COSMETICS

The newly established Cosmetics Committee recognizes and appreciates the efforts of the Taiwan Food and Drug Administration (TFDA) over the past year in promoting smooth communication between the government and industry. A productive win-win relationship is essential to ensure effective policy implementation and maintain a stable business environment for the cosmetics sector in Taiwan.

The Committee welcomes TFDA's initiative to modernize the Statute for Control of Cosmetics Hygiene (the Cosmetics Act for short), which was first promulgated in 1972. We urge TFDA to continue driving regulatory transparency in order to harmonize the Cosmetics Act with similar legislation enacted by Taiwan's major international trading partners. It is vital to avoid adopting unique regulatory requirements that may create technical barriers to trade and pose impediments to entering into bilateral or multilateral trade agreements. In addition, we urge TFDA to encourage areas of industry self-regulation to meet the future needs of the cosmetics market.

We offer the following recommendations:

Suggestion 1: Adopt a regulatory definition of cosmetics that covers the latest technological advances and is harmonized with that of trading partners.

Given the substantial technological advances in the more than 40 years since the Cosmetics Act was first enacted, the regulatory definition of cosmetics in the law is clearly outdated and out of sync with consumer needs. The current statute defines cosmetics as products that freshen the hair or skin, stimulate the sense of smell, cover body odor, or improve facial appearance. Under this definition, products that moisturize and nourish the skin, minimize facial lines of ageing, and protect the skin from harmful UV rays are not included. Yet all of those products are popular with consumers in Taiwan, just as they are with people in major markets around the world.

Consequently, we are pleased to see TFDA take the initiative to modernize the Cosmetics Act. At the same time, we note that the proposed definition of cosmetics in the "Draft Recast Cosmetics Act" announced in late 2016 is still not comprehensive enough, nor is it adequately aligned with the policies of the United States and other leading trade partners.

We urge the government to adopt a broad definition that encompasses all the product types and functions of cosmetics (including lotions serving as sunscreen, creams and lotions with anti-oxidation ingredients for shielding harmful environmental factors, oral care products with perfuming and protection functions, etc.). The most practical approach would be to adopt the definition used by most leading countries and territories: "A substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips, and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors." Emphasis should be placed on the key words *protecting them, keeping them in good condition*, which reflect the function of sunscreen products and skin-nourishing cosmetics such as lip balm, etc.

Suggestion 2: Recognize other countries' Cosmetics GMP as equivalent to Taiwan's under the Cosmetic Act.

Although a Cosmetics GMP (Good Manufacturing Practice) system is mandatory in the EU and ASEAN, both jurisdictions also accept other countries' GMP standards. TFDA, however, intends to regard the Taiwan standard as the only standard, which will inevitably lead to significant technical barriers to trade. Instead, the Taiwan government should recognize the Guidelines for Cosmetics GMP issued by the U.S. Personal Care Products Council (PCPC) and other health authorities as equivalent to the Taiwan Cosmetics GMP. It should also allow companies to self-certify compliance to equivalent overseas GMP standards as a means of fulfilling the Taiwan GMP requirement.

Suggestion 3: Drive regulatory transparency and avoid creating technical barriers to trade in the recast Cosmetics Act.

The Committee urges TFDA to start disclosing its decision-making rationales instead of merely maintaining unpublished internal guidelines. We offer the following specific recommendations:

3.1 Ensure that any restrictions on ingredient use are based on scientific evidence and adopted in a transparent manner. Certain ingredients are subject to limits on the scope of use and the dose, such as active ingredients for Special Use Cosmetics, cosmetic colorants, etc. We urge the Taiwan government to ensure that the adoption of any ingredient restrictions and/or sanitation standards for cosmetics is based on sound science and objective assessments. Scientific references regarding ingredient safety and use conditions can be found from governmental regulatory bodies in major markets, industrial consultation organizations, and such expert sources as the Cosmetics Ingredient Review (CIR) in the United States and the EU's Scientific Committee on Consumer Safety (SCCS).

The ingredient restrictions and sanitation standards should also be aligned with those of major trading partners such as the United States, EU, and Japan. Furthermore, we urge Taiwan to build a regulatory

environment that fosters industry self-regulation to help spur industry advancement rather than impose burdensome constraints. Taiwan should refrain from setting unique regulatory requirements that may result in technical barriers to trade.

*3.2 **Ensure that the proposed new PIF system is workable and reasonable by addressing only critical regulatory needs.*** We appreciate TFDA's assurances that it aims to establish "reasonable" and "workable" Product Information File (PIF) guidelines, with industry given adequate lead time for PIF preparation. As the new Cosmetics Act is in the legislative process, it is time to start considering the detailed guidelines and regulations related to the Act. We urge TFDA to work closely with industry associations and other stakeholders to identify and address the real needs to be met by the regulations, so as to establish a healthy PIF system that avoids creating any technical barriers to trade.

*3.3 **Remove pre-market registration from the new statutory requirements.*** Draft amendments to the Cosmetics Act propose creation of a five-year transition period during which the current pre-market registration system would remain in effect, while at the same time industry would be required to comply with a new system of post-market control through Notification and PIF. Such a dual-control system is a unique regulatory design found in no other country. It would impose a double burden on industry, while bringing no added value in protecting consumers. The Committee urges TFDA to follow the practice of other countries' regulatory bodies, which is simply to rely on post-market surveillance – for example, through Notification and PIF – as well as to foster industry self-regulation.

*3.4 **Regard labeling of the responsible local supplier as sufficient for consumer protection and post-market surveillance.*** The purpose of labeling on cosmetic products is to provide necessary product information to consumers and relevant reference for government agencies during market surveillance. Cosmetic products are typically very small in size. In the interest of efficient and effective labeling, regulations for labeling cosmetic products should aim at ensuring that only meaningful information is required. Such product labeling norms have already been adopted by leading countries and territories.

One of the key pieces of information is the name of the local supplier who holds the product liability. The United States and other leading trade partners of Taiwan do not demand inclusion on the label of any other company in the supply chain. The local product supplier is the entity that the consumer can reach in case of any problem. In line with that logic, the Consumer Protection Act stipulates that the domestic importer or distributor rather than the manufacturer abroad is the liable party for imported products. The current Cosmetics Act requirement for the physical manufacturer or processor to be included in the labeling is meaningless in terms of trade practice and consumer protection. We urge the government to follow the practice of leading countries in requiring only that the name of the local responsible supplier appear on cosmetic product labels.

Suggestion 4: Refrain from creating a unique "Corrective Advertisement" policy.

In contrast to the international best practice of promoting advertising self-regulation, the draft Cosmetics Act authorizes health-administration personnel to determine whether an advertisement or claim is "seriously exaggerating or untrue," including advertising content that is not safety or hygiene related. Violators would be required to broadcast or publish apologies by means of a "Corrective Advertisement." The Committee was distressed to learn that this "Corrective Advertisement" provision, which was previously removed from the draft legislation in the course of a public hearing in 2013, had afterwards been restored. The measure would grant health authorities enormous power, including the ability to damage a company's reputation and brand equity, extending to areas outside their professional competence and without providing the accused with timely recourse to due process in the judicial system.

In a meeting last September discussing AmCham Taipei's major concerns about the proposed new law, TFDA told Chamber representatives that only in the "most serious situation" – involving repeat offenders who have advertised their products with exaggerated or false claims that caused a severe threat to human safety – would TFDA consider taking the extreme step of demanding that the advertisers make public corrective advertisements/statements. TFDA further responded to industry's concern by saying that the term "serious situation" would be clearly defined in the sub-law or executive orders. The statement is not wholly reassuring, however, as it will still be up to the health authorities to decide what is "serious."

The Cosmetic Committee agrees with the previous position of the Retail Committee that the Legislative Yuan should withdraw this proposal. No other country in the world has a similar provision, and there is no need for a "Taiwan-unique" regulation.

If the "Corrective Advertisement" provision becomes effective, it could even be viewed as contravening the freedom of speech guaranteed under the national Constitution. As an alternative approach, we suggest that the authorities engage in broad-based discussions to establish advertising guidelines and a system of industry self-regulation – an approach that has proven its effectiveness in many other markets.

Suggestion 5: Treat toothpaste and mouthwash separately from other products under cosmetics regulations.

Toothpaste and mouthwash will be newly added categories of cosmetics after the amended Cosmetics Act is passed. Since the relevant cosmetics regulations were developed without considering the unique characteristics of toothpaste and mouthwash (particularly the fact that they are immediately rinsed off after use), the Committee urges TFDA to adopt the following measures to assure a smooth transition and minimize the impact on both industry and consumers:

a) ***Provide a sufficiently long transition period.*** A grace period of at least five years is needed for toothpaste and mouthwash manufacturers to prepare to come under the Cosmetics Law. In the meantime, all in-market products should be exempted from the provision of the new law. Although TFDA has conducted several workshops to communicate with industry, businesses are unable to begin assessing or investing in product labeling/formula changes until the final Cosmetics Act is passed and all relevant implementation regulations are settled. This problem is especially acute for multinational companies that source products worldwide and share product labeling/formulations across countries. If the product formulation must be changed, an even longer lead time will be needed to complete the product stability testing.

b) ***Harmonize technical requirements and ingredient standards for toothpaste and mouthwash with those of major trading partners.*** Current cosmetics regulations related to restrictions on ingredients or substances (for example, the cosmetics preservative ingredient list) were established without taking toothpaste and mouthwash into consideration. The Committee urges TFDA to review and make appropriate modifications to the cosmetics preservative ingredient list by accepting the substances allowed in oral care products by any one of Taiwan's major trade partners (such as the United States, EU, or Japan) so as to harmonize with international regulations and avoid adopting unique-to-Taiwan standards or restrictions.

c) ***Distinguish toothpaste from whitening toothpaste and oral preparation in current cosmetic regulations.*** Although toothpastes are not yet classified as cosmetics, TFDA recently incorporated whitening toothpaste and oral preparations with a regulated level of hydrogen peroxide into cosmetic regulations. The Committee urges TFDA to distinguish toothpaste from cosmetic whitening toothpaste/oral preparations in future material to avoid confusion to customers/consumers of the toothpaste industry.