



TECHNICAL FACT SHEET

Changing the makeup of Taiwan's cosmetics regulations

Science Inspired, Quality Driven.

For businesses aiming to expand in the global cosmetics market, one of the biggest factors in their success lies in how well they navigate the dynamic world of cosmetics regulations.

In recent years, Taiwan has significantly revamped its Cosmetic Hygiene and Safety Act. This replaced the Statute for Control of Cosmetic Hygiene, which was in place until July 2019, to align Taiwan more closely with international standards.

These substantial amendments have reshaped the cosmetics industry in Taiwan, introducing new mandates such as the establishment of Product Information Files (PIFs), and compliance with Good Manufacturing Practices (GMP) and new definitions and regulatory terms.

The primary aim of these changes is to bolster the safety management of cosmetics, and ensure companies are providing high-quality products to consumers. As the Taiwanese market holds immense potential, it's essential to understand these regulatory stipulations.

This technical bulletin provides a comprehensive guide to the Taiwan Food and Drug Administration (TFDA) requirements for cosmetic products, giving you the most up-to-date industry knowledge so that your company can successfully penetrate this lucrative market.

Changes in the new Cosmetic Hygiene and Safety Act:

- Was amended from the Statute for Control of Cosmetic Hygiene in July 2019
- Involves completing product notification and establishing Product Information Files (PIFs) and Good Manufacturing Practices (GMP) before going to market
- Replaces the outdated term "medicated cosmetics" with the new term "specific purpose cosmetics"
- Requires providing online access to product information

These amendments not only look to maintain the hygiene of cosmetics – but also to strengthen safety management and ensure stable, high-quality production.

Cosmetic Hygiene and Safety Act: Important definitions

- **Cosmetics** = applied externally to the human body, teeth or oral cavity mucous membranes. Used to moisturize skin and hair, stimulate the sense of smell, improve body odors, change appearance or cleanse the body
- **Cosmetics business** = a business engaged in the manufacture, import or sale of cosmetics
- **Specific purpose cosmetics** = cosmetics that contain sunscreen, as well as hair-dyeing, permanent-waving, antiperspirant, deodorant, tooth-whitening and others, as specified in the [List of Specific Purpose Ingredients in Cosmetic Products](#)
- **Product Information File (PIF)** = a document containing data about a specific cosmetic, including its quality, safety and functions

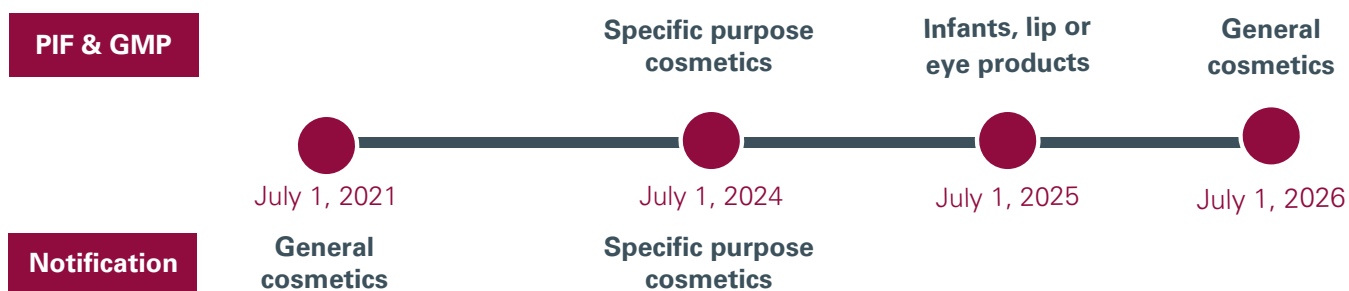
Cosmetics types and categories

- Shampoo & hair cleansing products
- Face cleansing & makeup removal products
- Bath & shower products
- Hair care products & hair spray
- Toner, oil, cream & lotion products
- Fragrances & perfume products
- Antiperspirant & deodorant products
- Lip products
- Covering products & foundation
- Eye products
- Nail products
- Teeth whitening products
- Toothpaste & mouthwash products*
- Soaps

*for non-medical use

The notification and PIF/GMP timeline

Cosmetics factories need to comply with Cosmetics Good Manufacturing Practice Regulations (GMP) and ISO 22716 for every stage of production, from design to packing. To do this, different categories will be implemented in phases.



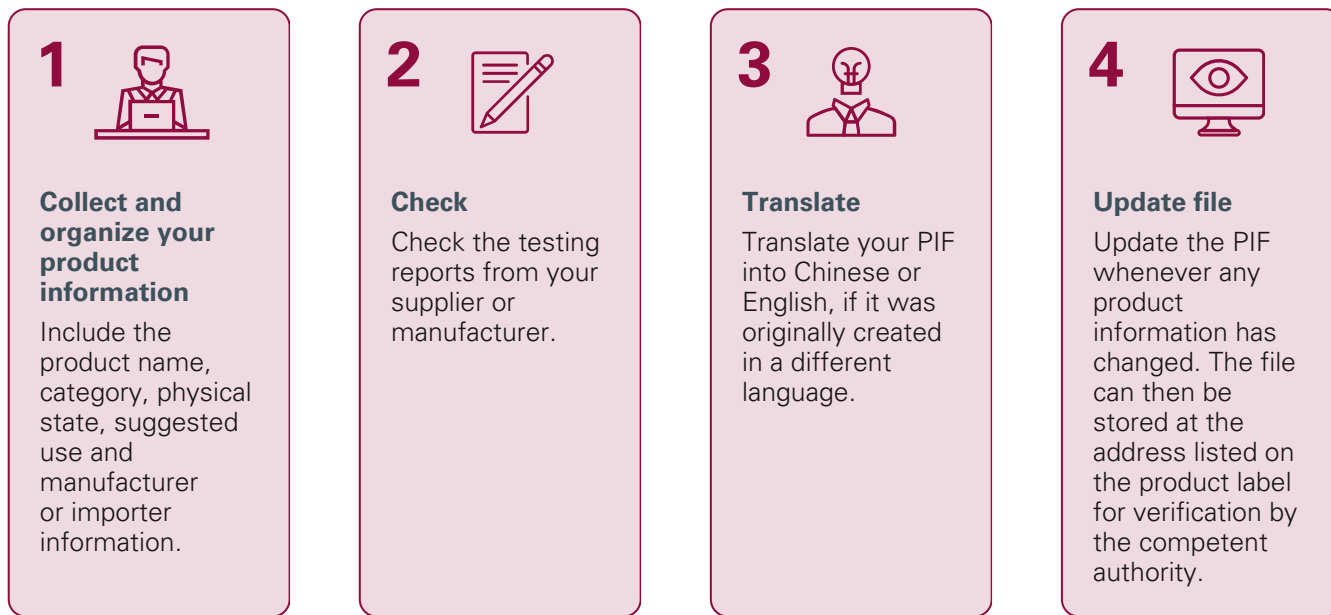
The timeline for compliance varies depending on the type of cosmetics product. For instance, specific purpose cosmetics have to comply by July 2024, while general cosmetics have until July 2026.



Understanding new cosmetics regulations: The PIF document

As a comprehensive document that contains data about the quality, safety and functions of cosmetic products, the PIF is a crucial component of the new regulations. As a live document, the PIF should be regularly reviewed and updated whenever there are changes to the product information.

The process of preparing a PIF involves four steps:



The amendments also require cosmetics businesses to comply with GMP regulations and ISO 22716. This applies even to factories that only perform packing operations, as these are included in the GMP process.

Another significant change is the prohibition of animal testing for cosmetic products. Cosmetics businesses are not allowed to test their samples on animals when conducting safety evaluations of cosmetics or cosmetic ingredients.

However, there are exceptions to this rule if certain conditions are met and approved by the central competent authority.

In lieu of animal testing, businesses can use alternative testing methods such as in vitro skin irritation or skin sensitization tests.

Guide to product compliance and market targeting

- The first step in the process is understanding the product container labels or leaflets. This involves having a clear labeling design for your PIF documents.
- The next step is the GMP Compliance Certification or Self-Declaration. To qualify for the GMP requirement, you must meet certain standards, such as ISO 22716.
- This is followed by the manufacturing master and procedure, which requires you to have your own SOP about a product, how to manufacture and how to proceed.
- The next aspect to consider is the intended usage (where on the body the product should be used), dosage, frequency and the target population. This essentially means understanding how to use the product and identifying your target market.
- It's also important to be aware of any adverse events following the product's application. Understanding the physical and chemical characteristics of the product and the individual ingredients is also crucial. This information is usually found in your COA and the USDA.

Comparing EU and Taiwan cosmetics regulations

There are some differences between PIF requirements in Taiwan and in countries within the European Union (EU). While both require basic product information, testing reports and safety assessment reports, Taiwan's PIF also requires additional documents, such as the evidentiary document of the completed product notification, as well as the full ingredient names and individual content. This makes Taiwan's PIF slightly more comprehensive than the EU's.

DIFFERENCE BETWEEN EU & TAIWAN PIF	
EU	TAIWAN
<ul style="list-style-type: none"> • A description of the cosmetic product • Cosmetic Product Safety Report (CPSR) <ul style="list-style-type: none"> • Part A-Cosmetics Product Safety Information <ul style="list-style-type: none"> • Quantitative and qualitative composition of the cosmetic product • Physical/chemical characteristics and stability of the cosmetic product • Microbiological quality • Impurities, traces, information about the packaging material • Normal and reasonably foreseeable use • Exposure to the cosmetic product • Exposure to the substances • Toxicological profile of the substances • Undesirable effects and serious undesirable effects • Information on the cosmetic product • Part B – Cosmetic product safety assessment <ul style="list-style-type: none"> • Assessment conclusion • Labelled warnings and instructions of use • Reasoning • Assessor's credentials and approval of part B • A description of the method of manufacturing and a statement on compliance with GMP • Proof of the effect claimed for the cosmetic product • Data on any animal testing 	<ol style="list-style-type: none"> 1. Basic information of the product. 2. Evidentiary documents of completing product notification. 3. Full ingredient names and the individual content. 4. The outer packaging of the products, containers, labels or leaflets. 5. GMP compliance certificates or self-declarations. 6. Manufacturing methods and procedures. 7. Usage methods, body parts, dosage, frequencies and the targeted population. 8. Adverse effects of the product application. 9. Physical and chemical characteristics of the products and individual ingredients. 10. Toxicological data of the ingredients. 11. The product stability test reports. 12. The microbiological test reports. 13. The antimicrobial effectiveness test reports. 14. Supporting information of the functional assessments. 15. Information about the packaging materials which have contact with the products. 16. Product safety information <ul style="list-style-type: none"> • Signature by safety assessment and the date, conclusion and suggestion of the safety assessment report. • Qualification documents of safety assessment

A new age for the Taiwanese cosmetics industry

The adjustments to the Taiwan Cosmetic Hygiene and Safety Act have set a new course for the cosmetics industry.

By implementing Product Information Files (PIFs), adhering to Good Manufacturing Practices (GMP) and banning animal testing, Taiwan has enforced progressive strategies aimed at enhancing the safety and quality of cosmetics.

These regulatory changes not only align Taiwan with international standards — they also provide a definitive framework for businesses. As the industry evolves, it's more important than ever for businesses to stay abreast of these regulations, as it secures compliance and reinforces consumer trust.

To amplify their market footprint, businesses need to gain a deeper understanding of the Taiwan regulatory environment. By complying with the Taiwan FDA stipulations for cosmetics, businesses can effectively equip themselves to penetrate this profitable market.

It's critical to keep in mind that these regulations are in place to ensure the safety and efficacy of cosmetics, safeguarding both businesses and consumers alike. With the right knowledge and resources, businesses can navigate these requirements and gain a solid place in the Taiwan market.

SGS cosmetics solutions

With a unique network of more than 40 laboratories and clinical testing sites in North America, Europe and Asia, we offer turnkey and innovative solutions including analytical, microbiological and in vitro testing, clinical studies for safety and efficacy as well as regulatory services from first development to market launch of your cosmetic products.

- Regulation support
- Ingredient review
- Safety assessments and reports
- Stability testing
- Microbiological testing
- Antimicrobial effectiveness testing
- Functional testing
- Packaging comparability testing
- Heavy metal testing
- Prohibited substance testing (e.g. phthalates, 1,4-dioxane, formaldehyde)
- 26 fragrance allergen testing

Contact us

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The SGS logo consists of the letters "SGS" in a bold, sans-serif font. To the right of the letters is a vertical line, and below the letters is a horizontal line, forming an L-shape.

When you need to be sure