Status of Cosmetics Regulations in Korea

*Doris Peters and Jae-Seong Choi**

I. The Cosmetic Market in South Korea

South Korea ranks amongst the top ten cosmetics markets in the world and represents about 2.8 percent of the global market¹. Korea is considered as global center of innovations in cosmetics – “K-Beauty” is on the rise. South Korean products impress through their effectiveness, packaging and sensory appeal and by thus, inspire Western brands. Cosmetics in South Korea are defined as products applied or sprayed onto the human body in order to clean, beautify, change, brighten, maintain or promote the health of skin and hair. The South Korean Cosmetic market is valued about 10bn USD today with an estimated CAGR of 4.95% during 2017-2030².

In order to contribute to improving national health and developing the cosmetics industry, the South Korean government issued the overarching regulation for cosmetics known as the Cosmetics Act³ (Act No. 17250) in 2000. The legislation provides measures for the manufacture, import and sale of cosmetics and cosmetic ingredients including detailed requirements for the labeling and advertising of products and has lately been revised in April 2020.

II. The Cosmetics Legislation before April 2020

Cosmetics were managed as a part of the Pharmaceutical Affairs Act before the Cosmetics Act was introduced in 2000. Since then, regulations on cosmetic

products and raw materials are legislated and managed by the Ministry of Food and Drug Safety (“MFDS”). The new law was adopted to improve the competitiveness of the domestic cosmetic industry and to keep pace with international regulatory trends. The Cosmetics Act has gone through various changes, such as subdividing related regulations, adopting Cosmetics Good Manufacturing Practice (cGMP) standards for cosmetics and preparing certification standards for Natural and Organic Cosmetics.

The legislative text mainly outlines the legal obligations specifically for importers of cosmetics to help non-Korean manufacturers exporting their products to South Korea. The obligations depend on the type and category of the cosmetic product.

1. Categories of cosmetic products

According to the Cosmetics Act, cosmetic products are categorized into “functional cosmetics” and “general cosmetics”. Unlike “general cosmetics”, where manufacturers or importers are permitted to market their products without registration but are subject to post-market monitoring, for products corresponding to the “functional cosmetics” it is obligatory to undergo a registration process related to their safety, efficacy and function by the MFDS before market launch. Further, functional cosmetics are subdivided into categories depending on the purpose of use, such as infants, baths, fragrances, washing and dyeing; accordingly the requirements are different.

Functional cosmetics should not be confused with consumer goods such as quasi-drugs (e.g. sanitary napkins, hand sanitizer, antiseptics, toothpaste and mouth refreshers, etc.) which are controlled under the Pharmaceutical Affairs Act and are subject to different registration obligations. Importers should stay updated for the latest regulations and categorization on consumer goods and functional cosmetics in place prior to imports to comply with the current applicable law in South Korea and avoid unnecessary actions.

DOI: 10.21552/icrl/2020/2/8

* Doris Peters is Managing Director at Consortia Management GmbH. For Correspondence: e-Mail: <peters@consortia-management.com>. Jae-Seong Choi is Branch Manager at Chemservice Asia, For Correspondence: <js.choi@chemservice-asia.com>

1 See, International Trade Administration <<https://www.trade.gov/>> accessed Oct 24, 2020

2 See, Goldstein Research <<https://www.goldsteinresearch.com/report/korean-cosmetics-market-report-south-korea-industry-analysis>> accessed Oct 24, 2020

3 Cosmetics Act (Act No. 17250, revision enforced on 7th April 2020 by MFDS)

Table 1: Categories of Functional Cosmetics

Application area	Categories	Remarks
Skin	Skin whitening	by preventing or fading melanin pigmentation
	Anti-wrinkle	
	Tanning	
	UV protecting	
	Alleviating acne	Rinse-off only
	Alleviating atopic skin	
	Stretch mark thinning	
Hair	Dyeing (incl. bleaching)	excl. temporary hair dyes
	Hair removing	excl. physical hair removing
	Alleviating alopecia	excl. physical hair thickening (i.e. coating)

2. Legal requirements of importing cosmetics

Overall, the legal obligations to manufacture, import, distribute or sell cosmetic products have been simplified since the Cosmetics Act has been firstly established in order to secure the market fluidity and competitiveness. However, authorities have increased safety examinations of products and raw materials to the benefit of the public health. The responsibilities on quality management and safety communication need to be strictly followed by each authorized actor in the supply chain. For example, importers should conduct product quality self-inspection of imported cosmetics and must not put any products containing any prohibited ingredients on the Korean market. In case of any violation observed, MFDS is able to recall the products by a public announcement with immediate effect, which would seriously impact the future business and reputation of not only the domestic distributor, but also of the manufacturer himself.

a. Import procedure

Figure 1 below demonstrates the overall procedure of importing functional cosmetics under the Cosmetics Act from business registration to labelling and market distribution.

b. Business registration

Any person or enterprise who intends to manufacture, import or sell cosmetics in Korea should register a cosmetic business first, differentiating between the following:

- Manufacturing business
- Responsible cosmetic distribution business
- Custom cosmetics sales business

When importing cosmetics, the importer should be registered as the “responsible cosmetic distributor” (the so called “Marketing Authorization Holder (MAH)”) who observes the duties on importing cosmetics under the Cosmetics Act. It is important to verify that the importer is properly authorized ac-

Figure 1: Import Process of Functional Cosmetics in Korea

cording to the business registration. The non-Korean manufacturer needs to provide the required documentation to the importer to comply with the obligations when importing cosmetic products under the Korean law.

c. Registration of Functional Cosmetics

As described in Chapter II.1., functional cosmetics are subject to a product registration by MFDS to get an approval letter before manufacturing or importing into Korea. The dossiers are evaluated to prove the safety and efficacy and to verify the quality management according to the testing standards specified in KFCC⁴ (Korean Functional Cosmetics Codex). Registration dossiers have to be submitted in Korean language.

Some of the dossier requirements can be exempted under designated conditions as specified in Annex 4 of the “Standard of Functional Cosmetics Evaluation (MFDS public notification No. 2019-47)”, e.g. origin and development background information and clinical and efficacy study data are exempted when a functional product contains only ingredients listed already in this standard.

4 Korean Functional Cosmetics Codex (MFDS public notice No. 2018-111)

5 Korea Pharmaceutical Traders Association <<http://www.kp-ta.or.kr/eng/main/main.asp>>, accessed October 24 2020

6 Electronic Data Interchange method

7 Transmissible Spongiform Encephalopathy

8 Bovine Spongiform Encephalopathy

9 International Nomenclature Cosmetic Ingredient (INCI)

d. Customs clearance

After approval of the registration of the functional cosmetics, customs clearance is required after the physical import of the product into Korea. The import notification should be submitted to KPTA⁵ to initiate a customs clearance procedure with the following requirements:

- Standard customs clearance report (submitted by importer in EDI⁶ format)
- Certificate of Manufacturing
- TSE⁷ (and/or BSE⁸) related documents

An approval letter of the product registration from MFDS is additionally required to process the functional cosmetic. After customs clearance, generally the products are stored in a warehouse until the quality inspection is completed and the approval letter is issued.

The overall process of customs clearance for raw materials is similar to finished products. When a single raw material is imported, the INCI⁹ name replaces the product name in the documentation. For bulk-mixtures (mix of different raw materials), it is sufficient to file one report for the mixture. The ICNI name of each ingredient should be indicated at the product name sector and the Harmonized System Code (HS Code) of its derived finished cosmetic product should apply instead of the raw materials code.

Raw materials, including bulk-mixtures, do not require a business registration as importer under the Cosmetics Act in Korea. Any company can import raw materials and resell it to registered manufacturers, after the self-inspection on raw material has been conducted.

e. Product quality inspection

Testing methods or frequency of the product quality inspection is not mandated under the Cosmetics Act, but the importer, as MAH, needs to conduct a self-inspection of the product ensuring the characteristics fulfil the safety standard obligation of the Cosmetics Act respecting the negative list of ingredients and criteria of the testing values. For functional cosmetics, different testing parameters have to be verified per category according to the KFCC standards. In case the manufacturer is cGMP certified or fulfills the Korean cGMP condition via a site-inspection by the Korean authorities, the importer’s obligation on quali-

Table 2: Dossier Requirements for Functional Cosmetic Registration

Categories	Required information	Remarks
Clinical & Efficacy information	Origin & development background	
	Clinical & Efficacy related study data	Can be exempted when ingredients are listed ^a
	Evidence on SPF ^b , PA ^c valuation	For SPF products only
Testing method and standards	Test items, validation on testing method	

a Standards for Evaluation Dossiers of Functional Cosmetics (MFDS public notice No. 2019-47) - [Annex 4] Types of functional cosmetics and maximum limit of ingredients for data submission exemption

b Sun Protection Factor

c Protection Factor of UVA

ty inspection can be exempted. If the importer does not have the ability to conduct the tests himself, he can outsource the task to designated laboratories or institutes.

f. Labelling

The final step to be accomplished before selling the cosmetic products on the Korean market is the labelling of the products. As a matter of course, labels are already attached to the imported cosmetics in the language according to the relevant regulations depending on manufacturers' location. Labels in Korean language need to be additionally attached to each final product for Korean consumers to easily check the information on the labels in their local language. The Korean importer needs to indicate its coordinates (name, address, etc.) and furthermore, the label should specify the manufacturing batch number (Lot number) in connection with the result of the product quality inspection after import.

3. Cosmetic GMP (cGMP)

In Korea, cGMP was initially introduced in 1990 under the Pharmaceutical Affairs Act, but was not actively transcribed due to the limited benefits to the industry. For manufacturing sites managing their facilities well and in compliance with international GMP standards, the quality inspection obligation in Korea in addition were without appropriate benefits

to maintain the cGMP certification in Korea, but impeded the international competitiveness of domestic cosmetic manufacturers. After years of continuous requests from the industry for changes to the cGMP obligations, the MFDS launched a revision of the existing cGMP regulation in 2009 not only to better manage the quality of cosmetics manufacturing, but also to enhance the global competitiveness of domestic companies. Today, the standard criteria of cGMP are comparable to ISO 22716¹⁰, the international standard with broader criteria for cosmetics manufacturing.

For importers, the product quality inspections can be exempted by inspecting the overseas manufacturer's facilities by authorities applying the Korean cGMP standard criteria during a site-inspection. Since the revised cGMP standard has much in common with international standards such as the EU cGMP or ISO 22716, cGMP-certified EU manufacturers meet the Korean standards and by thus, have an easier market access and better competitiveness in the Korean market.

4. Certification of Natural and Organic Cosmetics

Apart from the categorization by the function or purpose of use, both general and functional cosmetics

¹⁰ International Organization for Standardization, ISO 22716:2007 Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices

Table 3: Label Requirements per Contents Weight/Volume

Contents weight (or volume)	Label requirements
10g (or ml) and less	Product name Importer company name Lot number Expiry date Retail price ^a
11 – 50g (or ml)	In addition to above requirements: Importer's company address & contact info Country of origin Manufacturer company name & address ^b Net content weight/volume ^b Ingredients listed with max. limit ^b Cautions for use ^b Barcode ^b Separate discharge mark ^c
More than 50g (or ml)	In addition to above requirements: Full ingredients ^b

a Marked by final seller, if a secondary packaging exists, the retail price on the primary packaging can be omitted

b If a secondary packaging exists, the items on the primary packaging can be omitted

c Separate discharge mark can be omitted if contents weight (or volume) is less than 30g (ml)

can be labeled as Natural Cosmetic and Organic Cosmetic depending on the ingredients. According to the Cosmetics Act, a Natural Cosmetic is defined as a cosmetic product containing 95% or more of natural ingredients or ingredients derived from natural sources. And among the criteria of the Natural cosmetics, the Organic Cosmetics are specifically defined when cosmetic products contain 10% or more of organic ingredients.

As consumers interest in ingredients used in cosmetics increases, demand for cosmetics using organic or natural ingredients also increases. However, inappropriate advertisings and the use of unverified ingredients could cause concerns for the consumer safety, and called for the establishment of appropri-

ate standards and a certification system for Organic and Natural Cosmetics. The certification system for Organic Cosmetics in Korea was first enacted in 2015 as the “Regulations on the Standards of Organic Cosmetics (MFDS public notice No. 2014-200)”, with a positive list of organic ingredients and the standards on manufacturing processes and facilities. The regulation met the consumer’s safety demand for organic cosmetics by allowing label advertisements only for products that have been certified by MFDS. As of July 2019, the regulation was revised as “Regulation on the Standards of Natural Cosmetics and Organic Cosmetics (MFDS public notice No. 2019-66)” including the definition of Natural Cosmetics as broader criteria than only Organic Cosmetics and updating the ingredients standard and certification category. As in 2020 the grace-period¹¹ of the organic cosmetics certification mark applied to product labels under the former regulation ended, suppliers need to check for updates to their product labels effective 2021.

III. Changes in the Cosmetics Legislation revision April 2020

As mentioned in the previous sections, major changes of the revision of the Cosmetics Act in April 2020 have been implemented to the relief of obligations to the market players. This has drawn attention not only to domestic companies, but also the non-Korean manufacturers who intend to export their products. For the most part the revised legislation aims to improve the safety of consumers further. Changes apply to the “customized cosmetic” business together with other updates such as changes in safety standards and new obligations on labeling requirements.

1. Introduction of Customized Cosmetics system

A Customized Cosmetic is a cosmetic product that can be customized based on personal preferences or skin type by a certified “customized cosmetics technical manager” at a retail store.

The implementation of the Customized Cosmetics system is of the highest interest in the Korean market in 2020. Previously, the Cosmetics Act prohibited mixing or dividing cosmetics into small pro-

11 Regulations on the Standards of Natural Cosmetics and Organic Cosmetics (MFDS public notice No. 2019-66) – Supplementary provision Article 2 (Transitional measures related to labeling of organic cosmetics)

portions at retail stores while the demand on diverse options for customized products and personalized services increased. Thus, a new legislation was required to fulfil the consumer's demand while controlling and securing safety. According to the revised Cosmetics Act, a certified "customized cosmetics technical manager" can now legally subdivide or mix ingredients of cosmetic products. A registration of the Customized Cosmetics business is mandatory to operate a store with certified personnel.

The Customized Cosmetics system constitutes a big change in the Korean cosmetic market as not only companies directly related to cosmetic products, but also skin care professionals and beauty salons have an interest in this business. In addition, 3D technologies, AI and biotechnologies are also expected to be combined with this business area to develop the market further.

2. Updated safety standard

With the latest revision of the Cosmetics Act, the safety standard regulation¹² in form of a negative list of ingredients prohibited or restricted for use, has also been revised. For instance, *Tagetes erecta*, *Tagetes minuta* and *Tagetes patula* flower extracts and oils, which had been widely used as fragrance ingredients in many fragrances, are newly controlled under the Korean regulation. Specifically, *Tagetes erecta* flower extract and oil, which is already prohibited in the EU cosmetics market, is included in the negative list. Further, *Tagetes minuta* extract and oil and *Tagetes patula* extract and oil are also listed as restricted to use with the same concentration limit as in EU (0.1% in rinse-off products and 0.01% in leave-on products) so that the ingredients are commonly controlled by international standards. MFDS modified the regulation to adopt these changes in the revision of the Act. Further, a positive list of ingredients for Customized Cosmetics is newly adopted in Article 3 of the regulation.

Beauty soaps in solid form are transferred to the Cosmetics Act from the previous categorization as an industrial product under the Electrical Appliances and Consumer Products Safety Control Act (Act No. 15338), in line with other types of soaps (e.g. liquid soap, body cleanser, etc.) which are already controlled under the Cosmetics Act. Due to this regulation conversion of beauty soaps, new testing standard and method are established in Annex 4¹³ of the

regulation. In addition, prohibited substance¹⁴ that are newly designated under the K-REACH Act¹⁵ for chemicals are also prohibited according to the Cosmetics Act today.

3. Changes in Label requirements

Amongst the newly revised regulations in 2020, changes on label requirements can be considered as the most relevant to non-Korean manufacturers and distributors. The "Standard on Marking Cosmetics Usage Precautions and Fragrance Allergens" has been updated from the former version of the regulation to require all cosmetic products today to indicate the presence of 25 known allergenic chemical substances on their labels by its INCI name in Korean language in case concentrations in the finished products exceed the given concentration thresholds¹⁶. It is expected that complaints from consumers being allergic to certain ingredients can be greatly reduced by this update. Allergens were only marked as "fragrances" in the past.

IV. Conclusion

Since the implementation of the Cosmetics Legislation in 2000 in South Korea the law has been revised several times, most recently in April 2020. The MFDS has been making efforts to improve the competitiveness of the domestic cosmetic industry and to keep pace with international regulatory standards while securing consumer's health and safety. Under the Cosmetics Act in Korea, there is a defined procedure in place for the import of functional cosmetics from the business registration to the registration of the product itself, to labelling and market distribution. The legislation obliges manufacturers and importers also to fulfil standards on cGMP.

12 Regulations on cosmetics safety standards (MFDS Public notice No. 2020-12)

13 Test method for safety management of consumer cosmetics

14 Designation of restricted, prohibited chemical substances (Ministry of Environment public notice No. 2019-214)

15 Act on Registration, Evaluation, etc. of Chemicals (Act No. 17326, revision enforced on 5th May 2020 by Ministry of Environment)

16 Concentration threshold criteria: Rinse-off product: exceed 0.01%; Leave-on product: exceed 0.001%

Table 4: Fragrance Allergens

No.	Chemical name	CAS No.
1	Amyl Cinnamal	122-40-7
2	Benzyl Alcohol	100-51-6
3	Cinnamyl Alcohol	104-54-1
4	Citral	5392-40-5
5	Eugenol	97-53-0
6	Hydroxycitronellal	107-75-5
7	Isoeugenol	97-54-1
8	Amyl Cinnamal Alcohol	101-85-9
9	Benzyl Salicylate	118-58-1
10	Cinnamal	104-55-2
11	Coumarin	91-64-5
12	Geraniol	106-24-1
13	Anise Alcohol	105-13-5
14	Benzyl Cinnamate	103-41-3
15	Farnesol	4602-84-0
16	Butylphenyl Methypropional	80-54-6
17	Linalool	78-70-6
18	Benzyl Benzoate	120-51-4
19	Citronellol	106-22-9
20	Hexyl Cinnamal	101-86-0
21	Limonene	5989-27-5
22	Methyl 2-Octynoate	111-12-6
23	Alpha-Isomethyl Ionone	127-51-5
24	Evernia Prunastri (Oakmoss) Extract	90028-68-5
25	Evernia Furfuracea (Treemoss) Extract	90028-67-4

For cosmetics products marketed as Natural or Organic Cosmetics a certification system is in place to prevent incorrect labeling or advertisements. The legislation has further adopted risk ratings and classification standards for potentially hazardous cosmetic products or ingredients which may need to be recalled from the market in the future. Special attention has been given to infants and children's cosmetics to avoid any safety issues by adding detailed age standards and designated criteria for advertisement as well as conducting fact-finding surveys and establishing procedures to reduce risk factors.

Recent major changes of the Cosmetics Act concern the introduction of the Customized Cosmetics system allowing certified personnel to subdivide or

mix ingredients of cosmetic products, the updated safety standards with a negative list of ingredients that are prohibited or restricted for use and a positive list of ingredients for Customized Cosmetics as well as the labelling of 25 known allergenic chemical substances on the product labels by its INCI name in Korean language.

With the continuous revisions it can be stated that the MFDS ultimately aims to create a society where any concerns of consumers about safety can be managed or even removed when using high-quality cosmetics in Korea while giving way to a growing market in Korea. Due to the numerous revisions, importers should make themselves confident with the latest regulations in place.