

Guideline for cosmetics' approval in Korea

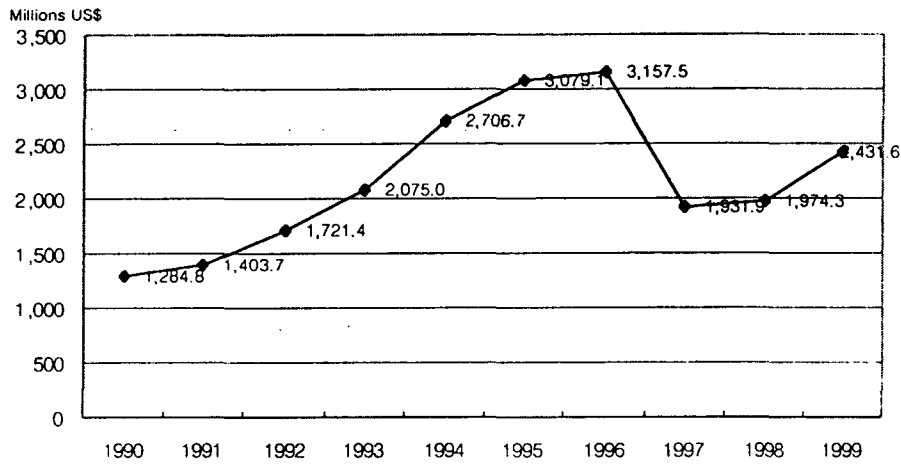
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1999 Cosmetic Market

- **Number of Manufacturer** 148
- **Shipment** 2,785,169 Million won
(US\$ 2,431.6 Millions)
- **Export** US\$ 50.6 Millions
- **Number of Importer** 630
- **Import** US\$ 216.412 Millions

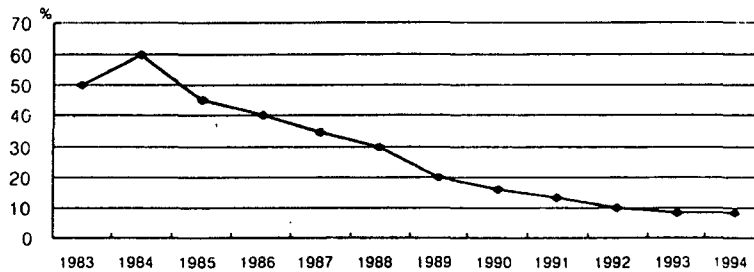
Change in Manufacturing Shipment



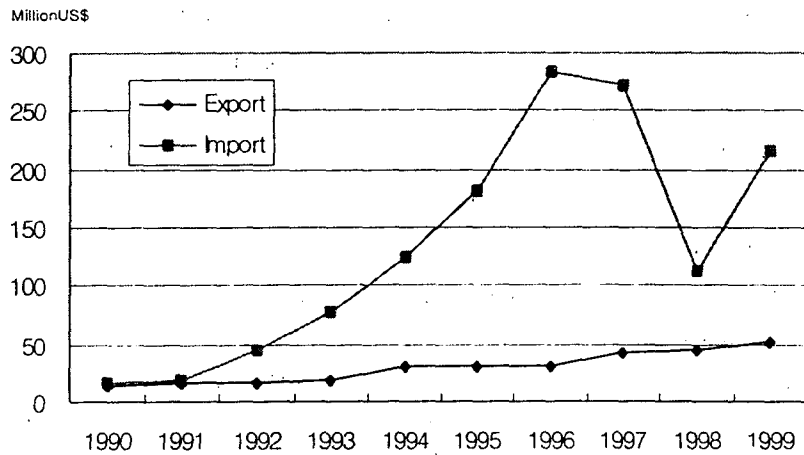
Korean Market Open

- 1983 - Import liberalization of some products.
- 1986 - Import liberalization of all products.
- 1990 - Open the wholesale business.
- 1996 - Open the retail business.

* The Change of a Tariff Rate



Change in Cosmetic Import & Export



Establishment of Cosmetic Laws

- The Cosmetics laws were promulgated on September 7th, 1999 as article 6,025 and it comes into effect on July 1st, 2000. (Article 32, additional clause 6.)

- Purpose

To contribute to the improvement of public health and the development of cosmetic industry by solving matters relating to the manufacture, importation and sale of cosmetics.

Main Contents of the Cosmetic Laws

- Extension of cosmetics definition and new definition of Functional Cosmetics
- Abolishment of Manufacturing License & Importer registration
- Abolishment of Product License System
 - * Introduction of Evaluation system for functional cosmetics and new ingredient
- Abolishment of the manager system in manufacturing and import
- Change of Labeling Requirement
- Prohibition on Unreasonable Labeling and Advertisement
- Reduction in fines
- Introduction of Approval system for manufacture, import, and bring in via high seas cosmetics containing wild flora and fauna listed in the Convention on the International Trade concerning Endangered Species of Wild Flora and Fauna

Definition of the Cosmetic & Functional Cosmetics

A Cosmetic is defined as:

Any article intended to cleanse or beautify the human body to enhance the attractiveness, alter the appearance and maintain or enhance the healthiness of the skin or hair, provided that the action of the article on the human body is mild.

*** Kind of Functional Cosmetics**

1. Whitening Product
2. Anti-Wrinkle Product
3. Suntan & Sunscreen Product

Product Categories for Cosmetics

- Baby products
- Eye - makeup preparations
- Fragrance preparations
- Hair-coloring preparations
- Manicuring preparations
- Bath preparations
- Makeup preparations
- Hair preparations
- Shaving preparations
- Skin-care preparations
- * **Functional Cosmetics**

Abolishment of License System

- **Change from license system into report system of manufacture industry**
- **Abolishment of importer registration system**
- **Abolishment of license system of cosmetic product**
- **Introduction of cosmetic review system**
 - Functional Cosmetics : Efficacy and safety evaluation
 - New ingredient : Evaluation of specification and safety

Cosmetic Labeling Requirement

- Name of Products
- Name and Address of Manufacturer or Importer
- Name of the Ingredients, if the product contains any ingredients MOHW regulation specifies such as tar pigment, etc.
- Volume or Weight of the Contents
- Serial Number of the Product and the Date of its Manufacture
- Price(marked by the seller)
- In the case of functional cosmetics the label "Functional Cosmetics"
- Caution in Use
- Other matters prescribed by MOHW Regulations
- * Under the MOHW regulation, the container (ex. small container and tester) may not include the other subject except name, company name and price.

Prohibition on Unreasonable Labeling and Advertisement

- Any description or advertisement on the container, label or attached documents that might mislead the customer into believing that the products have medically proven effectiveness.
- Any description or advertisement that exceeds, or is inconsistent with, the the scope of the evaluated safety and efficacy of the functional cosmetics.
- In case of cosmetics excepting functional cosmetics, any description or advertisement that might mislead the customer into believing that such products are functional cosmetics
- Any other description or advertisement that might deceive or mislead customers.

Duties of Manufacture and Importation

- A Manufacturer or Importer shall report any new data and information and seek proper safety measures
- A Manufacturer or Importer shall inspect the conformity of the Cosmetic Products that are manufactured or imported pursuant to MOHW regulations.
 - Local test may be exempted if CGMP of exporting country is proven to be the same as or more than that of Korea.
- A Manufacturer or Importer shall report the actual amount of production or importation to KFDA in a manner prescribed by Act, and regulations.