

Basic principles and developments in S. Korea's cosmetic regulations

Speaker : Seongmin(Mike) Sohn, REACH24H KOREA

A decorative image on the left side of the page, featuring a variety of natural ingredients and objects arranged on a light-colored surface. At the top left is a wooden bowl containing a light-colored, textured substance. Below it is a wooden spoon filled with a green powder. To the right of the spoon are several green leaves. Further down is a small black bottle with a white cap. At the bottom left is a small wooden bowl filled with green sprouts. Next to it is a single white daisy flower. At the bottom right is a piece of light-colored wood with a visible grain and a knot.

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Definition of Cosmetics

Chapter 1, Article 2 of the General Regulations (Definitions)

The term "cosmetics" means goods used in a similar manner, such as applying, rubbing, or spraying the human body in order to add charm by cleaning and beautifying the human body, change its appearance brightly, or maintain or promote the health of the skin and hair, and their actions against the human body are minor. However, items falling under subparagraph 4 of Article 2 of the Pharmaceutical Affairs Act shall be excluded.

2. The term "functional cosmetics" means any of the following cosmetics prescribed by the Prime Minister's Decree:

- a. Products that help skin whitening
- b. Products that help improve wrinkles on the skin.
- c. Products that can help you tan your skin or protect your skin from UV rays.
- d. Products that help change or remove color of hair or nourish it.
- e. Products that help prevent or improve dryness, cracks, dislocation, exfoliation, etc. due to weakened skin or hair.

Scope of Functional Cosmetics

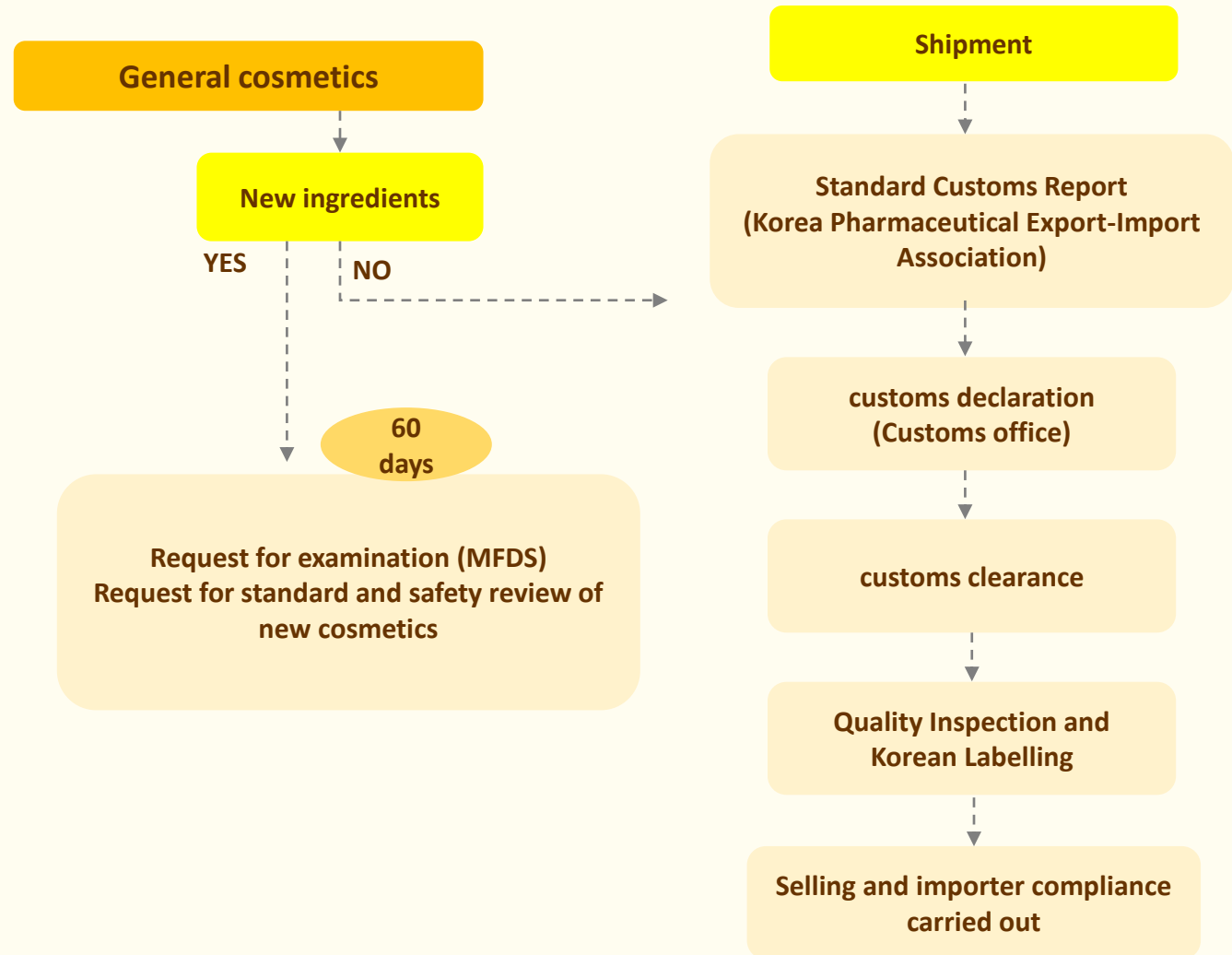


Functional Cosmetics' scope changes

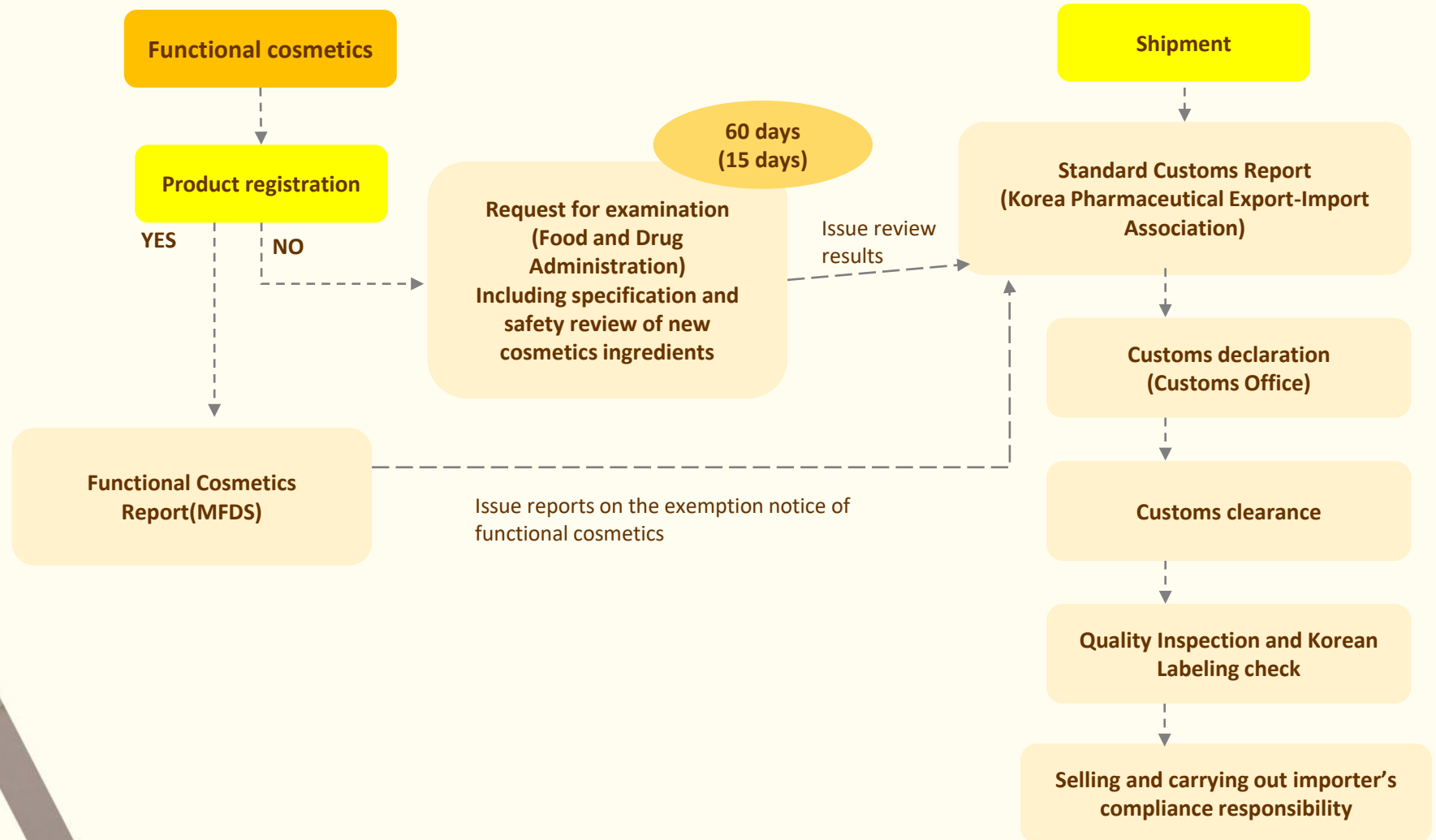
- **Industrial products → Cosmetics conversion:** Wipes(excluding sanitary wipes and medical-use wipes) and facial painting items (Enforcement Rule No. 1154 of the Cosmetics Act, 2015.4.2) from July 1, 2015.
- **Quasi-drugs → Functional Cosmetics Conversion:** Starting May 30, 2017, products for hair loss, hair removal, other hair removal products, and bath products for acne relief purposes (Enforcement Rules of the Cosmetics Act, enforcement of 2017.1.12)*
- **Industrial products → Cosmetics conversion:** From December 31, 2019, cosmetics items such as soap(bar), black coloring agent(for bold hair), and wax(hair removal waxing) converted to cosmetics(Enforcement Rule No. 1516 of the Cosmetics Act, effective January 31st, 2019).

**Should always update
category shuffle for cosmetics!!**

Import process(general cosmetics)



Import process(Functional cosmetics)



Pre-Import preparations

1. Issuing a registration certificate for the 'cosmetics responsible seller'
2. Recruitment of RP
3. Contract for consignment of quality control facilities (laboratory)
4. Confirmation or contract of warehouse
5. Check quality control standards and safety management standards
6. Check manufacturing certificates, sales certificates, and BSE certificates

Cosmetics Manufacturer



Cosmetic
Manufacturer

a person who intends to manufacture all or part of cosmetics.
(Businesses that process only secondary packaging or marking are not eligible for manufacturing registration.)

Registration

- A person who intends to manufacture cosmetics himself.
- A person who intends to manufacture cosmetics as OEM/ODM business

Application

- A person who intends to process the packaging of cosmetics (excluding the secondary packaging process)

Cosmetics Responsible Seller



**Cosmetics
Responsible
Seller(distributor)**

A person who intends to distribute or sell manufactured or imported cosmetics or to arrange for the purpose of import agency-type transactions;

Registration

Application

- A person who intends to distribute or sell cosmetics manufactured by himself/herself.
- A person who intends to distribute and sell cosmetics manufactured on consignment;
- A person who intends to distribute or sell imported cosmetics.
- A person who intends to receive cosmetics for the purpose of import agency-type transactions;

Sample Testing

For each batch number, the certain amount of samples should be tested at the designated labs by MFDS

The testing fee and lead time varies by labs, so it is quite important to select your partner with exclusive cooperation with the labs

Quality control documents

- **Enforcement Rules of the Cosmetics Act**

- Article 12 (Compliance of the Cosmetics Responsible Seller)**

4. For imported cosmetics, following documents should be kept as an import record:

A. The product name or the name to be sold in Korea

B. Specification and content of raw material components

C. Manufacturer's info; Manufacturer's Name and Manufacturer's Location

D. Copies of the examination results as functional cosmetics

E. Certificate of Manufacture and Sales

F. non-sale Sample product manual written in Korean

G. The date of the first import year

H. Date and amount of import by manufacturing number

I. Date and result of quality inspection by manufacturing number

J. Place of sale, date of sale, and sales volume

Exemption of customs clearance

Those exempt from checking import requirements are medicines, etc. (cosmetics, medicines, and non-medical products) brought in for the following purposes:

- **For self-medical treatment(less than US\$2,000)**
- **For relief use**
- **Manufacturing construction use**
- **for R&D**
- **for sample(not for sale) use**
- **Quasi-drug products and cosmetics for consumer research**
- **Raw medical ingredients necessary for the manufacture of medicines that are commissioned by a foreign country to manufacture and exported in full.**

Labelling



1. Name of products
2. Responsible seller(importer)'s name and address
3. All ingredients used in the manufacture of the cosmetics concerned
4. Mass or weight of contents
5. Lot number
6. Shelf life or period of use after opening
7. Price
8. In the case of functional cosmetics, the design prescribed by the Minister of Food and Drug Safety is a design representing the word "functional cosmetics"
9. Precautions for Use
10. Others indicated by the Prime Minister's Decree.

Others and major regulation updates

1. Laws and main contents related to “customized cosmetics”
2. Allergy-causing component of perfume(Labelling)
3. Natural & organic cosmetics certification(MFDS)
4. Recycling packaging regulations(MoE)



2021 regulation updates

Addition of Cosmetic product category

Category	Definition
Beauty Soap(Bar)	Solid soap (solid state) made for cleaning a person's face, etc.;
Black hair Powder	A black solid powdery substance that is sprayed on the head by a person with no hair to fill the area of the hair.
Hair removal wax	Products that physically remove body hair

* Above category products are classified as cosmetics from
1st Jan, 2021

Expanding the scope of use of customized cosmetics dispensing manager

Items		Current Status	Revision
Korea Cosmetic RP Qualification Standard		Two-year work, such as a doctor, pharmacist, bachelor's degree in science and engineering, or two-year work in cosmetics manufacturing and quality management;	(Addition) Having a certificate of preparation manager and meets 1+yr of cosmetics manufacturing and quality management;
Obligation to complete training	Korea Cosmetic RP	In the case of initial training, training must be completed before the end of the relevant year.	Completion of the initial training within six months from the date of appointment;
	Customized cosmetic s dispensing manager	* Need to complete quality safety management training annually	Exemption from initial training when appointed as a dispensing manager in the year he/she obtained qualification;
RP change of registration business processing		15 Days	10 Days

Allowing the payment of cosmetics fines in installments and the extension of the payment deadline;

<Fine payment conditions>

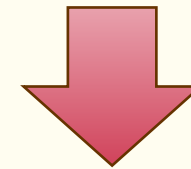
- The fine to be paid is more than 1 million won
- Property loss due to natural disasters
- Business crisis due to deterioration of business conditions
- If it is deemed difficult to pay at once

* **Payment deadline : ~ 1 year / Maximum installment ~3 times**

Exemption from submission data of functional cosmetics for hair loss



Combination Formulation of
Listed Functional Cosmetic Ingredients



'Safety/Efficacy data' Exemption
For Functional Cosmetics Registration Review

Expanding the scope of exemption from the examination of functional cosmetics

Functions	Ingredients & Formulations
Helps alleviate hair loss symptoms	(Ingredient) Niacinamide, Salicylic acid (Product) Niacinamide + dexpanthenol + biotin + zinc pyrithione solution (50%) compound (lotion, liquid, cream), dexpanthenol + salicylic acid + L-menthol compound (lotion, liquid, cream)
Whitening & anti-wrinkle	(Product) Ethyl ascorbic ether + Adenocine Compound(Lotion, Liquid, Cream, Mask)
Hair Dye	(Product) Sodium peroxide, potassium peroxide powder, and a 3-type oxidative hair dye with 3-type as conditioning agents

Expand development by increasing efficiency in screening functional products

* Ease the barriers for itching-relief product clinical tests

Items	Current Status	Revision
Human Application Test Lab Qualifications	Pharmaceutical Clinical Trial Labs for Functional Cosmetics	Non-pharmaceutical Clinical Labs are also allowed for itch-relieve cosmetics of human applied tests ** MFDS just released clinical guidelines for itching relief products

New Functional Product Standard and Test methods

* Establishment of standards for functional cosmetics and testing methods

Items	Current Status	Revision
Whitening & Anti-wrinkle	NEW	Ethyl Ascorbic Ether + Adenocine Compounds, etc
Hair Dye	NEW	Sodium peroxide + potassium peroxide powder, etc.


Cosmetic use pigments added with new test methods

* Additional types of pigments for cosmetics use, and clearly stipulate some pigments test methods

Pigment	Current Status	Revision
Lycopene	Only lycopene extracted from natural tomatoes is recognized.	Also recognized as 'Lycopene' extracted from microorganisms or a synthetic one.
Mica	(Confirmation test) Qualitative reactions (1-4 method) of potassium salts can be tested	It is prescribed that the method of qualitative reaction of potassium is tested in a clear manner (2-4 method)



Q&A



Thank you for your attention