long-lasting and easy to clean.

3.3 A sign with the text "Manufacture Site" made from a long-lasting material shall be made easily visible for outsiders.

3.4 Rooms shall be suitably apportioned into at least two separated rooms, i.e. a room for manufacture and packaging of cosmetic products and a room for storage of raw materials, packaging materials, bulk products and finished products.

3.5 The rooms involved in the manufacturing process of a cosmetic product shall be separated from the residence area and not be a pathway leading to other areas.

3.6 There shall be suitable and sufficient illumination and air ventilation for the performance of work.

3.7 Measures shall be put in place to prevent animals and insects from entering into the manufacture site.

4. Manufacturing Tools, Instruments and Equipment

4.1 Contamination which may occur during the production, e.g. from lubricant oil, fuel, dust or metal scraps, shall be prevented.

4.2 They shall be made from materials which do not react with the cosmetic product, cannot absorb or do not flake off into a cosmetic product, raw materials, cleaning agents or disinfectants.

4.3 They can be conveniently and safely used and maintained.

5. Sanitation and Hygiene

5.1 Personnel

5.1.1 The personnel involved in the manufacture, when entering into a clean area, such as a manufacturing room, a weighing area or a packaging area, must change to or wear over a work attire, a mouth and nose cover and shoes used for the clean area. Such equipment must be regularly cleaned and must not be worn outside the clean area. Gloves may be used if considered necessary.

5.1.2 The personnel performing work in relation to the production of a cosmetic product must not wear any ornament during the performance of work, regularly maintain cleanness of their hands and nails, and clean their hands every time prior to entering the manufacturing room.

5.1.3 Any unsanitary activity shall be prohibited in the manufacturing room, such as eating, smoking and storage of food or beverage.

5.1.4 The personnel must be in good health, not have a communicable disease, a skin disease or wounds, and undergo health checkup at least once a year. The health checkup record shall be kept as evidence.

5.2 Premises

In manufacture and packaging sites, the following measures must be put in place to properly and regularly control and maintain cleanness:

5.2.1 The manufacture and packaging sites must be kept orderly and clean, and do not have irrelevant objects or filth.

5.2.2 A toilet must be sanitary and well-equipped with equipment and tools for cleaning or disinfection as may be necessary, and must not directly connect to the manufacturing room.

5.2.3 There shall be good managing practices to control all wastes from the production, including sludges or residues, released from the manufacture site which have or may have effect on the quality of the environment or cause harm to the health of the public.

5.2.4 There shall be sufficient number of lidded receptacles to collect solid wastes and an appropriate solid waste disposal measure.

5.2.5 There shall be appropriate and efficient wastewater management and waste disposal systems.

5.2.6 There shall be appropriate safety measures, which must at least include having fire extinguishing equipment and a first aid kit.

5.3 Manufacturing Tools, Instruments and Equipment

5.3.1 Manufacturing tools, instruments and equipment must be clean and stored properly in a clean place.

5.3.2 The cleaning must be suitable and not cause contamination. There shall be written cleaning procedures. The personnel shall be trained to correctly perform the work.

5.3.3 The cleaning shall be recorded in writing.

6. Production

6.1 Raw Materials and Packaging Materials

6.1.1 They must be in good conditions. Their containers must have no rapture or crack, and not be damaged or get gnawed by animals.

6.1.2 They must be kept appropriately to prevent confusion and disorderliness.

6.1.3 A label showing details shall be displayed on the container of raw materials and packaging materials.

6.1.4 There shall be accompanied by a document showing results of quality test or of inspection of specification, or a certificate of analysis.

6.1.5 Raw materials and packaging materials shall be used in a manner that those acquired first are used first or those expiring first are used first.

6.1.6 The quality of water used in the manufacture of cosmetics must at least be in conformity with the quality of drinking water under the Notification of the Ministry of Public Health on drinking water in sealed containers.

6.2 Practices and Manufacturing Process

6.2.1 Manufacturing Process

6.2.1.1 Before and after using raw materials in the manufacturing process, it shall be ensured that raw materials are contained in a container which can prevent contamination with a tag showing their name and expiration date. Before using in the manufacture of a cosmetic product, raw materials must not expire.

6.2.1.2 Manufacturing tools, instruments and equipment must be cleaned to prevent contamination both before and after use in manufacturing cosmetic products.

6.2.1.3 During manufacturing process, there must be no object irrelevant to the manufacturing process in the area of the manufacturing room.

6.2.1.4 Within the same manufacturing room, if there are multiple formulations of cosmetic products being manufactured at the same time or another cosmetic product was manufactured before, measures shall be put in place to prevent potential cross-contamination among each formulation of cosmetic products.

6.2.1.5 The steps and procedures for control of manufacturing process specified by the master formula of the respective cosmetic product shall be followed.

6.2.1.6 There shall be a batch number or lot number for each lot of cosmetic products being manufactured.

6.2.1.7 A bulk product must be stored in a sealed container with a clear identification tag indicating its name, batch number or lot number and month and year of manufacture.

6.2.2 Packaging

6.2.2.1 The packaging shall be in accordance with the steps specified in the master formula.

6.2.2.2 Each type of packaging materials must have an identification tag, and be checked before use.

6.2.2.3 A label displayed on a container, a package or a box must be checked before use.

6.2.2.4 A cosmetic product must be labelled as prescribed by law.

6.2.2.5 There shall be an inspection of the net volume.

7. Quality Control

7.1 There shall be a quality inspection of bulk products and finished products. The quality control inspection shall be recorded in writing.

7.2 A specimen of a finished product shall be collected in the quantity sufficient for the quality verification.

8. Document

8.1 The master formula shall be prepared. Such master formula shall specify the formulation of ingredients of all manufactured cosmetic products and be in conformity with the details so notified, and also specify the steps of manufacture.

8.2 For each lot of cosmetic products manufactured, a record on every step of production starting from weighing of raw materials, mixing, packaging of bulk products and finished products, shall be made and must be consistent with the master formula.

9. Storage

Raw materials, packaging materials, bulk products, finished products, and relevant manufacturing tools and equipment shall be stored in a manner that is suitable, orderly, convenient to use and easy to clean. They shall be attached with a clear Identification tag, and stored under controlled temperature and suitable humidity. If there are inflammable substances, they shall be appropriately stored.

10. Complaint

10.1 There shall be a document describing steps for handling complaints. Complaints shall be recorded and investigated to find out the cause and corrective and preventive measures.

10.2 Results of an action taken to resolve a complaint shall be recorded in writing.

10.3 In the case where it has been found that a cosmetic product manufactured is harmful to consumers, the manufacturer must report the adverse effects occurring from the use of such cosmetic product to the Food and Drug Administration as prescribed by the Ministry of Public Health.

10.4 There shall be a measure to recall a cosmetic product in accordance with the rules, procedures and conditions on recall, destruction and delivery of cosmetic products prescribed by the Ministry of Public Health.

Annex B
Attached to the Notification of the Ministry of Public Health
Re: Rules, Procedures and Conditions on the Manufacture or Importation of Cosmetics, B.E. 2561 (2018)

Specifications regarding the import facility, importation procedure and storage method of cosmetics

Definitions

"Cosmetic product" means a cosmetic under the law on cosmetics.

"Bulk product" means a cosmetic product that passed through the manufacturing process and is prepared to undergo the packaging stage in order to become a finished product.

"Finished product" means a cosmetic product which has undergone all stages of manufacture.

"Cosmetic import site" means a place, a building or a part of a building, including the vicinity thereof, used for importation and storage of cosmetic products.

1. General Information

The person importing a cosmetic product for sale shall undertake to prepare a document providing general information on the cosmetic import site, information of cosmetic products, information on historical background or on organization's history and information on the notification of the cosmetic product.

2. Personnel

2.1 Every personnel working in the cosmetic import site and storage site must have knowledge in relation to rules on importation of cosmetic products, knowledge on hygiene and operational precautions.

2.2 Personnel involved in the notification must have knowledge on the relevant laws and regulations, such as notification and preparation of labels.

2.3 The personnel under 2.1 and 2.2 must undergo a training or self-education, and the record thereon shall be kept as evidence.

2.4 The personnel under 2.1 must be in good health, not have a communicable disease, a skin disease or wounds, and undergo health checkup at least once a year. The health checkup record shall be kept as evidence.

3. Cosmetic Import Site and Storage Site

3.1 Import Site

3.1.1 It shall be suitably separated from a residential room.

3.1.2 A sign with the text “Cosmetic Import Site” made from a long-lasting material shall be made easily visible for outsiders.

3.2 Storage Site and Storage Method

3.2.1 It shall be suitably separated from a residential room.

3.2.2 A sign with the text “Cosmetic Storage Site” made from a long-lasting material shall be made easily visible for outsiders.

3.2.3 Imported cosmetic products shall be suitably stored and attached with a clear identification tag.

3.2.4 There shall be personnel to control the discharge and to prepare a record on the dispatch of finished products as evidence for traceability purpose.

3.2.5 There shall be suitable and sufficient illumination and air ventilation for the performance of work.

3.2.6 Measures shall be put in place to prevent animals and insects from entering into the cosmetic storage site.

3.2.7 The environment for the storage of cosmetic products, such as temperature, humidity, and sunlight, shall be controlled in accordance with the specification of the cosmetic products.

3.2.8 The site must be kept orderly and clean, and do not have filth or objects irrelevant to cosmetic products.

3.2.9 There shall be sufficient number of lidded receptacles to collect solid wastes and an appropriate solid waste disposal measure.

3.2.10 There shall be appropriate safety measures, which must at least include having fire extinguishing equipment and equipment necessary for first aid.

4. Importation

4.1 Importation Procedure

4.1.1 A person importing a cosmetic product for sale shall import a cosmetic product manufactured by the manufacturer who has been accredited in accordance with the standards prescribed in Annex A or a standard related to manufacture which is equivalent or not lower than the specifications under the Notification of the Ministry of Public Health on rules, procedures and conditions on the manufacture or importation of cosmetics, as follows:

(1) WHO Good Manufacturing Practices (GMP) for pharmaceutical products;
(2) Pharmaceutical Inspection Co-operation Scheme (PIC/S);
(3) Australian Good Manufacturing Practices (GMP) for pharmaceutical product;
(4) ISO 22716 Cosmetic Good Manufacturing Practices (GMP) – Guideline for Good Manufacturing Practices;
(5) CTFA Guideline for Cosmetic Good Manufacturing Practices, U.S.A.;
(6) Cosmetic Good Manufacturing Practices, COLIPA – The European Cosmetic Toiletry and Perfumery Association;
(7) ASEAN Guideline for Cosmetic Good Manufacturing Practice.

4.1.2 An importer must obtain a letter of authorization from trademark owner or manufacturer.

4.1.3 The customs entry and the document showing the list of items as well as the lot number shall be maintained for five years from the date of import of the cosmetic product.

4.1.4 A specimen of an imported cosmetic product shall be collected in the quantity sufficient for inspection for at least until its expiration. Relevant documents must be able to be submitted for the purpose of traceability.

4.2 Label

A cosmetic product imported for sale must be labelled as prescribed law.

5. Quality Control

With regard to an imported cosmetic product, a certificate of analysis (COA) or a document showing that the product conformance is in line with the specifications of a finished product or their equivalent of an imported product shall be maintained for the purpose of inspection for three years after the expiration date or for five years after the manufacturing date of the cosmetic product. Such document, including a safety data sheet (SDS), shall be kept in the product information file (PIF).

6. Complaint

6.1 There shall be a document describing steps for handling complaints. Complaints shall be recorded and investigated to find out the cause and corrective and preventive measures.

6.2 Results of an action taken to resolve a complaint shall be recorded in writing.

6.3 In the case where it has been found that a cosmetic product imported is harmful to consumers, the importer must report the adverse effects occurring from the use of such cosmetic product to the Food and Drug Administration as prescribed by the Ministry of Public Health.

6.4 There shall be a measure to recall a cosmetic product in accordance with the rules, procedures and conditions on recall, destruction and delivery of cosmetic products prescribed by the Ministry of Public Health.