

Decree N° 239/02

TITLE I

GENERAL PROVISIONS

Article 1: The registration, importation, production, storage, possession, sale or distribution, advertising and promotion of cosmetic products is regulated by the provisions stated herein.

Article 2: The Chilean Institute of Public Health, hereinafter referred to as the Institute, is the sanitary authority responsible for the sanitary control and registration of cosmetic products throughout the country and for ensuring compliance with the corresponding provisions stated in the Sanitary Code and in the complementary regulation, as well as for verifying the quality control and certification of the said products.

Article 3: Likewise, the Institute shall authorize the installation of facilities for the manufacture of cosmetics and supervise its operations, pursuant to the provisions stated herein and in the general technical norms approved by the Ministry of Health.

Article 4: Cosmetic products, imported or manufactured, to be marketed and distributed in the country, shall previously have a sanitary registration as set forth herein.

Article 5: Pursuant to the regulations hereto, the following terms shall have the following meaning:

a) Cosmetic or cosmetic product: any preparation for external use on the human body for beauty purposes or to modify the physical appearance of the skin or to preserve the normal physical chemical conditions of the skin and its annexes,

b) Products of a low production risk such as solid soap exclusively for personal hygiene, soaps qualified as such and specifically defined by the Public Health Institute, polish remover, nail polish, wax, finishing spray, sanitary napkins,

c) Personal hygiene products such as liquid soap, shampoo, conditioners, dental paste, collutories or mouth-rinsing solutions, deodorants, antiperspirants, beard shaving products and aftershaves, makeup remover, cotton pads, powders and others specifically defined by a resolution of the Public Health Institute.

d) Children's cosmetics: cosmetics for children under 6, including perfumes, lotions and eau de toilette, having the requisites necessary for such age, according to the cosmetic forms dealt with, such as pH and microbe level, whenever is the case. In any case, they shall be non-allergenic or non-irritating.

e) Cosmetic form: outward appearance or state in which a product is presented according to its specifications.

- f)** Good cosmetic manufacturing practices: procedures established to ensure a uniform and satisfactory quality of cosmetic products.
- g)** Production or production process: the set of operations necessary to manufacture a particular product, from its manufacturing to its final cosmetic form, its separation in final containers, labeling and the corresponding quality controls.
- h)** External quality control laboratory: an authorized institution which conduct tests and assays for the products, upon request of either an individual or any legal entity.
- i)** Raw material: any substance directly involved in the manufacturing of a cosmetic product, whether unchanged, modified or removed during the production process.
- j)** Cosmetic ingredient: any substance authorized by the Public Health Institute to be used in a cosmetic product, remaining in the finished product which can be a common ingredient or one with cosmetic activity.
- k)** Ingredient with cosmetic activity: a substance that, by itself or together with other substances, produces the cosmetic effect stated in the corresponding registration.
- l)** Common ingredient: ingredient used to obtain a cosmetic form without modifying the natural effect of the product or used only as odorant or colorant.
- m)** Specifications: the technical document defining the attributes and parameters that must be met by raw materials, container materials, products or services. It indicates all tests and studies that will be used to establish such attributes or parameters and it determines [the](#) acceptance or rejection criteria.
- n)** Tolerance margins: percentage of maximum acceptable deviations with regard to the attributes and parameters stated in a specification.
- o)** Analysis bulletin: document issued by the quality control department of the producer laboratory, whether local or foreign, or by the external quality control laboratory, showing the results obtained after evaluating each of the specifications defined by the producer.
- p)** Quarantine: condition during which raw materials, container and packaging material, semi-manufactured products, bulk or finished products, as applicable, are temporarily kept, prohibiting its use to ensure its certainty until the approval or rejection report issued by the quality control system.
- q)** Internal brochure: document by which users are informed about the proper use, warnings and precautions of a cosmetic product.
- r)** Container and packaging material: the material used to contain and label a product for its final presentation. It can be internal or external, depending on whether it is in direct contact or not with the cosmetic form.

- s)** Primary or internal container: the container that is in direct contact with the product.
- t)** Secondary or external container: the container that is used as the external presentation of a product for consumers, when there is a primary container.
- u)** Final container: this container consists of a single primary container or also includes a secondary container, with or without full labeling, as long as the cosmetic product is not subject to further handling.
- v)** Lot or series: the amount of a product obtained in a production cycle, through continuous stages, standing out for its homogeneity. In continuous automatic processes, it will be determined by its primary container with regard to an amount of product confirming homogeneity
- w)** Sublot: specific and identified portion of a lot or series.
- x)** Semi-manufactured product: product found in any of the intermediate stages of its manufacturing process, prior to the final cosmetic form.
- y)** Bulk-manufactured product: product found in its final cosmetic form, but still not separated in final containers.
- z)** Finished product: product found in its final container, labeled and ready for its distribution and marketing.
- aa)** Stability: the ability of a cosmetic product to keep the specifications stated in the register unmodified.
- bb)** Minimum effective period: the time frame during which a product must remain stable under the storing conditions defined by its stability study.
- cc)** Expiration date: the date indicated by the month and calendar year beyond which a product is not expected to remain stable.
- dd)** Advertising: the set of procedures used to inform about, highlight or emphasize publicly, whether directly or indirectly, and through any information procedure or means, the features, distribution, selling and usage conditions of cosmetic products.
- ee)** Register: the registration of a cosmetic product, once it has been previously approved as set forth in article 30 and following, in a special record kept by the institute, authorizing its marketing or distribution in the country.
- ff)** Label or tag: the graphic representation reproducing the wording attached to or written on the product containers;

gg) Free-sale certificate: the document issued by the sanitary authority of the export country, at the request of the interested party, stating:

a. that the producer facilities meet the requirements established by the sanitary authority of the manufacturing country.

b. that it has been granted the authorization to manufacture and distribute the product intended to be imported to the country, fully reproducing the authorized formulation.

c. that its sale is subject to a restrictive procedure or special control, if any.

hh) Official cosmetic product certificate: document issued by the sanitary authorities of the export country in which, at the request of the holder of the respective registration, the following information must be confirmed:

a) Any or all indications typical of a free-sale certificate.

b) Any or all such indications, together with other circumstances certified in the register statement.

c) Any other condition or situation confirmed by the sanitary authorities or duly confirmed by the petitioner.

ii) Market control: steps to be taken by the Public Health Institute of Chile, during the marketing stage of a cosmetic product, aimed at ensuring compliance of sanitary standards on import, production, storage, possession, quality control, sale or distribution of cosmetic products.

jj) Safe use: the satisfactory safety evaluation for human health of a finished product, taking into consideration the general toxicological profile of the ingredients, concentrations, chemical structure and exposure level at normal use conditions.

Article 6: Contaminated cosmetic product is the product that has pathogenic or non-pathogenic microorganisms beyond the limits authorized, or disease-causing parasites in humans, based on general technical standards officially established by a resolution of the Ministry of Health.

Article 7: Adulterated cosmetic products are those whose composition has been modified with respect to the formulation stated in the registration, with the purpose of concealing alterations or removing, totally or partially an ingredient or to include prohibited ingredients or concentrations other than those stated, except for the varieties of the same product referred to in article 22 herein.

Article 8: Falsified cosmetic product is:

- a) the product whose label on the container does not indicate what is stated in the registration;
- b) the product that declares to contain ingredients that do not correspond to the formulation stated in the registration;
- c) the product sold under the same fantasy name or trademark of another similarly registered product, and not corresponding to that product; or
- d) the product whose content had been separated, totally or partially, from the original container and replaced by another substance.

Article 9: Altered cosmetic products are those products that as a result of their manufacturing, storage, transportation, preservation or any other reasons whatsoever:

- a) have been modified, thus altering their quality;
- b) show damage on their packaging, labels or containers; or
- c) are distributed or sold beyond the expiration date that appears on their labels.

Article 10: Any sanitary register shall be valid for a period of five years starting from its date of approval and shall be granted upon prior request of the interested party and payment of the corresponding tariff rate, notwithstanding what is stated hereinbelow. This time period shall be understood as automatically and successively extended upon the payment of the tariff rate, for an equal number of periods, as long as it is not expressly voided. A register will be established based on a company record number.

Article 11: The sanitary register of a product may be cancelled in any of the following situations:

- a) Upon request of the registration holder;
- b) If falsification or fraud is confirmed in any of the statements submitted to request the registration;
- c) If significant qualitative or quantitative changes are confirmed in the ingredients stated in the registration;
- d) If serious infringement to the sanitary provisions is confirmed, understanding as such those that endanger the health of the population;
- e) If one of the product ingredients is eliminated from the list of ingredients authorized for cosmetic use, its use is limited, its concentration is reduced or is included in the list of ingredients prohibited for cosmetic use.

Article 12: The Ministry of Health shall previously refer to the cancellation of a registration or to the refusal for its granting as requested by the Institute.

Article 13: When as a result of any situation encountered during the performance of its control duties or by scientific data from the World Health Organization, from national or international institutions or entities or from its own research, the Institute establishes, by founded resolution, that a cosmetic product or ingredient affects the public health when applied under normal use conditions, it may:

- a) Modify the respective List of Ingredients;
- b) Request or instruct the necessary changes in the corresponding registrations ensuring the safety and effectiveness in the use of a product or ingredient, whether in its formulation, cosmetic purpose, usage, labeling or other condition that needs to be modified within a definite period of time;
- c) Request the Ministry of Health to refer to the immediate cancellation of the registration; and
- d) Reject the registration request in process, pursuant to what is stated in article 23.

Article 14: The manufacturing of cosmetic products shall be conducted by production laboratories and those laboratories authorized to manufacture personal hygiene products with a low production risk.

The above-mentioned laboratories will not be forced to register cosmetic products exclusively intended for exports, and shall only notify the Institute about this situation. However, distribution and marketing of said products in the country shall be made prior registration pursuant to the norms stated herein.

Article 15: Import of cosmetic products may be carried out by individuals or companies, according to the norms established in the current legislation and in the regulations hereto.

Only production laboratories may import or receive, on their own account or on the account of third parties, semi-manufactured or bulk products, for finishing purposes.

However, finished imported products whose labeling of origin does not contain letters f) to j) of article 40 herein, may be received in authorized warehouses, where the missing indications shall be added, prior to their distribution. Notwithstanding the above, if the labeling of said products, also does not include any reference to letters a) to e) of article 40, the products shall be considered as bulk-manufactured products.

Article 16: Once the processing of customs destination of raw materials, semi-manufactured cosmetics or bulk manufactured and finished cosmetic products is completed, the National Customs Service has previously processed the certification issued by the respective Health Service and the products have been removed from customs premises,

they shall remain under the responsibility of the consignee. The consignee shall, under no circumstances, use, employ, sell, market, distribute, assign, or dispose of any of them, without the authorization of the Public Health Institute.

Said authorization shall be issued within three working days from the date in which the interested party informs the authority about the arrival of the products to its storage place, enclosing a copy of the Health Service certificate authorizing its transfer to this place.

The Customs National Service shall monthly report the Institute about the cosmetic products that have been brought in the country, as well as quantity and name of importer.

Article 17: In order for the Public Health Institute to process this authorization for use and/or disposal, the importer shall enclose to the request the analysis bulletin issued by either the foreign manufacturer or by a Chilean quality control laboratory expressly making reference to the lot that intends to be cleared through customs. The authorization shall be granted within three working days.

Article 18: Cosmetic products may be distributed and sold in pharmacies, drugstores, and other stores.

Likewise, production laboratories may publicly sell their own products, under the selling conditions applicable to their nature.

TITLE II

ABOUT COSMETIC REGISTRATIONS

1. GENERAL NORMS

Article 19: All cosmetics, regardless of their cosmetic use or purpose, shall be governed by the provisions stated herein.

Article 20: In general, without necessarily expressing the specific use that may or may not be included in said norms, cosmetic purposes shall be understood, among others, as:

- a) Personal hygiene products
- b) Make-up
- c) Hair coloring
- d) Tanning
- e) Sun protectors

- f) Hair embellishment
- g) Depilation and epilation
- h) Skin care
- i) Any other function that meets the purposes of a cosmetic product.

Products referred to in letters b) and c) of Article 5 and odorizers, preparations containing aromatic natural or synthetic substances shall be understood as registered based on the sole fact that the producer or importer facilities have been sanitarily authorized.

Consequently, those facilities that manufacture or import this type of products shall submit a statement before the Institute within thirty days from the start-up date of its operations or activities, identifying the respective owner, location, line of business and the formulation and characteristics of each of its products. Once the background information has been submitted, the above facilities will be registered under the stated line of business.

Each of the new products referred to in letters b and c) of Article 5 shall be notified to the Public Health Institute, before they are marketed in the country.

Notwithstanding the above, manufacturers or importers of these products may voluntarily request the registration, thus meeting what has been stated herein.

Article 21: Any cosmetic product, regardless of its denomination, class or purpose, shall only act locally on the skin and its annexes; and if absorbed by the body, it shall have no systemic effects.

Article 22: Any compositions with the same concentration of ingredients, cosmetic activity, with the same common ingredients and without one or more of the colorants, flavorings or odorizers included in its qualitative formulation shall be considered as varieties of the same products, and will therefore not require additional registration.

Article 23: The registration request to market and distribute local or imported cosmetic products, shall be submitted to the Institute, in special forms approved by the said Institute, as an affidavit, signed by the interested party or its legal representative, as applicable, and by the person responsible for technical matters.

The reception of requests containing all the statements included in Article 25 and 26 may not be objected.

The register shall be approved or rejected within five working days from the date of reception of said request in the Institute. In case of rejection, a previous statement from the Ministry of Health shall be required.

Likewise, requests shall be submitted and resolved by magnetic, electronic, computer and internet means, or by any other means as established by the Institute, who will prepare special forms for this purpose and take all the necessary steps to duly protect the respective public interests. Whenever the above processing system is used, requests shall be resolved within three working days.

Article 24: The Institute shall grant a registration number to the holder acting directly or engaging a third party as cosmetic importer or manufacturer. The above number will be granted only upon presentation or submittal of a form in which the name, company name, legal representative, company tax number, address and telephone are indicated, enclosing ID card of deponent, together with a copy of registration as a company in the Registrar of Commerce, as applicable.

These figures shall be the basis for the registration number granted by the Institute.

Article 25: Forms shall include the following statements:

- a) Identification of the individual or company requesting the registration. In the case of the authorized agent representative, they shall identify the individual or company they represent, who shall be the holder of the registration for all legal purposes.
- b) Identification of the requester's advisor technical director, who takes on the responsibility of the technical requirements of the product;
- c) Product denomination and specification of cosmetic purpose;
- d) Purpose of Request, such as:
 - d.1. own manufactured products;
 - d.2. products manufactured in Chile by third parties;
 - d.3. finished imported products;
 - d.4. bulk imported products or semi-manufactured products finished; in Chile by the holder or by third parties
- e) Full name of the foreign authorized agent, if reference are made to the use of a license or power of attorney.
- f) The registration number in the Institute of the requester who acts directly or engages a third party as importer or manufacturer of cosmetics, followed by whomever may correspond to the proper sequential order of products.
- g) Description and interpretation of the password or code, if the product is imported or the requester, by any reason whatsoever, had not confirmed it.

h) Full name and address of the local and foreign companies that manufacture the cosmetic product.

Article 26: The forms indicated in article 25 hereinabove shall at least enclose the following written statements, also signed by the requester:

a) Full qualitative formulae and quantitative expression of the ingredients with cosmetic activity or subject to concentration restrictions.

The quantitative formulae shall be expressed in weight or volume units of the decimal metric system or in conventional units internationally accepted, as applicable.

Therefore, all product ingredients shall be identified by the names of the Cosmetic Ingredient Registration of the Public Health Institute of Chile or by INCI nomenclature;

b) Technical statement, in Spanish. It shall at least include the following:

b.1. specifications for finished products, especially included in its physical description, physical-chemical and microbiological characteristics with the respective tolerance margins, as applicable;

b.2. indicate the methodology to be used to identify and access ingredients quantitatively expressed in the formulae;

b.3. effective period of validity, stating its technical grounds; and

b.4. type and material of containers.

c) Safe use certification, granted by qualified professionals;

d) Legal documents, including, as applicable:

d.1. legal certification and requester representation, in case of individuals;

d.2. certification of product characteristics and circumstances referred to in letters a) and b) of letter gg) of article 5, through free-sale certificate, official cosmetic product certificate, or any other certificate from the respective sanitary authority, or when authorized by the legislation of the export country, the certification from the cosmetic business or industrial entity. Whenever, in the country of origin no certifications are issued by official entities or business associations, the legalized certificate evidencing the product information of the foreign manufacturer may be submitted;

e) Payment receipt of the customs fee corresponding to whatever is requested.

Article 27: The following documents shall be considered as strictly confidential and may only be revealed by the Institute upon request of the competent institutions, keeping the same degree of confidentiality:

- a) documents described in letters a) and b) above of the previous Article;
- b) technical or commercial information known by the Institute's supervisory personnel currently on duty, that may be shown or seized at the facilities or domicile of importers, marketers, or manufacturers of cosmetic products; and
- c) technical and commercial information received at the Institute's premises at the time of confirmation of the statements or information at the time of registering the product or upon requesting any changes.

This exception, under no circumstance, shall prevent or restrict notifying the analysis of said information conducted by the Institute or of any of the decisions made to this regard.

Article 28: Cosmetic products are prohibited to be designated with a fantasy name that may be misleading with regard to its cosmetic properties or composition.

Under no circumstances shall the cosmetic product have denominations used in pharmaceutical products or those which may be related to its properties.

Article 29: The holder of any registration may request the Institute to issue an official cosmetic product certificate. This document may, at the request of the holder of the said register, include:

- a) Any or all of the references commonly used in a free-sale certificate;
- b) Any or all of the references of said certificate, together with other circumstances certified in the register statements; or
- c) Any other condition or circumstance confirmed by the sanitary authority or confirmed to its satisfaction by the requester.

2. EVALUATION

Article 30.- The Institute will evaluate the registration requests based on the statements of Articles 25 and 26 and will only include the verification of the following aspects:

- a) denomination;
- b) cosmetic purpose;
- c) formulae, and

d) legal capacity of the requesters.

The Institute may ask the requester to correct any omissions or mistakes found in the requests. Likewise, the Institute may return to the interested party those requests that do not include the information stated hereinabove.

Article 31: The approval of the product whose registration is requested, shall be made by comparing the ingredients that make up the formulation of the cosmetic product with the list of authorized, limited, or forbidden ingredients approved and published by the Institute. Should they not be indicated, the European Union lists contained in Council Directive 76/768/CEE dated July 27, 1976, will be used, as well as its further amendments, with regard to the approximation of the laws of the Member States in as far as cosmetic products is referred; and the lists approved by the Food and Drug Administration of the United States of America.

Article 32: Product specifications shall be clear, accurate and complete, pursuant to the requirements established in letter b) of Article 26.

Article 33: The request to register different cosmetic products, although the said request has been made to market them as a whole, shall be considered as a separate request for each of the products, meeting each of the conditions stated herein.

Article 34: The Institute shall grant the registration when the statements mentioned in Article 25 and 26 are enclosed, and once the information indicated in Article 30 has been satisfactorily evaluated.

The Institute will issue a resolution rejecting the above registration only once the decision of the Ministry of Health has been received.

The interested party who does not agree with the resolution issued by the Institute may resort to the said Ministry, as set forth in article 53 of Supreme Decree N° 1.222, 1996, of the same Ministry.

Article 35: The Institute shall oversee the fulfillment of the sanitary norms that govern the granting of sanitary registrations, pursuant to what is stated in Title V herein.

Article 36: The Institute, by founded resolution, may request the amendment of the registration of a cosmetic product pursuant to the terms stated in Article 13 herein.

Article 37: The amendment of a registration shall be made by founded resolution

Article 38: Any sanitary registration granted for the distribution and marketing of a cosmetic product may be transferred by whomever obtained it to another individual or legal entity.

In the case of registrations granted by virtue of a license or power of attorney, its transfer may only be authorized with the consent of the licensor, known by the licensee and upon request of the new representative.

3. LABELING

Article 39: The labeling of cosmetic products must conform to the norms contained in the regulation hereto and fulfill with what is stated in the registration.

Article 40: The labeling of containers of any cosmetic product must be made in Spanish, notwithstanding what is set forth in Article 41 and shall, at least, include the following information:

- a) Name of product;
- b) Cosmetic purpose, except if it is obvious by the product's denomination;
- c) Qualitative list of the complete formulae indicating ingredients, according to International Nomenclature of Cosmetic Ingredients (INCI), in decreasing order of concentration. However, the list of all colorants that can alternatively be included in the product may be preceded by the words "may contain;"
- d) Minimum effective period or expiry date, when necessary;
- e) Code or password of the manufacturing lot or series. If the product is imported, it shall keep its series of origin, subject to what is set forth in letter g) of Article 25;
- f) Net content expressed in units of the decimal metric system;
- g) Name or company name and address of the holder, and whenever it does not match, also the name or address of the manufacturer or importer, as applicable, indicating the country where the product was manufactured;
- h) Usage instructions, indications, warnings and precautions regarding use, as applicable;
- i) Number of registration approved by the respective Institute according to letter f) of Article 25, preceded by the acronym "I.S.P."
- j) Storage and preservation precautions, when necessary.

When due to the size of the product container it is not possible to include all the indications in the label **or** when the use of the cosmetic may represent a risk for people's health, a leaflet must be enclosed to the container of the same product with the respective instructions, warnings and precautions.

Article 41: In the label or in the wording of the appendixes of an imported cosmetic product or of a product manufactured in Chile for its export, foreign languages may be additionally used.

T I T L E I I I

ABOUT INGREDIENTS

Article 42: The official lists of cosmetic ingredients will be those approved by the Institute of Public Health.

The Institute, by official letter or at the request of any individual or company, shall evaluate and resolve the acceptance and classification or the rejection of the ingredients that may be used in the manufacturing of cosmetic products. Any resolution rejecting the above must be duly founded and shall require the prior statement of the Ministry of Health.

Notwithstanding the above, in order to prepare and make a record of the official lists of cosmetic ingredients, the official lists of the European Union will be used as reference as well as the norms of the Food and Drug Administration of the United States of America, and the recommendations of well-known national or international technical organizations.

The lists of ingredients shall be published once a year in the Official Gazette for suitable advertising.

Article 43: To update the lists referred to in Article 44 hereinabove, the Institute will annually appoint an interdisciplinary commission who will act as an advisory body of the sanitary authorities.

Article 44: The Public Health Institute will be in charge of updating the following lists and proposing their approval before the Ministry of Health.

- a) List of Cosmetic Ingredients.
- b) List of Prohibited Ingredients in Cosmetics.
- c) List of Cosmetic Ingredients with Limited Use or Concentration.
- d) List of Authorized Colorants for Cosmetics.
- e) List of Authorized Preservatives for Cosmetics.
- f) List of Authorized Sun Screens for Cosmetics.

All cosmetic ingredients must meet the quality specifications defined in the above lists.

At any time, an amendment request of the above lists may be submitted to before the Institute which shall come into effect from the date in which the resolution is approved.

Article 45: Requests for addition of ingredients, extension or restriction of use or concentration and other amendments to the lists established in Article 44, shall include the respective scientific information regarding:

- a) General toxicological profile of the ingredients.
- b) Chemical structure, when applicable.
- c) Clinical studies.
- d) Use or authorization of the ingredient for cosmetic purposes in other countries.
- e) Other background information necessary to assess its safe use and safety of ingredients.

TITLE IV

ADVERTISING AND PROMOTION

Article 46: Advertising or promotion by any means of cosmetic products must conform to the nature of the product and meet the cosmetic purpose stated in the registration.

Article 47: To make known or advertise in any way a cosmetic product, no terms, expressions, graphs, figures, references or interpretations may be used that may contradict scientific truth and be misleading or deceptive.

Article 48: Advertising or promotion of cosmetic products cannot be attributed, whether directly or indirectly, therapeutic properties or effects or characteristics that the product does not have or which cannot be proven.

Article 49: The giving out, delivery or distribution to the public with advertising or promotion purposes, even free of charge, of cosmetic products without a sanitary registration is prohibited.

The Institute may suspend or prohibit, by founded resolution, the advertising and promotion of cosmetic products whenever the said product does not meet any of the provisions stated herein.

TITLE V

ABOUT MARKET CONTROL

Article 50: Market control will be focused on confirming and promoting the fulfillment of the sanitary norms on cosmetics, especially regarding the following aspects:

- a. Test of the documents and other background information that confirm the truthfulness of the statements contained in the registration, user complaints and other information that may be available on its adverse effects.
- b. Sanitary quality control of cosmetic products during import, production and marketing stages.
- c. Supervision of the advertising and promotion activities related to these products, pursuant to Title IV of the regulation hereto.
- d. Control of the operation of cosmetic production laboratories, external quality control laboratories and all those facilities that manufacture cosmetic products with a low production risk.
- e. Sampling of cosmetic products at distribution or sales points and testing and respective countersamples.

Article 51: As a result of supervisory measures, the Institute shall request, as applicable, the correction of the registration statements, or if needed, propose their cancellation before the Ministry of Health.

Article 52: The holders of cosmetic product registrations, whether manufacturers or importers, shall submit, present and inform to the Institute of Public Health of Chile, the documents, instruments, reports, studies and other background information requested by regulatory agencies under the following circumstances:

- a) Technical backup of the indications and statements made upon requesting a sanitary registration for a cosmetic product.
- b) Background data, studies and/or scientific backup information, when applicable, on the safe use of a product, referred both to its formulation, characteristics and specifications as well as all its adverse effects.
- c) Production processes, modalities, controls and registrations.

Article 53: Whenever the background information stated in Article 52 hereinabove is not presented, submitted or reported as required by the Institute within a suitable period of time established to this effect, this will constitute a sanitary infringement and will be penalized notwithstanding the respective investigation.

T I T L E VI

ABOUT QUALITY CONTROL

Article 54: The responsibility for the quality of the products will always be borne by the respective importers or manufacturers, as applicable.

Notwithstanding the above, cosmetic distributors, sellers or marketers shall take the necessary control measures to ensure the quality of the cosmetics during storage, possession, distribution, or sale, as applicable.

Article 55: The Institute is the entity in charge of evaluating the quality of the cosmetic products through inspections at the manufacturing, importing, distribution and selling facilities.

Article 56: Any individual or legal entity acting as manufacturer of the cosmetic products shall implement a quality control system to certify the fulfillment of the production specifications for raw materials and finished products.

Individuals or companies acting as importers of semi-manufactured or bulk products shall have the corresponding quality control system to cover the finished products manufactured by them.

Individuals or legal entities acting as importers of finished products shall conduct or engage analyses to certify the quality of the products, unless that by a founded resolution from the Public Health Institute they are released from doing so, validating the quality control conducted in the country of origin.

Article 57: Production laboratories not having a full quality control department may request the services of external quality control laboratories authorized by the Institute, pursuant to Article 85 hereto.

Article 58: The quality specifications of the finished products will correspond to those stated at the time of requesting the sanitary registration or its further amendments.

The records to meet the requirements of the quality system can be kept in a hard copy or electronic copy and duly validated.

Article 59: Quality control laboratories shall follow good laboratory practices, based on their line of business.

Article 60: The Institute may request samples and countersamples for each lot or series of cosmetic products undergoing import processing, imported or manufactured by local production laboratories in order to conduct the tests required to ensure the quality of the product.

External quality control laboratories, in turn, shall keep the countersamples of the finished products under study for a period of 3 years.

Article 61: The manufacturer, importer and distributor, as may correspond, will be accountable for the prompt and expedite recovery of a lot or series manufactured, imported or distributed by him when so instructed by founded resolution from the sanitary authorities.

Article 62: Production, import, distribution or selling facilities, as well as the Health Services, must receive all complaints related to the quality, usage, storage, preservation and advertising of a cosmetic product, which shall be duly informed to the Public Health Institute Board.

Article 63: Notwithstanding what is set forth in the previous Articles herein, during the performance of those activities related to the sampling of products, the Institute may resort to the services of other quality control laboratories authorized by it.

T I T L E V I I

ABOUT THE FACILITIES

1.º GENERAL PROVISIONS

Article 64: A production laboratory is any facility where the manufacture, separation and packaging of cosmetic products, pursuant to the norms established herein is carried out. These facilities may also manufacture, import or distribute raw materials used in the cosmetic industry.

Article 65: The installation of a cosmetic production laboratory shall be authorized by the Institute who shall in turn supervise its operation, notwithstanding any cooperation agreements that may be entered into with the Health Services as required by law.

When cooperation agreements have been entered into, the Health Services shall send to the Institute copies of the resolutions issued to authorize the manufacture of cosmetics as well as the cancellations and temporary or final closure instructed through sanitary investigations.

Those laboratories that only manufacture low-risk cosmetic products shall meet the special rules stated in paragraph 5 herein.

Article 66: The operation authorization granted by the Institute shall remain in effect as long as none of the grounds for cancellation established in the regulation hereto are incurred.

Article 67: The operation authorization of a production laboratory may be cancelled whenever:

- a)** The holder of the laboratory authorization or its legal representative notifies his intention of not continuing operating,
- b)** The holder of the laboratory authorization has definitely stopped operating, or at least, for more than 180 days; or

c) it is applicable as a result of a sanitary penalty, pursuant to the instructions of the respective investigation.

Article 68: The Institute shall duly authorize the transfer or extension of the physical plant and of the business line of the facilities.

If a laboratory conducts production of non-authorized business lines, whether they correspond to own manufacture cosmetics or those manufactured by third parties, the Institute may instruct the immediate interruption of the production line, regardless of the penalties that may be applied in the respective sanitary investigation.

Article 69: Individuals or legal entities acquiring a cosmetic production laboratory or in charge of exploiting or managing it by their own account or by third parties, shall notify the Institute, within a period of 60 days, enclosing the instruments confirming their right.

2.º ABOUT INSTALLATION AND OPERATION AUTHORIZATIONS

Article 70: The installation of a production laboratory shall be made in a separate facility. In case the manufacture of pharmaceutical and cosmetic products coexist in the same facilities, cosmetic products shall be manufactured in separate areas duly equipped for this purpose.

The approval of the plans and facilities will be made within a period of thirty days from the date the following documents are submitted by the interested party:

- a) Instruments that certify the legal right in virtue of which the property may be used as a laboratory and its commercial denomination;
- b) Plans of the facilities, layout, and diagrams indicating movement of staff;
- c) Production lines to be operated; and
- d) Payment receipt of the respective tariff rate.

Grounds for rejection shall be duly provided.

Article 71: Once the plans and facilities have been approved, the interested party shall request the Institute authorization to operate. To this effect, the request shall contain, at least, the following information:

- a) List of installations and equipment found in the facilities, both for production processes as well as for quality control.
- b) Description of the password (s) that will be used pursuant to what is set forth in Article 74 and following herein.

c) Payment receipt of the respective tariff rate.

Article 72: Each lot or series of a cosmetic product will be identified using a code or password that will help recognize it at any of the production, storage, distribution and marketing stages.

The said code or password shall be notified by the production laboratory to the Institute, who shall in turn register it in an official record. Likewise, the same procedure will be followed for amendments and different passwords used by the same laboratory or distributor, with regard to imported products or those products manufactured by third parties, as applicable.

Article 73: Passwords used to identify lots or series, shall be indicated in the labels of each finished product unit.

Article 74: Passwords of local and imported products shall be made up of numbers or combinations of letters and numbers including, at least, the month and year of manufacture and the series number corresponding to the lot, in consecutive and chronological order.

Article 75: If a cosmetic product belonging to a same lot or series is finished in interrupted stages, each lot or series will represent a subplot, which will be identified by adding a number to the original code.

Article 76: After inspecting the facilities and confirming that the requirements stated in the previous Articles herein are met, the resolution authorizing the operation of the facilities will be issued, within a maximum period of thirty days from the date the respective background data is submitted.

If this were not the case, grounds for rejection shall be duly provided.

Article 77: The holder of the laboratory authorization of its legal representative, as applicable, shall promptly notify the Institute about the temporary or final closure of its production laboratory.

Once the temporary closing period has expired, the interested party shall request its reopening and the Institute shall authorize it prior to the confirmation of its operating conditions.

If the closing period extends for more than one hundred and eighty days, the operation authorization will definitely expire. This shall be stated by a resolution of the Institute, issued by official letter or at the request of the owner or its legal representative, except for justified grounds.

3.º ABOUT THE PHYSICAL PLANT

Article 78: Any building used for the manufacture of cosmetic products will be especially designed, built or adjusted and its size and construction shall conform to the company's line of business.

Article 79: The physical plant of a cosmetic production laboratory shall at least include the following areas or sections which shall be clearly specified in the plans submitted and approved by the Institute.

- a) storage;
- b) restrooms and changing rooms;
- c) manufacturing;
- d) packaging;
- e) delivery; and
- f) quality control laboratory.

Article 80: Plants, and especially the production, storage, manufacturing and quality control areas must conform to the norms established in Articles 78 and 79.

Article 81: There can be modular and specifically defined areas to conduct each of the following procedures separately:

- a) Reception and quarantine of the materials before approval;
- b) Storage of rejected materials;
- c) Storage of approved materials;
- d) Storage of products in process;
- e) Storage of finished products in quarantine; and
- f) Storage of approved finished products and countersamples.

Article 82: The cosmetic production laboratory shall assign special and independent areas for the storage of flammable substances or substances that may represent risk of explosion, are corrosive, toxic or polluting. These areas will strictly meet the safety measures established by the respective entities.

Article 83: The production areas and the quality control laboratories will be physically separated from the administration offices and other areas of the facilities.

Article 84: The production department shall at least include the following areas:

- a) manufacturing;
- b) washing and drying, when applicable;
- c) packaging; and
- d) warehousing.

Article 85: The quality control department shall include the following areas, when applicable:

- a) area or place equipped for the reception of samples;
- b) physical-chemical analysis;
- c) washing of material;
- d) microbiology, as required by manufacturing processes;
- e) biological assays, when applicable; and
- f) biotery, if applicable.

The areas indicated in letters d), e) and f) may be replaced by external services with the respective authorizations.

Article 86: The manufacturing and packaging sections may be included in one single unit, when using production technical systems in series that will not allow the separation of the different manufacturing phases of products as long as there is no risk of cross contamination.

Article 87: The quality control department of a cosmetic production laboratory may also render its services to third parties as an external quality control laboratory.

4.º ORGANIZATION AND OPERATION

Article 88: The production department of cosmetic and quality control products shall operate under the responsibility of chemical-pharmaceutical professionals.

Article 89: The technical director, or whomever may legally replace him, in general shall be responsible for the organization and development of the components of the production process pursuant to their technical order and shall ensure that the formulation of the products manufactured, packaged or imported conforms with the one stated and approved in the registration documents.

Likewise, it shall exercise any other duties assigned by the law and regulations with regard to its professional activities.

Article 90: The production process of each lot or series of a product shall remain consigned in recorded documents known as: “Manufacturing Sheet” and “Packaging” Sheet.

Article 91: The production department shall keep the manufacturing and the packaging sheets of each manufactured series or lot, for a period of three years from their date of manufacture. This information may be kept in electronic files.

Article 92: The quality control system of the cosmetic production laboratories shall be developed pursuant to the quality assurance requirements.

The quality methodologies and specifications for raw materials shall conform to those established by the professional responsible and the quality specifications of the finished products shall conform to those stated in the sanitary registration or in the notification for personal hygiene products.

Article 93: The head of the quality control department of the facilities shall be accountable for the activities inherent to the quality system implemented, and in particular, for the following duties:

- a) Determine the specifications and analytical methodology for each of the raw materials, packaging materials, products in process and finished products, conducting a representative sampling of each, pursuant to the plans that have been established and designed using statistical criteria.
- b) Approve or reject raw materials, products in process, bulk manufactured products, finished products and packaging materials, proposing the corresponding corrections or reprocessing when applicable, keeping a written record with the respective observations;
- c) Design and instruct the preparation of stability studies and other studies for each of the finished products;
- d) Study the critical parameters for the manufacturing processes applicable to such processes;
- e) Verify on a regular basis the programs established to confirm reliability and accuracy of the laboratory instruments and equipment;
- f) Design and conduct a program to confirm the reliability of the methods used for inspecting and analyzing the quality characteristics of materials and products.
- g) Validate the manufacturing processes that may be responsible for causing variations in the characteristics of products in process and of finished products;

- h) Record and review complaints on the quality of the products returned by users or investigated by the sanitary authority;
- i) Ensure that countersamples of finished products are properly kept; and
- j) Be accountable for the quality, stability and conformance with the registered formulations of the products manufactured, packaged or imported on their own account or by third parties.

Article 94: The quality control department shall keep records of each of the operations and tests conducted to each series or lot manufactured and its respective raw materials and packaging material for a period of three years from the date of manufacture.

Article 95: The provisions stated herein shall apply to external quality control laboratories for cosmetic products.

5.º ABOUT THE AUTHORIZATION OF LABORATORIES THAT MANUFACTURE LOW-RISK PRODUCTS

Article 96: Laboratories that manufacture low-risk products shall submit a statement before the Institute 30 days from the date they start operating or upon start of their line of business which will include:

- a) identification of the holder of the laboratory authorization;
- b) sketch or plan of the facilities and layout, taking into account manufacturing area and/or storage of supplies;
- c) statement of acceptance of responsibility signed by the person in charge of manufacturing, pursuant to what is stated in Article 88;
- d) description of the equipment and tools that will be used in the laboratory for the manufacturing of low-risk cosmetic products;
- e) reference to the quality controls procedures used for products;
- f) payment receipt of the respective tariff rates;

Once the above information is submitted and the respective tariff rates have been paid, it shall be understood that the laboratory is authorized to manufacture the respective products.

Article 97: This authorization will remain in effect as long as it does not incur in grounds for cancellation or upon confirmation of the infringement of the conditions stated herein.

The following will be considered as grounds for cancellation:

- a) the manufacturing of cosmetics without authorization;
- b) that the holder of the laboratory authorization or its legal representative informs his intention of not continuing operating; and
- c) that the holder of the laboratory authorization has definitely stopped operating or at least has stopped operating for more than 180 days.
- d) That the holder of the laboratory authorization, pursuant to the respective sanitary investigation, as applicable, is penalized for manufacturing falsified, adulterated, contaminated or altered products.

Article 98: Individuals or companies who acquire this type of facilities, or who are accountable for their exploitation or administration on their own account or on the account of third parties, shall inform the Public Health Institute about it, within a period of 60 days, enclosing any documents that certify said right.

The holders of the laboratory authorization or the legal representative shall promptly inform the Public Health Institute about any temporary or final closure.

Article 99: The Technical Director shall supervise activities, give work instructions and keep a “General Production Registration” with the comments of the day, indicating, at least, date, product name, number of assigned series and number of units obtained.

Additionally, he will be accountable for the following activities:

- a) keep countersamples of the series manufactured;
- b) record and review complaints regarding the quality of the cosmetics returned by users or those investigated by the Public Health Institute;
- c) keep countersamples and manufacturing records for a period of three years from the time of manufacture; and
- d) conduct all other duties assigned by the laws and regulations.

6. ABOUT THE RESPONSIBILITIES

Article 100: The responsibilities that may affect the technical director and the head of the quality control department will fall within the scope of the holder of the laboratory authorization or his legal representative when applicable, pursuant to the general rules that govern this matter.

Article 101: The holders of a laboratory authorization, professionals, heads of areas and those in charge of production at laboratories that exclusively manufacture low-risk products will be accountable for the obligations stated in paragraph 4 hereto as applicable.

TITLE VIII

ABOUT THE PENALTIES

Article 102: Infringement to the provisions stated herein will be penalized by the Institute, prior instructions of the respective investigation, pursuant to what is set forth in Book X of the Sanitary Code and other norms established in the current legislation.

Article 103: Against the resolutions issued by the Institute on those matters which refer to the regulation hereto, it will be possible to resort to the Ministry of Health as set forth in Article 53 of Supreme Decree No. 1,222 of 1996 of the same Ministry.

FINAL TITLE

Article 104: All regulatory provisions that govern in a different form those matters referring to the regulation hereto, and especially those related to cosmetic products contained in Title IV “About Cosmetics” of Supreme Decree No. 1,876 of 1995, of the Ministry of Health. Likewise, all references to cosmetics made in its clauses, will be eliminated.

TRANSITORY ARTICLES

Article 1 The Regulation hereto will come into effect from its date of publication in the Official Gazette. Registered requests, however, submitted before the date in which the regulation hereto comes into effect, will continue to be processed as set forth in Supreme Decree No. 1876 of 1995 of the Ministry of Health, as otherwise stated by the requester.

Article 2 With regard to the cosmetic products that contain substances which do not conform to the Lists referred to in Title III, there will be a period of six months to remove them from the market or modify their formulation, and said period will start from the date of publication of the Lists or its further amendments.

Article 3 Sanitary authorizations granted by the Institute of Public Health to the production laboratories that currently manufacture cosmetics will continue in full effect.