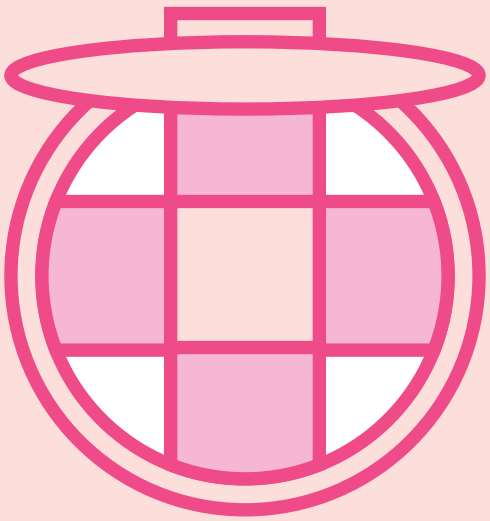

Korea Cosmetic Regulatory Updates 2015

A ChemLinked Team Work Shared
Angelita | Albert | Antonia

CHEMLINKED
by REACH24H Consulting Group

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Compared to China's policy of sweeping reforms to its cosmetic regulatory framework, Korea adopts a more gradual approach through the implementation of smaller changes over an extended period of time via minor amendments to official acts, rules and standards. Generally the overarching cosmetic regulation in a country isn't modified or supplemented frequently but in Korea this is not the case. Almost every year the MFDS revises or supplements some clauses of the Cosmetic Act. As such 2015 was not an eventful year in terms of regulatory updates in Korea. The most significant change was Korea's progress in eliminating mandatory animal testing requirements.

A CHRONOLOGY OF PROGRESS IN ELIMINATING ANIMAL TESTING IN KOREA

In January 2015, it was reported that South Korea will join the countries dedicated to banning animal testing of cosmetics. MFDS announced its intent to eliminate animal testing for finished products and in the coming months will make provisions about the permitted alternatives to animal testing along with more specific implementation procedures (see *CL news on 12 Jan 2015*).

In March congresswoman Jung-Lim Moon proposed a bill to revise Korea's Cosmetic Act, however the bill only proposed the ban on animal testing where accepted non-animal alternatives are available. If an alternative is not available, animal testing will be allowed. In addition, the bill exempts several product categories and types of ingredients from the scope of the ban including preservatives, sterilization agents, colorants, sunscreen chemicals and other ingredients that are required to perform risk evaluation according to Article 8-3 in the Cosmetic Act. Furthermore, ingredients that are animal tested for other regulatory purposes or to meet mandatory regulatory requirements of other countries are also permitted to be sold in Korea. Several exemptions were contained in the bill, which mean it is likely some animal testing to continue well beyond 2017 (see *CL news on 12 Mar 2015*).

Although the above two steps were welcomed by companies advocating cruelty-free, no news of adopting the bill or issuing some provisions about the permitted alternatives to animal testing have been published by the MFDS. On July 24, the MFDS formally announced some clauses related to animal testing in the Cosmetic Act, which will be implemented from July 16 2016. Manufacturers are not permitted to use animals for R&D, safety management and quality control of cosmetics. In such case, the MFDS will take into consideration the circumstances to restrict the use of animals in a gradual phasing out process. The details and applicable scope related to the restriction will be stipulated by the Ministry of Health and Welfare (see *CL news on 24 Jul 2015*).

This was the first time that MFDS responded to the issue of animal testing. The announcement indicated that the MFDS is indeed endeavoring to end animal testing but it seems that the MFDS didn't make clear provisions about the ban or develop the implementation rules. Even so, it is still a historic and substantial step toward eliminating animal testing.

Recently, news from Human Society International reported that South Korea has passed a law that from 2018 the use of non-animal alternative tests for cosmetics where such alternatives have been accepted by the Ministry of Food and Drug Safety will be mandatory. The new law is almost the same as the bill proposed by the congresswoman Jung-Lim Moon. (see *CL news on 27 Nov 2015*).

Provided the law is implemented animal testing will still be required for the following assessments:

Endpoint	Alternative	Outcome
Single dose (acute oral) toxicity (7 rats per test)	The validated in vitro 3T3 Neutral Red Uptake cytotoxicity test can screen out substances that would be non-toxic, which could reduce the use of this lethal animal test by nearly 90 per cent, but is not yet accepted by MFDS.	Some animal testing for this endpoint is likely to continue.
Skin irritation (1-3 rabbits per test)	Human skin model replacement for irritation is accepted by MFDS	Full replacement possible, animal testing should stop for this endpoint
Eye irritation (1-3 rabbits per test)	The BCOP and ICE tests are accepted by MFDS, but the fluorescein leakage test is not accepted yet in Korea	Full replacement possible, animal testing should stop for this endpoint
Skin sensitization (32 guinea pigs or 16 mice per test)	Only a refinement method (mouse Local Lymph Node Assay), is accepted by MFDS; non-animal testing strategy based on validated in vitro tests is not yet accepted	Animal testing for this endpoint is likely to continue
Photo-toxicity and photo-sensitization (no internationally recognized animal test guideline for either endpoint)	The in vitro 3T3 NRU test is accepted for photo-toxicity, but there is currently no internationally accepted replacement for photo-sensitization	Animal testing is likely to continue for photo-sensitization
Repeated dose toxicity (40-80 rats per test)	No internationally accepted replacement	The MFDS appears not to explicitly require this endpoint for cosmetics, although the law allows regulators to demand data for this or any endpoint, leaving room for animal testing to continue.
Reproductive and developmental toxicity(1,400-2,600 rats per reproductive toxicity test; 660 adult female rabbits and pups or 1,300 adult female rats and pups per developmental toxicity test)	No internationally accepted replacement	The MFDS appears not to explicitly require this endpoint for cosmetics, although the law allows regulators to demand data for this or any endpoint, leaving room for animal testing to continue.

CHANGE OF COSMETICS/QUASI DRUGS CLASSIFICATION

MFDS legally divides cosmetics into four categories: general cosmetics, functional cosmetics, quasi drugs and drugs.

Classification	Scope
Functional Cosmetics	Whitening products/anti-spot products
	Anti-wrinkle products
	Sunscreens