



Cosmetics Regulatory Framework in Korea

K-Cosmetics, Recognized and Trusted by the World



Ministry of Food and
Drug Safety

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What is Cosmetic Product?

Any item intended to be used by means of spreading, rubbing, spraying on or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness or brightening the appearance, or maintaining or improving the health of skin and hair, which have mild effect on the human body

*Oral care products (such as toothpaste, mouthwash, etc.) belong to quasi-drug

Cosmetic Products

 Baby products * Under the age of 3 years old	 Bath products	 Body cleansing products	 Eye make-up products	 Fragrance products
 Hair colorants	 Make-up and make-up removers	 Hair-conditioning products	 Nail care products	 Shaving products
 Skin care products	 Deodorants and antiperspirants	 Depilatories		



Functional Cosmetics
Cosmetics with functions, defined in the Cosmetics Act, such as aiding in skin whitening, improving skin wrinkles, etc.

Skin

- Products aiding in the whitening of the skin
- Products aiding in improving wrinkles in the skin
- Products aiding in tanning skin gently or protecting skin from ultraviolet rays
- Products aiding in alleviating acne breakouts
- Products aiding in alleviating dryness caused by atopic-prone skin
- Products aiding in thinning red lines caused by stretch marks

Hair

- Hair-dye (Excluding temporary dyes)
- Bleaching or dye-removing products
- Products aiding in alleviating hair loss symptoms (Products that increase hair volume by physical means are excluding)
- Body hair removal products (Excluding products that remove hair physically)

Legal Basis of Cosmetics Regulation

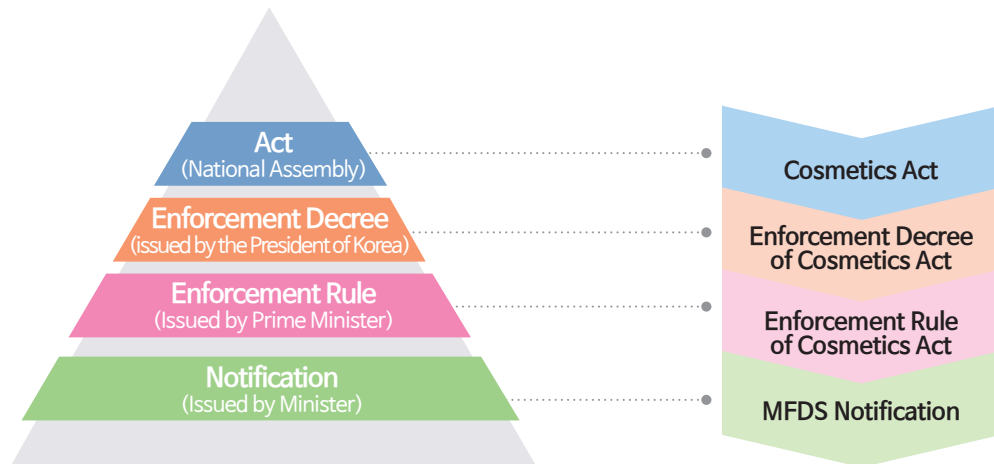


Cosmetics Safety Management System



To ensure the safety and quality of cosmetic products and protect the public health by providing accurate information to consumers, the MFDS vows to ensure the safety of cosmetic products in all stages from R&D to distribution to consumer use.

Cosmetics Legal System



MFDS Notifications

- Specifications and Test Methods of Functional Cosmetics
- Regulations on the Evaluation of Functional Cosmetics
- Regulations on the Remission of Quality Testing for Imported Cosmetics
- Standards on Cosmetics GMP
- Risk Assessment of Cosmetic Products
- Cosmetics Price Display System
- Regulations on the Designation of Training Institutes and the Training of Cosmetics Regulatory System
- Regulations on the Management of Safety Information for Cosmetics
- Regulations on the Substantiation Labeling and Advertisement for Cosmetic Products
- Notification of Annual Cosmetics Production/Import and Ingredients List
- Regulations on the Standards of Organic Cosmetic Products
- Regulations on the Safety Standards, etc. of Cosmetics
- Types, Standards, and Test Methods of Cosmetic Color Additives
- Regulations on the Authentication of Liability of Certification Assurance Institutions for Cosmetic Labeling and Advertisements



Import

- Entry notice of imported cosmetics
- Batch testing for quality before sales

Cosmetics laws and regulations

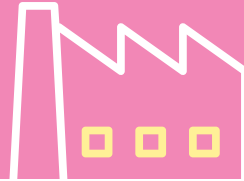
MFDS website ▶ Bio & Cosmetics ▶ Regulations or National Law Information Center
 (www.mfds.go.kr) (www.law.go.kr)

Cosmetics guidelines

MFDS website ▶ Bio & Cosmetics ▶ Guidances
 (www.mfds.go.kr)

Cosmetics Manufacturer

- Those who intend to directly manufacture cosmetics
- Those who have been contracted to manufacture cosmetics
- Those who intend to engage in packaging or labeling processes only (Excluding the process of secondary packaging or labeling only)



Cosmetics Responsible Person (Brand Holder)

- Those who intend to distribute and sell cosmetics they manufactured.
 - Those who intend to distribute and sell the cosmetics produced by contracts manufacturing
 - Those who intend to distribute and sell imported cosmetics (e-commerce only)
- Those who intend to solicit or provide cosmetics to conduct import services

"Cosmetics manufacturer/seller" is changed to "Cosmetics Responsible Person (Brand Holder)" starting in March 2019.



Cosmetics Manufacturers

- Cosmetics manufacturers shall register with the MFDS as a cosmetics manufacturer (With the regional office that has jurisdiction over where the manufacturing facility is located).
- Guidances, supervisions and requests from a Cosmetics Responsible Person shall be respected and followed in line with quality management standards.
- Manufacturing sites, facilities and instruments shall be managed in a hygienic and sanitary manner to prevent risks to public health.
- Any article that could cause harm at workplaces shall not be left behind, and no material jeopardizing public health shall be emitted/leaked into the environment.
- Written manufacture management standards, manufacture management records and quality control records shall be prepared and retained (Including an electronic copy).
- Facilities and instruments used to manufacture cosmetics shall be inspected regularly to ensure manufacturing operations.

Cosmetics Good Manufacturing Practices (CGMP)

- CGMP certification is granted by the MFDS to the cosmetics manufacturers who apply for an inspection and comply with CGMP standards. (MFDS Notification 'Standards on Cosmetics GMP')

Cosmetics Responsible Person (Brand Holder)

- Cosmetics Responsible Person shall register with MFDS cosmetic marketing responsible person (With the regional office that has jurisdiction over where the manufacturing facility is located)
- To comply with the standards for quality control
- To prepare and maintain written manufacture management standards, written manufacture management records and written quality control records
- To distribute products after conducting a thorough quality inspection thoroughly by manufacturer batch numbers
- To comply with standards for safety management after manufacturing and selling
- To prepare and maintain the written import and management records
- A Cosmetics Responsible Person shall hire a Qualified Person who is responsible for the safety and quality of cosmetic products a person who has a qualification as a responsible marketing officer, and the sales officer must complete a training on ensuring safety of cosmetics once a year
 - A qualified person shall complete a training on ensuring safety of cosmetics once a year and ensure safety of cosmetic products, supervise cosmetic manufacturers in conformity with the standards of quality control
- To report a list of raw materials before sales, and manufactured & imported amount to the Minister by the end of February of the following year
 - For domestically manufactured products : report to the Korea Cosmetic Association (KCA)
 - For imported products: to Korea Pharmaceutical Trades Association (KPTA) through Entry Notice of Imported Products : Entry Notice of Imported Products

Introduction of Personalized Cosmetics Regulation (As of March 2020)

- Definition: cosmetics that are manufactured and sold for a single consumer, reflecting skin condition, taste and etc.
 - cosmetics mixed with contents of finished products, or spiked with the ingredients which are safely used in cosmetics
 - cosmetics subdivided from the bulk or finished products
- Those who intend to sell personalized cosmetics shall register with the MFDS, hire a person qualified for on-site preparation (mixing and subdividing), and comply with the facility and safety management standards

Import Procedures

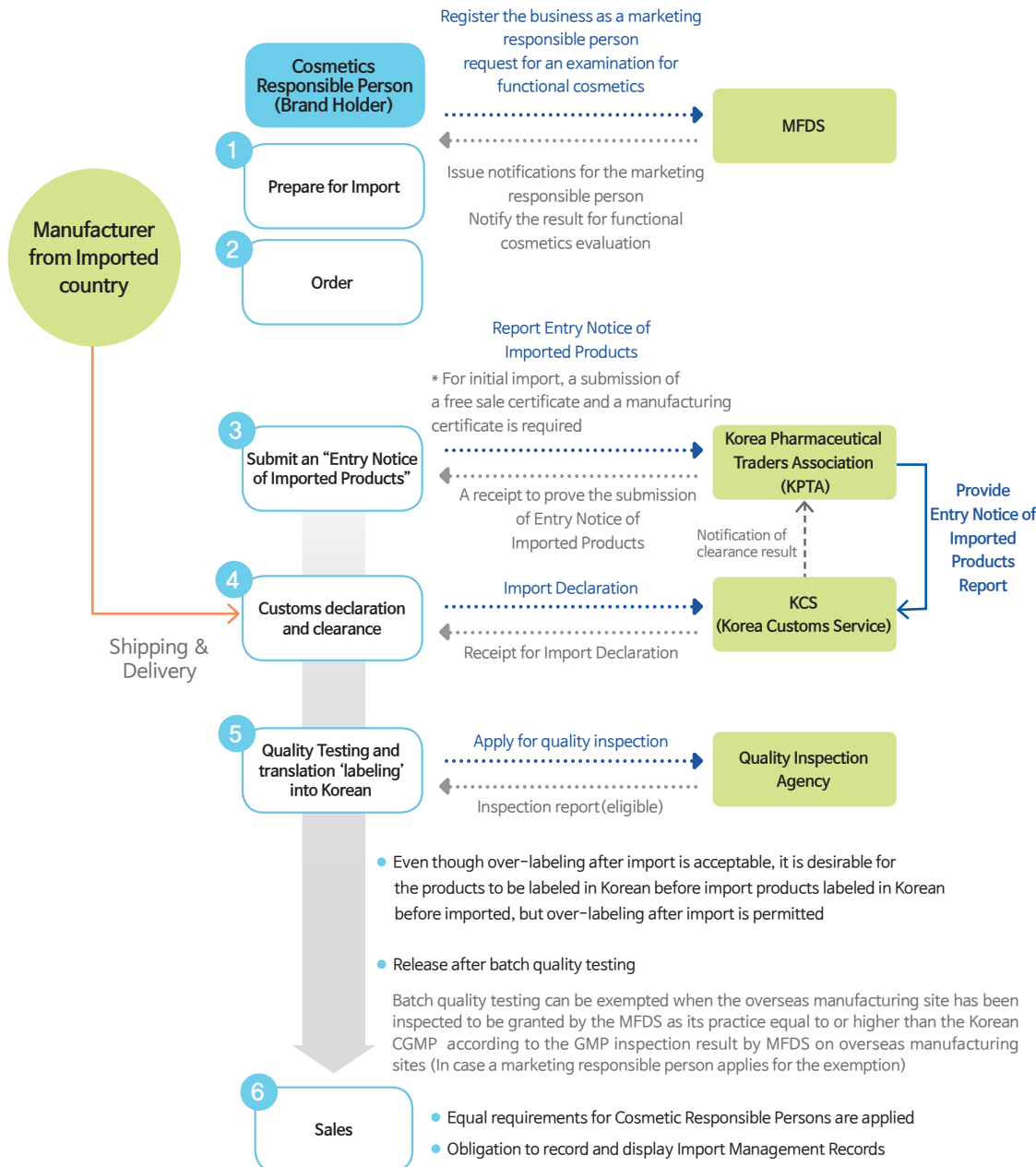
In case of import, the marketing responsible person shall be registered, and must submit an "Entry Notice of Imported Products Report" before every customs clearance



Safety Standards



The MFDS has notified 'prohibited ingredients' on the basis of negative list system, so all ingredients except prohibited ingredients could be used under the Cosmetic Responsible Person's responsibility for their safety. For the preservatives, UV-filters, and colorants only the ingredients notified by MFDS can be used. In addition, the MFDS establishes safety management standards for cosmetic products through risk assessment.



Prohibited Ingredients

About 1,030 ingredients (Steroids, Radioactive materials, Antibiotics, etc.)

Ingredients in restricted use

- Preservatives: 59 ingredients
- Sun-screens: 30 ingredients
- Others: 75 ingredients
- Colorants: the type and amount of the colorant allowed to be used in cosmetics are specified (MFDS notification 'Colorant Specification and Test Methods')
 - Include Tar and Non-tar
 - *Other ingredients for the preservatives, sun-screens, and colorant not notified or specified cannot be used
- Include tar and non-tar, 126 ingredients

Limit of detection

- Ingredients that are prohibited to use on purpose, but are unintentionally derived and technically impossible to remove
 - Lead: 20ppm (50ppm for clay powder products)
 - Arsenic: 10ppm
 - Mercury: 1ppm
 - Antimony: 10ppm
 - Cadmium: 5ppm
 - Nickel: 10ppm (35 ppm for eye make-up products, 30ppm for make-up products)
 - Dioxane: 100ppm
 - Methanol: 0.2% (0.002% for wet-wipes)
 - Formaldehyde: 2,000ppm (20ppm for wet-wipes)
 - Phthalates (as a sum of dibutyl phthalate, butyl benzyl phthalate and diethylhexyl phthalate) 100ppm
- Microbiological limits
 - Total aerobic microbial count: 1,000cfu/g(ml)
 - For baby products and eye make-up products: 500cfu/g(ml)
 - 100cfu/g(ml) Bacteria and Fungi each for wet-wipes
 - Escherichia Coli, Pseudomonas aeruginosa, Staphylococcus aureus shall not be detected
- Standards for contents, pH, permanent wave products, etc.
 - *MFDS Notification 'Regulations on the Safety Standards, etc. of Cosmetics'

MFDS Provides DB information on cosmetic ingredients

The MFDS provides with information DB on prohibited or restricted ingredients for cosmetics in 9 countries

- (nedrug.mfds.go.kr) ▶ Information ▶ Cosmetic Regulations Information

Risk Assessment

MFDS conducts risk assessment that scientifically assesses and predicts the possibility of risk to human health when people are exposed to cosmetics



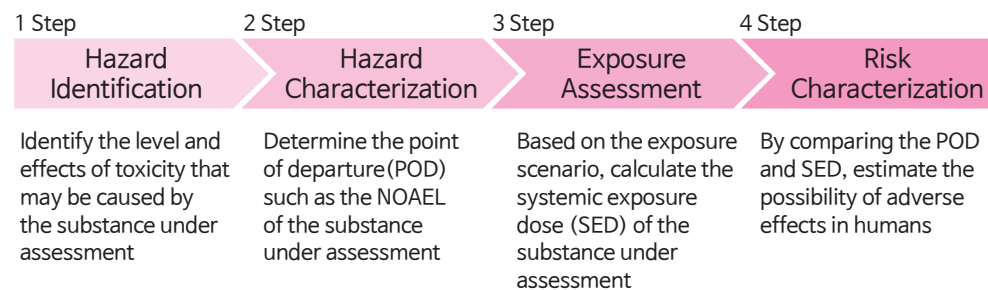
Evaluation of Functional Cosmetics

Those who intend to manufacture or import functional cosmetics are required to have them approved by the MFDS through evaluation

Purpose of Risk Assessment

- To determine the allowable amount when the manufacturing cosmetics, for such cases of UV-filters or preservatives that are necessary to produce cosmetics but are concerned of adverse effects when used without regulations. (Restricted ingredients)
- To designate a certain substance with a fact that it is harmful as a substance that cannot be used for cosmetic production. (Prohibited ingredients)
- To prioritize safety management of substances used in cosmetics
- To ensure that no certain cosmetic ingredient causes a risk to human health

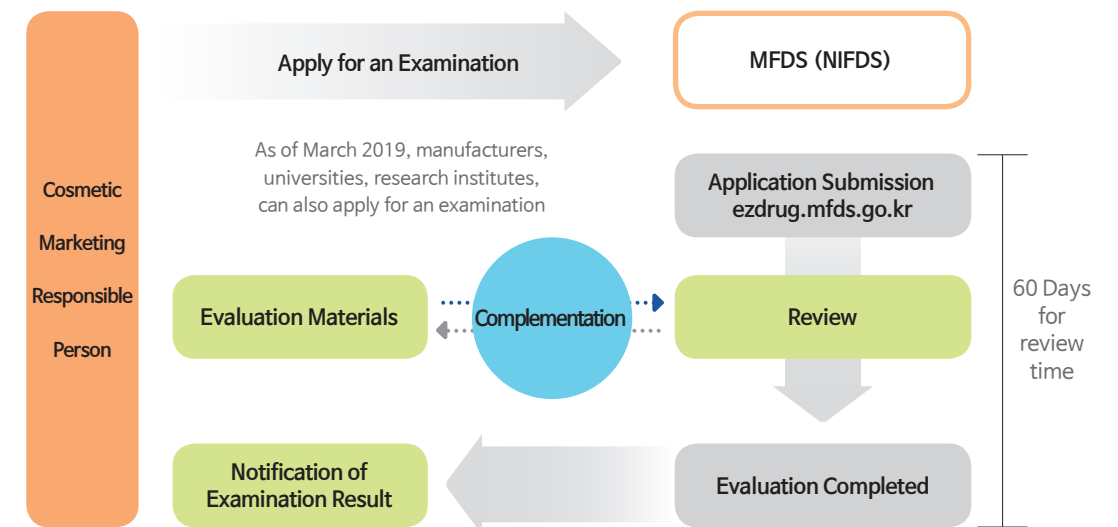
Steps of Risk Assessment



Recent Cosmetic Risk Assessment in Korea

- ('14~'16) Completed risk assessments on 159 substances (Globalization of Risk Assessment of Cosmetics) ('14) 30 substances including UV-filters → ('15) 60 substances including preservatives → ('16) 69 substances restricted in use → ('17)
- ('17~) Continuing the risk assessments on ingredients with safety issues by monitoring the current status of foreign regulations such as Europe's

Subjects and Examination Procedures



Data Requirement

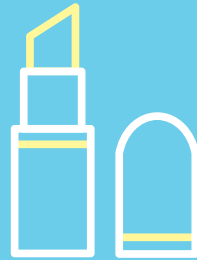
- Data that verify safety, effectiveness, or function**
 - Data concerning the origin and the details of R&D
 - Data concerning the safety
 - Data that verify effectiveness, or function
 - Sun Protection Factor (SPF), waterproof Sun Protection Factor (SPF), and Protection Factor of UV-A (PA) data
- Data concerning the standards and test methods (Including samples)**

Subject Exempt from Evaluation

- Items with the same active ingredients, functions, applications, forms, specifications and test methods as ones notified by the MFDS (KFCC)
- Items with the same active ingredients, functions, applications, forms, specifications and test methods as previously approved ones

Labeling and Advertisement

A cosmetic manufacturer, responsible person shall not make any false or misleading labeling or advertisements and shall be able to substantiate claims they displayed and/or advertised



Safety Information Management of Cosmetics

The MFDS arranges safety measures by collecting and reviewing safety information from consumer use.



Scope of Prohibited Labeling and Advertisements

Labeling or advertisements that can mislead consumer the products as medicines	Labels or advertisements that can mislead non-functional cosmetics and non-organic cosmetics to functional cosmetics and organic cosmetics
Any indication or advertisement beyond the scope of evaluation on the claims safety & efficacy of functional cosmetics or that is different from the examined results	In addition, labeling/advertisements that deceive or mislead consumers

Cosmetic Manufacturer / Marketing Responsible Person / Seller

Shall be able to actually substantiate the claims they displayed or advertised



MFDS

In case any label or advertisement needs an actual evidence, the Minister could request for a submission of data specifying the details

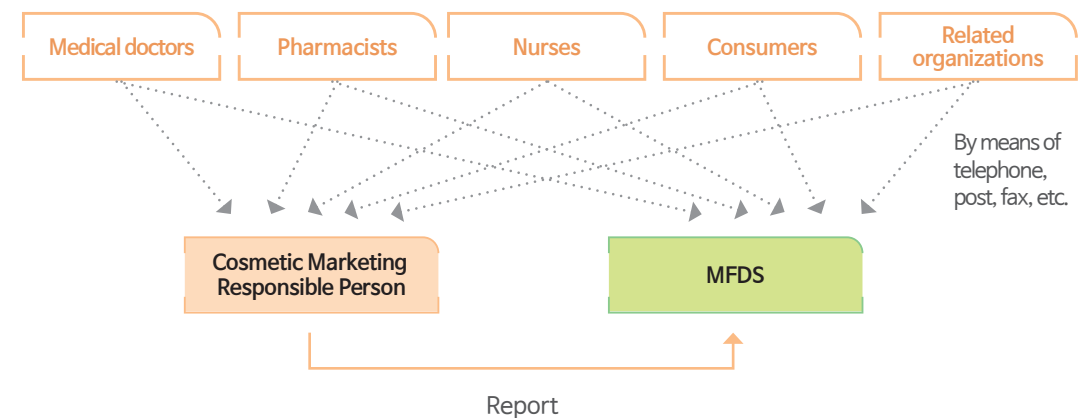
Claims of Cosmetic Labeling

- | | |
|---|--|
| - Name of a cosmetic product | - All ingredients used to manufacture cosmetics |
| - Name and address of the manufacturer and marketing responsible person | - Volume or weight |
| - Batch number | - "Functional Cosmetics" has to be displayed in case of functional cosmetics |
| - Expiration date or use-by dates after opening | - Precautions for use |
| - Price | - Others required by the Enforcement Rule |
- Primary packaging: Name of a cosmetic product, Name of a manufacturer, Marketing responsible person, Batch number, Expiration date or Use-by dates after opening

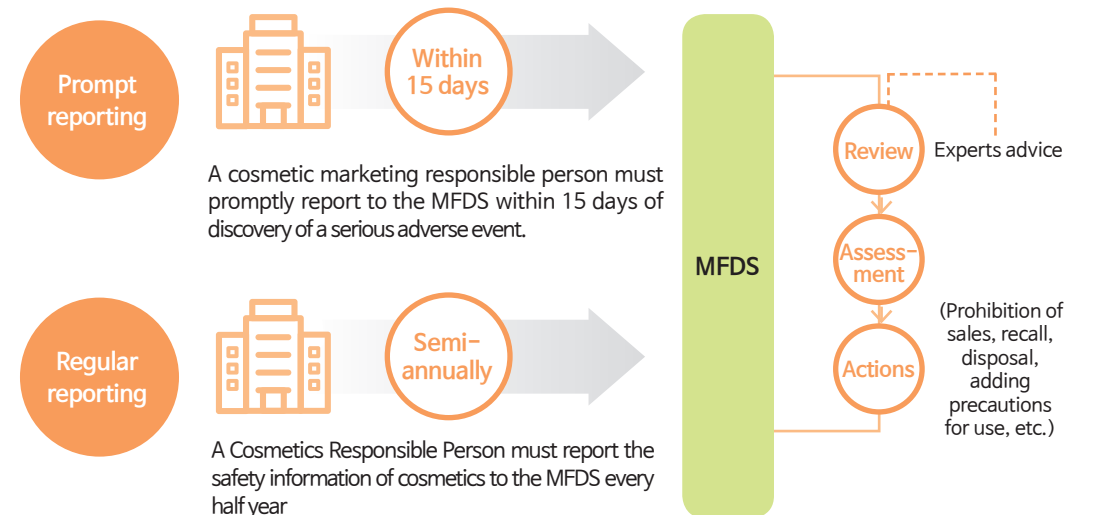
Enactment of Natural or Organic Cosmetics Certification (As of March 2019)

- Natural Cosmetics : cosmetics containing animals, plants, their derivatives, etc. and meeting the criteria notified by the MFDS
- Organic Cosmetics : cosmetics manufactured from organic ingredients, plants, animals, or their derivatives, etc. and meet the criteria set by MFDS

Cosmetic Safety Information Management System



Requirements for Marketing Responsible Person



Market Surveillance

The MFDS conducts regular and ad-hoc on-site inspection of cosmetic manufacturers and responsible person, tests distributed products, monitors labeling and advertisements, and monitors risk information from overseas



Management and Surveillance Activities

Field Surveillance

Regularly inspects cosmetics manufacturers and marketing responsible person for the compliance with the cosmetics regulations under the Cosmetics Act, and conducts ad-hoc inspection when necessary.

Testing

Determines whether distributed products meet the safety standards (heavy metals, microbiological limits, etc.) by collecting distributed products

Advertisement and Labeling Monitoring

Monitors various media including on-line to detect false or misleading advertisements/labeling

*Operating 'Cyber Inspection Office' for monitoring online advertisements ('18~)

Monitoring Overseas Risk Information

Constantly monitors risk information released by foreign regulatory bodies such as US and Europe, and analyzes and evaluates the risk information to take measures

Administrative Imposition & Penalties

Depending on the types and severity of the violation, fine, suspension, correction, or warning is imposed. If necessary, criminal prosecution can be filed.

*Operation of Criminal Investigation Office

Introduction of 'Consumer Cosmetic Safety Management Watchdog' System (As of March 2019)

- MFDS appoints a person who has a knowledge of cosmetics safety management such as a cosmetics business group or representatives of consumer organizations as a consumer cosmetics safety management watchdog
- The consumer cosmetics safety management watchdog reports by monitoring market and assists in the MFDS surveillance activities such as inspection, questioning, collecting, etc.

International Cooperation



「K-Cosmetic World Roadshow」 (2019~)

In connection K-POP, the MFDS takes overseas exhibition every year to expand the export market and promote Korean Cosmetics Industry, enhancing their global brand images.

「One-Asia Cosmetics and Beauty Forum」 (2014~)

Share the current status of cosmetics industry and safety control in Asian countries, and promote Korean cosmetics through cooperation with industry and regulatory bodies

- (2014) Beijing, China, (2015) Shanghai, China, (2016) Ho Chi Minh City, Vietnam, (2017) Jakarta, Indonesia, (2018) Bangkok, Thailand

Engagement in ICCR (Int'l Cooperation on Cosmetics Regulation)

MFDS has actively been participating in ICCR annual meeting and its working groups.

* ICCR: a voluntary international group of cosmetics regulatory authorities to discuss common issues on cosmetics safety and regulation

Support to Building up Regulatory Capacity for ASEAN Countries (2018~)

MFDS hosts seminars and trainings forThe MFDS invites regulators from ASEAN countries and provides with training course to improve their ASEAN countries to improve their cosmetics safety management capabilities, and to cooperate and promote regulatory harmonization.

Cooperation between Countries to Reduce Technical Barriers

The MFDS contributes to export and import more smoothly through the continued network between MFDS and overseas Regulatory Authorities based on mutual understanding of each country's safety management system

Supportive Activities for Industrial Growth



Export Assistance Center (Online Service)

Provides with information on the export including market status, relevant law, registration procedure, etc. to support export for SME having difficulties to obtain overseas information (can be found at Korea Cosmetic Association website)

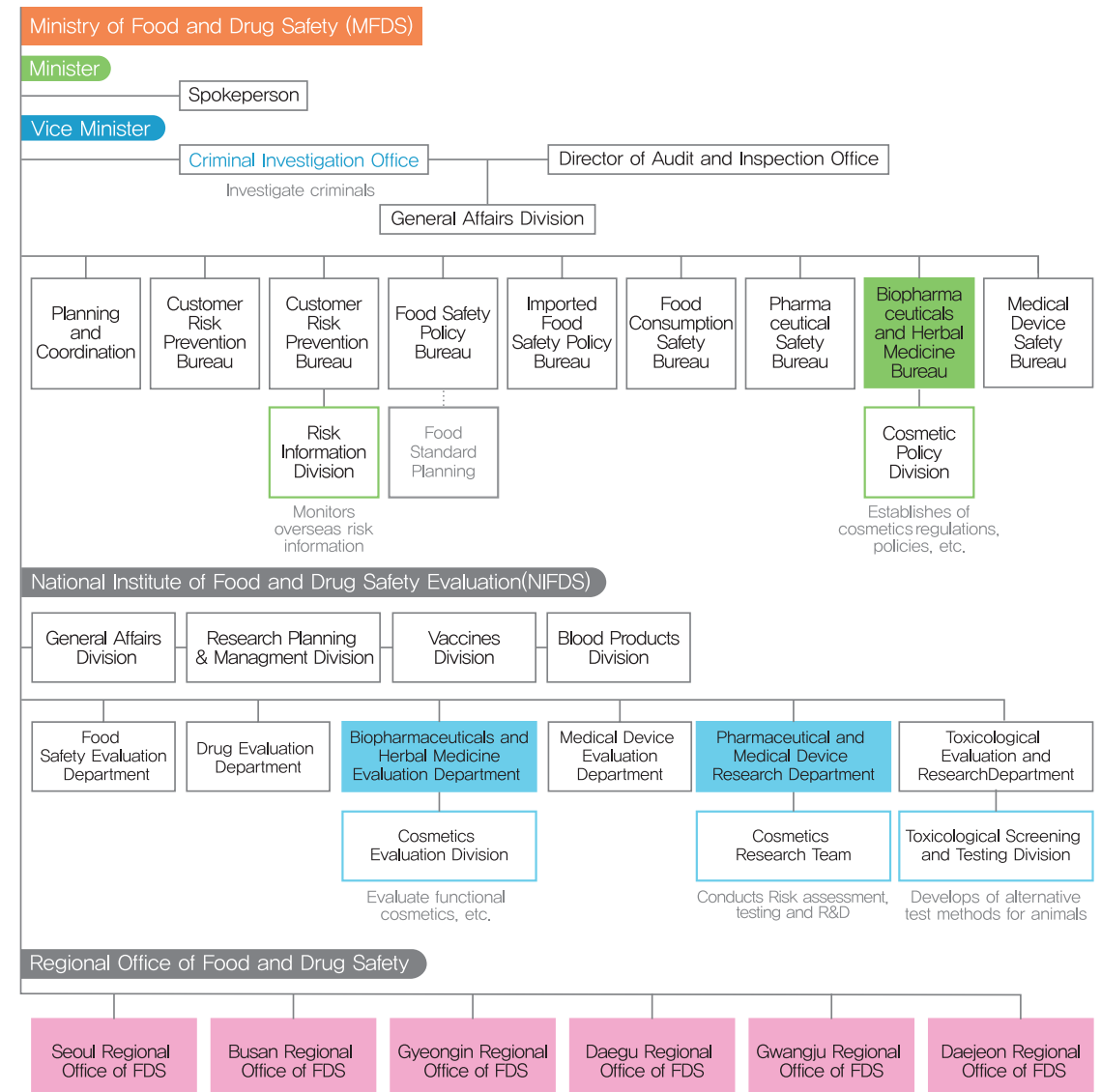
Training and Customized Consulting for Halal Certification (2016~)

provides with training and consulting for preparing manuals required for Halal Assurance System (HAS), etc.

Training and Customized Consulting for CGMP Certification (2016~)

Provides CGMP training and consulting for SMEs to acquire CGMP certification

Organization



Registration of manufacturer and marketing authorization holder, declaration of sales management, follow-ups (audit, collection · inspection, recall · disposal, advertisement · labeling inspection, administrative disposition, etc.)



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Drug Safety**

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January 2019



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