

Asia Alert

China Removes Mandatory Animal Testing Requirement for Certain Cosmetic Products

By Suat Eng Seah and
Xinxing Chen

China's food and drug administration authorities removed a mandatory animal testing requirement for certain types of cosmetic products under a new regulation which came into effect on June 30, 2014.

According to Circular 10 [2013] of The China Food and Drug Administration (CFDA), for "ordinary cosmetics", which include shampoo and certain skin-care products, only standard risk assessments proving the safety of the relevant products are required for filing and registration. In the past, mandatory toxicology tests, which broadly involved animal testing, had to be conducted, and the results of such tests had to be submitted to the CFDA.

As the new rule is only applicable to "domestic ordinary cosmetics", the relaxation of the animal testing requirement only applies to cosmetic products made in China by domestic Chinese or foreign-owned companies; it does not apply to imported cosmetic products — at least for the time being. It is uncertain if and when the new rule would be expanded to apply to imported products. Further, the new rule does not apply to any "specialty cosmetic products" such as hair dyes and sun-blocks.

The following is a brief summary of certain significant changes introduced by the new rule:

- **Mandatory Toxicology Test Replaced by Risk Assessment**
Manufacturers are required to conduct risk assessments instead of toxicology tests on new products. Unlike toxicology tests where animal testing is extensively involved, alternative methods such as using existing data on ingredient toxicology or tissue culture are adopted in the risk assessments.
- **Pre-filing Review Replaced by Post-filing Examination**
Manufacturers are required to submit filings for new products through an on-line filing system. This shifts the CFDA's focus from conducting pre-filing reviews of the documents and materials submitted by manufacturers, to the post-filing examination of substantive aspects of the products.
- **Certificates of Filing Replaced by Product Information Publication**
Information filed in respect of the cosmetics products would be published online and accessible to the public. This would provide the public with knowledge or whether a filing has been duly made in respect of a cosmetic product and basic data regarding such product, including any violations of law discovered by the CFDA in its post-filing examination of such product. CFDA would no longer issue a Certificate of Filing of Domestic Ordinary Cosmetics, which was previously used to indicate the completion of the filing of the relevant product.
- **Applicable to Domestic Ordinary Cosmetics Only**
As mentioned above, the new rule applies to domestic ordinary cosmetics only. The filing procedure of and approval requirements for imported cosmetics products, and specialty cosmetics (such as hair tonic, hair dye, hair perm, hair removal, breast massage, deodorant, fading cream and sun-block products), either domestic or imported, remain unchanged.

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Suat Eng Seah
[Bio Page](#)
E suateng.seah@weil.com
T +86 21 6016 6301

Xinxing Chen
[Bio Page](#)
E xinxing.chen@weil.com
T +86 21 6016 6363