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NAVIGATING THE ASEAN COSMETIC SAFETY FRAMEWORK
- THE ASEAN COSMETIC SCIENTIFIC BODY AND CASE STUDIES

INSIGHTS INTO THE EVOLVING AND EMERGING REGULATIONS GLOBALLY SURROUNDING GREEN CLAIMS

EXPORT VALUE INCREASED BY 8.7% YEAR-ON-YEAR AND TRADE DEFICIT CONTINUING TO NARROW
——ANALYSIS OF FOREIGN TRADE SITUATION OF CHINA'S COSMETICS IN THE FIRST HALF OF THIS YEAR

COSMETICS ADVANCEMENT COMMITTEE OF CHINA HEALTH CARE ASSOCIATION

CHINA COSMETICS

REGULATIONS AND DEVELOPMENT

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Navigating the ASEAN Cosmetic Safety Framework - The ASEAN Cosmetic Scientific Body and Case Studies

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Abstract: Consumer safety assessment of cosmetics and its ingredients are the main driving force for cosmetics regulation in ASEAN. At the ASEAN Cosmetic Scientific Body (ACSB) meetings, ten countries of ASEAN Member States (AMS) have an evidence-based policy making procedure since 2004. Many of cosmetics regulations are based on the ingredient safety assessments which is reviewed and approved by the ACSB members - AMS and ACA. The industry conducts its own safety assessment following the methodology set out in the ASEAN Cosmetic Safety Assessment Guideline and the SCCS Notes of Guidance for the Testing and Safety Assessment of Cosmetic Ingredients. If the methodology complies with these guidances and the safety assessment is robust, ACSB adopt the conclusion, even when the industry's proposal is different from the EU or other region's decision. This paper introduces cosmetic safety framework in ASEAN and an innovative safety assessment case study at ACSB.

Key words: ASEAN Cosmetic Directive (ACD), The ASEAN Cosmetic Scientific Body (ACSB), Zinc Pyrithione (ZPT), Titanium dioxide (nano), Zinc Oxide (nano), cosmetic safety assessment

1. ASEAN Cosmetics Regulation - ACD, ACC, ACSB

1.1 The ASEAN Cosmetic Directive (ACD)

At the ASEAN Economic Ministers' Meeting in September 2003, the member states of ASEAN signed the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS) [1] and

adopted unified guidance for the management of cosmetics, the ASEAN Cosmetic Directive (ACD) [2]. The ACD was developed to enhance cooperation amongst the ASEAN Member States in ensuring the safety and quality of cosmetic products marketed in ASEAN and aims to eliminate technical barriers to trade of cosmetic products without compromising public health and safety to the ASEAN population through the harmonization of technical requirements. All ASEAN members should have undertaken appropriate measures to adopt and implement this in 5 areas of the ASEAN Cosmetic Directive (ACD) which were (i) definition and scope of cosmetics products (ii) ingredients' listing (iii) labelling (iv) product claims and (v) good manufacturing practice (GMP). The levels of ACD implementation could be different among member countries which depend on national regulation background. For example, Indonesia, Malaysia, and Thailand, all of these countries had their existing national cosmetics laws and regulations. In order to implement the ACD in such countries, legal process to transpose the ACD content must be done. For the countries which had no existing cosmetics laws and regulations, such as Singapore, the ACD could be completely implemented. The level of ACD implementation also depends on the country context; culture, language, and way of life [3].

The ACD has provisions from Article 1 to Article 12. Article 1 stipulates that member countries must take the necessary measures to ensure that only cosmetics that comply with the provisions, appendices, and annexes of this directive are placed on the market. However, considering the circumstances of each member country, there are exemptions from the ACD regarding ingredients under certain conditions. Articles 2 to 11 stipulate the definition of cosmetics, safety requirements, a listing of ingredients whose use is prohibited or restricted, as well as coloring agents, preservatives, and UV filters that can be used, the approval procedures for ingredients not included in the above list, which is call ASEAN Handbook, labeling, judgment of whether a cosmetic is in compliance with the ASEAN Directive, the obligation to provide product information, documents on analytical methods, and the establishment of an organization to coordinate, evaluate, and monitor the introduction of ACD (Table 1).

ACD Articles 1 - 12		ACD Appendix I - XIV		ACD Annex I - VII	
1	General Provisions	I	ASEAN Definition of Cosmetic and Illustrative List by Category of Cosmetic Products & Annex I	I	(see Appendix I)
2	Definition and Scope of Cosmetic Product	II	ASEAN Cosmetic Labelling Requirements	II Part 1	List of Substances Which Must Not Form Part of The Composition of Cosmetic Products
3	Safety Requirements	III	ASEAN Cosmetic Claim Guidelines	III Part 1	List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down
4	Ingredients Listings	VI	ASEAN Guidelines for Cosmetic Good Manufacturing Practice	IV Part 1	List of Coloring Agents Allowed for Use in Cosmetic Products
5	ASEAN Handbook of Cosmetic Ingredients	VII	Adverse Event Reporting of Cosmetic Products	VI	List of Preservatives Which Cosmetic Products May Contain
6	Labeling	VIII	Guidelines for Products Information File	VII	List of UV Filters Which Cosmetic Products May Contain
7	Product Claims	IX	Botanical Safety Assessment Guidance Document	VII Part 1	List of Permitted UV Filters Which Cosmetic Products May Contain
8	Product Information	X	ASEAN Sunscreen Labelling Guideline		
9	Product Analysis	XI	ASEAN Guidelines for The Safety Assessment of Cosmetic Products		
10	Institutional Arrangements	XII	Safety Assessment Report		
11	Special Cases	XIII	ASEAN Guidelines on Limits of Contaminants for Cosmetics		
12	Implementation	XIV	Question and Answer on Specific Provisions of the ASEAN Cosmetic Directive		

Table 1: Article of ACD and Technical Documents

1.2 Guideline for the safety assessment of a cosmetic product in ASEAN (ACD Appendix XI)

The ACD stipulates that a cosmetic product put on the market must not cause damage to the human health when applied under normal or reasonably foreseeable condition of use taking into account in particular of the product presentation, its labeling, instruction for its use and disposal warning statements as well as any other information provided by the manufacturer, an authorized agent or person who is responsible for placing the product on the market. Hence cosmetic products must be safe for both consumers and, if relevant, involved professionals including hairdressers, beauticians, etc.

The "GUIDELINES FOR THE SAFETY ASSESSMENT OF A COSMETIC PRODUCT" [4] serves as the important guidance for the safety assessment of cosmetic product in line with Article 8 d of the ASEAN Cosmetics Directive. According to this, first, the safety of raw materials used in the product must be ensured, and then there must be no safety concerns associated with the method of use for example exposure condition, instruction for use, application of cosmetics, at the time of application of cosmetics, etc. If the raw materials and method-of-use are within the range of existing market track records, the track record is important information. On the other hand, when new raw materials are used, or when existing materials are used in a new category

of cosmetic product, a safety evaluation must be conducted considering changes. Health hazards that should be evaluated include local toxicity such as skin irritation, skin sensitisation, and eye irritation, as well as systemic toxicity. For each end point which deems necessary to evaluate, it is possible to use existing information on each raw material or to conduct new tests to evaluate them. When using existing information, any of followings can be referred: the test results of raw material manufacturers, information from the ASEAN Cosmetic Scientific Body (ACSB), scientific literature, databases such as Toxline, and Medline, reports issued by the US Cosmetic Ingredient Review (CIR) program, an opinion published by the EU Scientific Committee on Consumer Safety (SCCS), the Research Institute for Fragrance Materials (RIFM) monographs, reports by ECETOC, NTP, BIBRA, and other domestic and international public databases. After evaluating all raw materials contained in the cosmetic product through literature or testing, a safety evaluation of the product itself may be necessary. Product safety evaluation tests include in vitro tests such as BCOP and human tests such as closed epicutaneous application (single or repeated). Additionally, the new technologies for safety assessment methods are constantly adopting by ACSB. And this safety assessment guidance is also used for preparing the Product Information File (PIF).

1.3 The ASEAN Cosmetic Scientific Body (ACSB) and The ASEAN Cosmetic Committee

The ACC was established in 2003 in accordance with Article 6 "Institutional Arrangements" of the Agreement to oversee and monitor the implementation of the Agreement. They are composed of the ASEAN National Cosmetic Regulatory Authorities and the ASEAN Cosmetics Association (ACA).

In 2004, the ACC agreed to establish the ASEAN Cosmetic Scientific Body (ACSB) [5], which comprises ASEAN Member States (AMS), ACA, and ACSB Secretariat, to assist the ACC with the effective implementation of the ACD by providing technical supports and recommendations based on scientific justification regarding ingredients used or intended to be used or prohibition to be used in the cosmetic products.

The ACSB is supported by Technical Working Groups to facilitate the technical

discussion for specific areas, which will be led by the lead countries for the particular area and may comprise representatives from regulatory authorities, academia and experts from ASEAN Member States.

The functions of the ACSB in achieving its objectives within the scope of its work are as follows, and compatible with SCCS:

(a) facilitate exchange of information on the cosmetics and its ingredients among ASEAN Member States

(b) review and discuss the available technical data on cosmetics and its ingredients, as well as technical and safety issues.

(c) monitor the regulatory developments on the listing of Cosmetic Ingredients, especially in the EU and the relevant draft international standards on cosmetics.

(d) propose new or revised restriction on certain cosmetic ingredient and adaption of new international standards which deem necessary to ensure the safety of consumers for adaption by the ACC.

For ASEAN, the ingredients' listing (ACD Annex) is updated twice a year according to the ACSB meeting and ACC meeting.

2. Case study of Safety Assessment in ACSB

Since 2004, ACSB has been handling scientific discussions on various cosmetic ingredients, particularly the important CMRs in Annex II, restricted ingredients in Annex III, colorant in Annex IV, safety standards for various preservatives in Annex VI, and safety criteria for UVFs in Annex VII. For each of these agendas, ACSB compiles scientific opinions and ACD regulatory proposals based on exposure assessments based on recommended consumer usage, hazard assessments based on the toxicological profiles of the target ingredients, and comprehensive quantitative risk assessments (MoS approach, QRA approach, etc.). The scientifically agreed upon regulatory proposals at the ACSB are approved by the ACC in the form of ACD regulatory revisions, and the ASEAN cosmetic safety regulatory framework is updated regularly.

In this chapter, we will introduce two recent safety assessment case studies from among the examples of evidence-based policy making by ACSB. The first, ZPT, is regulated as a preservative in ACD ANNEX VI and other functions in Annex III. The second is TiO2 (nano) and ZnO (nano) in ACD ANNEX VII. Both are examples of regulatory standards that can guarantee consumer safety based on full scientific evidence.

2.1 Zinc Pyrithione (ZPT)

2.1.1. Introduction to Zinc Pyrithione (ZPT)

Zinc pyrithione (ZPT) is a broad spectrum antibacterial and antifungal agent that has been used worldwide for more than eight decades to treat topical skin conditions, including dandruff [6], and seborrheic/atopic dermatitis [7], as well as providing skin-hygiene benefits [8]. Dandruff is estimated to affect half of the world's population [9], producing scalp-flaking and erythema, which can significantly impact the daily lives and well-being of consumers. ZPT has its origins in a targeted discovery program to model after the natural antibiotic, aspergillic acid and was first synthesized in the 1950s [6]. Aspergillic acid was earlier isolated in the 1940s from Aspergillus strains and was shown to have antimicrobial activity. After it was identified as an antidandruff active in the 1960s, ZPT became a key commercial ingredient in the haircare industry. Subsequently, ZPT emerged to become the most popular antidandruff ingredient globally with listings in over 100 different topical products across multiple regions [10], at concentrations up to 2% in rinse-off formulations.

2.1.2. Classification of ZPT

Prior to March 1, 2022, ZPT was regulated under the EU Cosmetic Regulation as a preservative in rinse-off products (excluding oral hygiene products) up to 0.5% in general and up to 1.0% in hair products (Annex V/8). ZPT was also allowed in a concentration up to 0.1% in leave-on hair products (Annex III/101). In 2018, ZPT was classified as a CMR (i.e., Carcinogenic, Mutagenic or Toxic for Reproduction) substance of category 1B - Toxic for Reproduction, according to Regulation (EC) No. 1272/2008 (CLP Regulation). This highly contentious classification was based on developmental effects which, up until this point, had been attributed to excessive maternal toxicity

at high doses, by experts in developmental reproductive toxicology and multiple regulatory authorities [11,12].

Following the EU classification and in accordance with EU Cosmetic Products Regulation (Regulation (EC) No 1223/2009) Article 15, CMR substances of category 1A or 1B may only be used in cosmetic products by way of exception where certain conditions are fulfilled [13]. Accordingly, the substance needs to meet the following requirements in Article 15.2:

(a) comply with the food safety requirements as defined in Regulation (EC) No 178/2002 of the European Parliament

(b) there are no suitable alternative substances available

(c) application is made for a particular use of the product category with a known exposure, and,

(d) to be evaluated and found safe by the European Scientific Committee on Consumer Safety (SCCS) for use in cosmetic products

With respect to the provision in Article 15.2 (a), the pyrithione moiety is naturally occurring in food (zinc pyrithione is a salt and in the body's systemic circulation will dissociate to the zinc and pyrithione moieties). Specifically, the genus Allium comprises hundreds of species including garlic, onion, shallot, leeks and chives. Allium Stipitatum (syn. Allium hirtifolium Boiss), also known as Persian shallot (musir or mosseer), is one of four plants in this group which pyrithione and pyrithione disulfide have been identified [14,15,16]. Persian Shallot (Allium stipitatum) is recognized as food by Regulation (EC) No 396/2005. Annex I of Regulation (EC) No 396/2005 lists Persian Shallot as a food in or on which pesticide residues may be present [17]. Persian Shallot is also listed as a food type with the UK Food Standards Agency [18].

Although not used as a direct food additive, ZPT has been addressed under national provisions governing food safety, namely in food contact materials. The US FDA has accepted the use of ZPT, by Arch Chemicals, as a preservative in paper and board food contact materials (FCN No. 1169) [19]. In Germany, ZPT is included in BfR

recommendation XXXVI (2017) for paper and cardboard in food contact as well as in recommendation XIV (2016) for polymer-dispersions in food contact, with maximum use levels of 17 µg/dm (as preservative) and 8 µg/dm (as processing aid), respectively. Based on this recommendation, ZPT is included in food contact applications of paper, cardboard, and polymer-dispersions across Europe. Accordingly, ZPT can be considered to comply with food safety requirements, thus fulfilling the provisions of Article 15.2 (a) of the Cosmetics Regulation.

Most importantly, the EU Scientific Committee on Consumer Safety (SCCS) and its predecessor, the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) have reviewed the safety of ZPT on four separate occasions. With each and every single review, the SCCS came to the same conclusion that ZPT is safe for cosmetic applications. In its latest Opinion published in 2020, the SCCS concluded that ZPT can be considered safe when used as an antidandruff active in rinse-off hair products up to a maximum concentration of 1% thus meeting the requirements of Article 15.2 (c) & (d)) [20, 21]. However, it was not established that there are no suitable alternative substances available with regards to antidandruff actives in rinse-off hair products (Article 15.2 (b)). Consequently, for only this reason, the EU has decided to add ZPT to the list of substances prohibited in cosmetics (Annex 2) [22].

2.1.3. ZPT Regulatory Status in ASEAN

In ASEAN, ZPT is listed in the ASEAN Cosmetic Directive (ACD) Annex III and Annex VI whereby it is allowed at a concentration up to 2.0% in rinse-off hair products and up to 0.1% in leave-on hair products (Annex III/101) in addition to being allowed as a preservative in rinse-off products (excluding oral hygiene products) to 0.5% in general and up to 1.0% in hair products (Annex VI/8) [23]. The question on whether to follow EU and ban ZPT in ASEAN was first raised at the 35th ACSB (May 2022) and the ASEAN Cosmetics Association (ACA) presented a preliminary defense on the safety of ZPT, which was followed-up with additional safety data and more in-depth safety assessment calculations to support the safety of the various applications at subsequent ACSB meetings.

2.1.4. Summary of SCCS Opinions Related to ZPT and Calculations of Additional Margin of Safety (MoS) Presented at the ACSB meetings

ZPT has a long history of safe use with well-established and documented safety reviews. In their independent reviews beginning in 2002 [20] and again in 2014, 2018 and 2020 [24, 25, 21], the SCCS reconfirmed that ZPT is safe for consumers in rinse-off hair care products (Figure 1). It is noteworthy to highlight that the margin of safety (MoS) in these Opinions are well within the range of > 1000 to > 8000 for the various intended cosmetic applications.

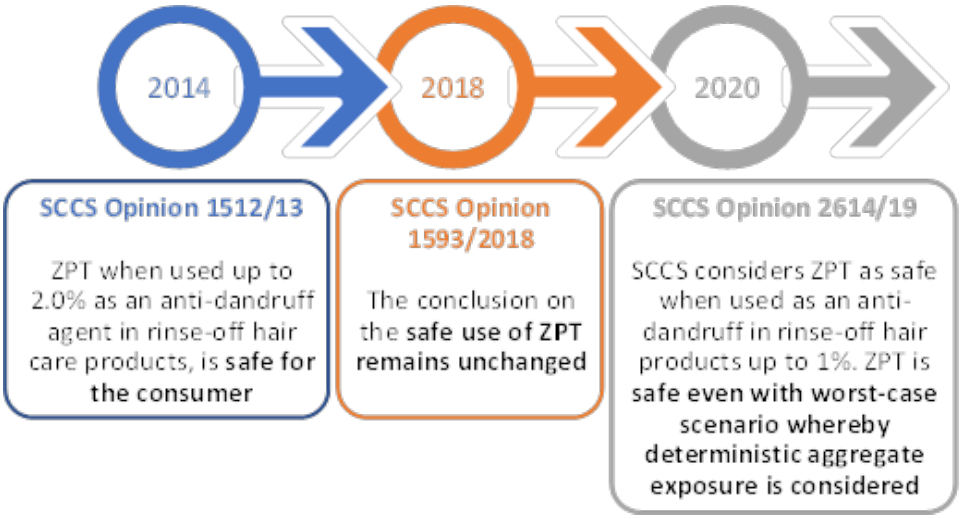


Figure 1: Timeline and respective conclusions from SCCS Opinions on ZPT

SCCS Opinion on ZPT (Safe for Rinse-Off Hair Products):

For shampoo and conditioner:

Absorption through the skin	**DA_p**	= 1%
Amount of product applied daily	**A**	= 2.17 mg/kg/d
Concentration of ingredient in product	**C**	= 1%
Systemic exposure dose (SED)	**A x C /100 x DA_p**	= 0.000217 mg/kg/d
No adverse observed effect level (oral chronic/carcinogenicity study)	**NOAEL**	= 0.5 mg/kg/d
Bioavailability 100%		= 0.5 mg/kg/d
Bioavailability 88% (based on SCCS 2014)		= 0.44 mg/kg/d

Margin of Safety (Bioavailability 100%)	**NOAEL/SED**	=	**2304**
Margin of Safety (Bioavailability 88%)	**NOAEL/SED**	=	**2027**

Figure 2: Calculation of Margin of Safety (MoS) for rinse-off hair products containing ZPT by SCCS (2020)

In the SCCS Opinion (2020) [21], the safety of ZPT in antidandruff shampoo and conditioner when used at 1% was confirmed after a very high MoS was calculated despite a worst-case scenario using a deterministic aggregate exposure being applied (Figure 2). This deterministic method is used by the SCCS for assessing exposure to preservatives in cosmetics [26].

The SCCS Opinion (2020) did not include MoS safety calculation for leave-on hair application as it was not requested of SCCS. However, such application is popular in ASEAN and using the same methodology as the SCCS Notes of Guidance (2021) [26],

Safe Use for Hair-Styling Product with 0.1% ZPT:

Absorption through the skin	DA_p	= 1%
Amount of product applied daily	A	= 5.74 mg/kg bw/d (SCCS Notes of Guidance, 2021)
Concentration of ingredient in product	C	= 0.1%
Systemic exposure dose (SED)	A x C/100 X DA_p	= 0.0000574
No observed adverse effect level (Oral chronic/carcinogenicity study)	NOAEL	= 0.5 mg/kg bw/d
Bioavailability 100%		= 0.5 mg/kg bw/d
Bioavailability 88% (based on SCCS 2014)		= 0.44 mg/kg bw/d
Margin of Safety (Bioavailability 100%)	**NOAEL/SED**	**= 8,711**
Margin of Safety (Bioavailability 88%)	**NOAEL/SED**	**= 7,666**

Figure 3: Calculation of Margin of Safety (MoS) for hair-styling product containing ZPT

Safe Use for Leave-On & Rinse-Off products with ZPT:

Using a very conservative deterministic exposure assessment for 0.1% leave-on and 1% rinse-off (shampoo + conditioner) hair products combined daily-use

Systemic exposure dose (SED)	A x C/100 X DA_p	= 0.0000574 + 0.000217 = 0.0002744
No observed adverse effect level (Oral chronic/carcinogenicity study)	NOAEL	= 0.5 mg/kg bw/d
Bioavailability 100%		= 0.5 mg/kg bw/d
Bioavailability 88% (based on SCCS 2014)		= 0.44 mg/kg bw/d
Margin of Safety (Bioavailability 100%)	**NOAEL/SED**	**= 1,822**
Margin of Safety (Bioavailability 88%)	**NOAEL/SED**	**= 1,603**

Figure 4: Calculation of MoS for aggregate exposure of leave-on & rinse-off products containing ZPT

it is possible to add hair-styling product application using a deterministic aggregate exposure whereby it is assumed all consumers will be using a shampoo (1% ZPT), conditioner (1% ZPT), and hair-styling product (0.1%) every single day (Figure 3 & 4). The resultant calculation showed the MoS to be well in excess of 1,600.

However, some ASEAN Member States (AMS) requested additional information regarding the use of ZPT as a preservative in other non-hair cosmetic applications to justify maintaining its status in Annex VI of the ACD. At the 39th ACSB meeting (Nov, 2023), ACA presented additional safety information and calculations on ZPT as below.

Rinse-Off (Non-Hair) Products (as a preservative) – Safe Use for Shower Gel + Hand Soap Products with 0.5% ZPT:

For rinse-off (non-hair) products

Absorption through the skin	DA_p	= 1%
Amount of product applied daily	A	= 2.79 + 3.33 = 6.12 mg/kg bw/d (SCCS Notes of Guidance, 2021)
Concentration of ingredient in product	C	= 0.5%
Systemic exposure dose (SED)	A x C/100 X DA_p	= 0.000306
No observed adverse effect level (Oral chronic/carcinogenicity study)	NOAEL	= 0.5 mg/kg bw/d
Bioavailability 100%		= 0.5 mg/kg bw/d
Bioavailability 88% (based on SCCS 2014)		= 0.44 mg/kg bw/d
Margin of Safety (Bioavailability 100%)	**NOAEL/SED**	**= 1,634**
Margin of Safety (Bioavailability 88%)	**NOAEL/SED**	**= 1,437**

Figure 5: Calculation of MoS for rinse-off (non-hair) products containing ZPT

Assuming an exaggerated scenario whereby ZPT is used in rinse-off (non-hair) applications such as shower gel and hand soap where high amount of the products are applied together, the calculations showed a MoS to be above 1,400 (Figure 5).

As before, we can then consider a deterministic aggregate exposure whereby it is assumed all consumers will be using a shampoo (1% ZPT), conditioner (1% ZPT), hair-styling product (0.1%), shower gel (0.5%), and hand soap (0.5%) every single day (Figure 6). The resultant calculation showed the MoS to be above 700. Even in such an exaggerated and somewhat unrealistic exposure scenario whereby practically all these products, which a consumer is using will contain ZPT, we still see a MoS well in excess of 100. This clearly demonstrates in the worst-case scenario,

the use of ZPT in these cosmetic products is not anticipated to be of concern to the health and well-being of consumers.

Leave-On & Rinse-Off Combined Products Daily Use – Safe Use for ZPT

Using a very conservative deterministic exposure assessment for 0.1% leave-on product, 1% rinse-off hair (shampoo + conditioner) products & 0.5% shower gel/hand soap combined daily-use

Systemic exposure dose (SED)	A x C/100 X DA_P	= 0.0000574 + 0.000217 + 0.000306 = 0.0005804
No observed adverse effect level (Oral chronic/carcinogenicity study)	NOAEL	= 0.5 mg/kg bw/d
Bioavailability 100%		= 0.5 mg/kg bw/d
Bioavailability 88% (based on SCCS 2014)		= 0.44 mg/kg bw/d
Margin of Safety (Bioavailability 100%)	**NOAEL/SED**	**= 861**
Margin of Safety (Bioavailability 88%)	**NOAEL/SED**	**= 758**

Figure 6: Calculation of MoS for aggregate exposure of leave-on & rinse-off products containing ZPT including rinse-off (non-hair) products

It is also worthwhile to note that the SCCS Opinion (2020), considered new information on a combined repeated-dose toxicity and carcinogenic toxicity rat study with sodium pyrithione (NaPT), which was made available and evaluated by the SCCS [21]. As there were treatment-related degenerative changes of sciatic nerve and skeletal muscle described in all treatment groups from the NaPT study, the SCCS considers 0.5 mg /kg bw/d as the NOAEL for NaPT. The substance was not found to be carcinogenic in the study. Studies performed in pigs using NaPT and ZPT pointed to a common metabolic pathway (see Diamond et al. (2017) [27] and (2021) [28] for pharmacokinetic details). Furthermore, neither Zn2+ nor Na+ ions are considered to be neurotoxic at the doses which produced such effects in rodents. Thus, it can be assumed that neurotoxic effects observed after ZPT exposures were due to the pyrithione moiety. The SCCS concluded that the results from other pyrithione-liberating salts could support the findings obtained with ZPT and therefore, chronic studies performed with NaPT were considered as supporting studies. Based on the available data, the SCCS also concluded that ZPT is unlikely to be of concern with respect to fertility. The adverse effects on development were observed at higher dosages than those leading to neurotoxic effects, with the latter being considered by the SCCS as the most sensitive endpoint in animal studies

with the above NOAEL considered as the point of departure (POD).

In accordance with SCCS Notes of Guidance, the SCCS did not use the NOAEL from the reproductive toxicity study and chose a more conservative endpoint for MoS calculation, which still shows more than adequate Margin of Safety (MoS with a factor of thousands). It is worthwhile to note that the US Environmental Protection Agency (EPA) came to the same conclusion as the SCCS that there is no evidence of quantitative susceptibility in developmental and reproductive toxicity studies of ZPT [12]. Lastly, and perhaps most important, NaPT itself is not classified in the EU as a reproductive toxicant under ECHA CLP [29]. If we consider pyrithione as the toxic moiety associated with both ZPT and NaPT, then it becomes obvious that there is a striking inconsistency with the different CLP classifications.

The rationale for classifying and ultimately prohibiting ZPT is inconsistent with multiple historical regulatory reviews, opinions of reproductive toxicology experts, and at odds with regulations in established geographies such as Australia, Canada and the United States. Despite the favorable SCCS Opinions on the safety of ZPT in hair rinse-off cosmetic applications, the eventual decision in EU to prohibit ZPT was a result of the failure to satisfy one of the exemption clauses for CMR (carcinogenic, mutagenic, or reproductive toxicity) ingredients in Article 15.2 (b) [13], which stipulates that 'there are no suitable alternative substances available'. The EU decision on ZPT is primarily driven by hazard classification as part of EU-specific chemical legislation that does not assess safe-use in cosmetics. Its eventual ban being a ramification of a "downstream" regulatory framework, which does not exist in markets outside of the EU. Any potential prohibition of a safe cosmetic ingredient due to application of a non-cosmetic and non-safety-related regulatory framework outside of the EU region will have significant adverse economic ramifications and inadvertently inhibit industry innovation while limiting consumer choices.

At the 39th ACSB meeting (May 2024), after 2 years of discussions between ACA and the AMS on the CMR criteria for ASEAN, which will not take into account the

EU-specific and non-safety requirements in conjunction with the safety information and calculations on ZPT applications in cosmetics at the ACSB meetings, all ASEAN Member States with the exception of the Philippines (which announced that they need to have additional internal consultations) finally agreed to adopt a new ASEAN Criteria for CMR Categories 1A and 1B for cosmetic products which does not include the EU Article 15.2 (b) equivalent (Figure 7). Based on the application of the new ASEAN CMR Criteria in addition to focusing primarily on the safety assessment data and MoS calculations, all AMS except the Philippines (for reasons stated above) agreed to allow the continuing usage of ZPT in cosmetic products. ZPT is allowed in ASEAN as follows: (a) at concentrations up to 1.0% in hair rinse-off products, (b) 0.1% in leave-on hair products (ACD Annex III, Ref. No. 101), and as a preservative in (c) rinse-off products up to 1.0% in hair products, and (d) rinse-off nonhair care products (excluding oral hygiene products) for up to 0.5% (ACD Annex VI, Ref. No. 8). Crucially, ZPT has laid the foundation and precedent to ensure other similar safe cosmetic ingredients are not removed from the ASEAN market due to non-safety reasons.

CMR Category 1A: **a) The application is made for a particular use with a known exposure; b) Substance has been evaluated by ACSB and found safe for use in cosmetic products, in particular in view of exposure to those products; and c) There are no alternative substances available**
CMR Category 1B: **a) The application is made for a particular use with a known exposure; and b) Substance has been evaluated by ACSB and found safe for use in cosmetic products, in particular in view of exposure to those products**
CMR Category 2: **Substances have been evaluated by the ACSB and found safe for use in cosmetic products**

Figure 7: ASEAN CMR Criteria

In the cosmetic industry, regulatory changes have a tendency to migrate across regions. It is evident from the global regulatory status for ZPT (Figure 8) that it is crucial to continue advocating for a science risk-based approach in regulating ZPT to avoid adverse commercial and technical burden to the industry, particularly across non-EU markets. Like ASEAN, other regions have also recently reviewed ZPT based on safety considerations and came to the conclusion not to follow the ban in EU. In

August 2023, Brazil notified a change to its cosmetic regulation to align with Mercosur Resolution no. 35/22, which allows for the use of ZPT as an antidandruff active at 1% in rinse-off hair products. Similarly last year, the New Zealand EPA initially proposed to ban ZPT in cosmetics to follow EU but after discussion with the industry and evaluating its safety, the NZ EPA made the final decision in January 2024 to retain the entry of ZPT in both Schedule 5 (Restricted List - 0.1% in leave-on hair products) and Schedule 7 (Preservative List – 1% in rinse-off hair products & 0.5% in other rinse-off products) of the New Zealand Cosmetic Products Group Standard [30].

Market	Maximum allowable regulatory limits	
	Rinse off	Leave on
US (OTC)	0.3-2% (as anti-dandruff agent)	0.1-0.25%
Canada (OTC)	0.3-2%	0.1-0.25%
China	1.5% (as anti-dandruff agent) 0.5% (as preservative)	0.1%
Japan	Cosmetic (no AD claim): 0.1% QD: 0.3-1.0% as Shampoo 0.3-0.75% as Conditioner	Cosmetic (no AD claim): 0.01%
Taiwan	1% (as preservative in hair rinse off)	0.1% (for purposes other than preservative)
Australia	2%	0.5% (immobilized in solid prep)
New Zealand	1% (for hair products)	0.1% (for purposes other than preservative)
India	1% (for hair products)	0.1% (for purposes other than preservative)

Figure 8: Global Regulatory Landscape for ZPT in Cosmetics

2.1.5. Efficacy of ZPT

In order to understand the importance and utility of ZPT in the cosmetic industry, it is worthwhile to highlight its high level of efficacy as a preservative and antidandruff active, which stems from two key attributes. First, ZPT has a very broad antimicrobial spectrum of activity, spanning from fungi (of both mold and yeast forms) to gram-positive and -negative bacteria [31,32,33]. In a recent study conducted at the Skin Research Institute of Singapore [34, 35], the superior efficacy of ZPT in inhibiting Malessezia growth (the Malessezia species are associated with the pathogenesis of dandruff and seborrheic dermatitis) was further validated against a panel of shampoo-relevant antifungals, wherein ZPT had the lowest

minimal inhibitory concentration (MIC) amongst non-antifungal and antifungal shampoo isolates of M. globosa.

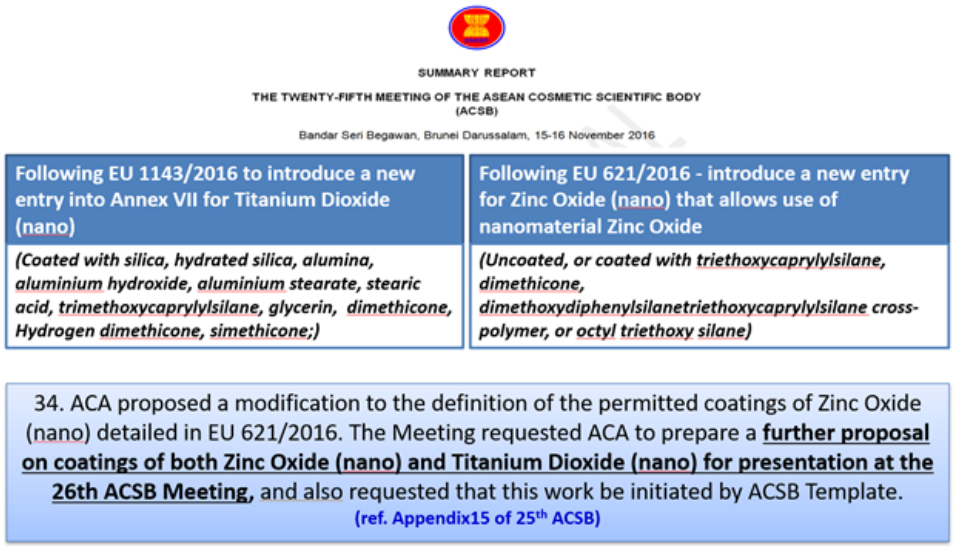
The second attribute pertains to its tendency for persistence as a consequence of the 'reservoir' effect which primarily stems from its topical delivery as a physical particle to slowly release active molecules over an extended duration to enact its antimicrobial efficacy [36, 37]. In addition to the pyrithione portion of ZPT, the delivery of zinc itself may also confer topical skin benefits similar to other more well-known skin protectants such as zinc oxide, zinc carbonate and zinc acetate. In a related study, ZPT has been demonstrated to inhibit surfactant irritancy caused by cleansing products [38]. While the 'reservoir effect' can also be observed with some other antimicrobial actives, the key differences and advantage of ZPT can be seen in its broad-spectrum antimicrobial efficacy and dual skin-care benefits.

2.1.6. Conclusion of ZPT

ZPT has been used for decades because it is safe and efficacious. Based on the SCCS Opinions and the ACSB's additional safety assessment review of ZPT, ASEAN recognized that the inclusion of ZPT in cosmetics is safe for consumer use.

The classification and subsequent ban in EU represent a failure in the European regulatory framework, which classifies and labels hazard without considering risk-based safety assessments. Unless there is a clear understanding of the regulatory context and ingredient safety assessments, some countries may choose to adopt the EU ban of ZPT in cosmetics. This will deprive the industry and consumers of a proven highly effective preservative and antidandruff agent with a long history of safe use. This will also hinder potential trade with many major trading partners that have assessed the safety and continue to allow the use of ZPT in cosmetic products. ASEAN recognized these concerns and have chosen to implement a regulatory framework by way of the ASEAN CMR Criteria, which will provide ASEAN with more flexibility to evaluate robustly the safety of cosmetic ingredients without factoring other non-safety considerations or region-specific requirements. This will ensure the continuing progress of innovation

in ASEAN for the cosmetics industry. To this end, ZPT is a landmark case study where a key geographical and trading region developed a science-based regulatory framework and additional safety assessment to support the continuing use of a safe cosmetic ingredient instead of just following the regulatory outcomes from EU.



SUMMARY REPORT

THE TWENTY-FIFTH MEETING OF THE ASEAN COSMETIC SCIENTIFIC BODY (ACSB)

Bandar Seri Begawan, Brunei Darussalam, 15-16 November 2016

Following EU 1143/2016 to introduce a new entry into Annex VII for Titanium Dioxide (nano)	Following EU 621/2016 - introduce a new entry for Zinc Oxide (nano) that allows use of nanomaterial Zinc Oxide
(Coated with silica, hydrated silica, alumina, aluminium hydroxide, aluminium stearate, stearic acid, trimethoxycaprylylsilane, glycerin, dimethicone, Hydrogen dimethicone, simethicone;)	*(Uncoated, or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilanetriethoxycaprylylsilane cross-polymer, or octyl triethoxy silane)*

34. ACA proposed a modification to the definition of the permitted coatings of Zinc Oxide (nano) detailed in EU 621/2016. The Meeting requested ACA to prepare a **further proposal on coatings of both Zinc Oxide (nano) and Titanium Dioxide (nano) for presentation at the 26th ACSB Meeting**, and also requested that this work be initiated by ACSB Template.
(ref. Appendix15 of 25th ACSB)

Figure 9: Background of Background for nanomaterial proposal (ref. Appendix of 26th ACSB)

2.2. ACD AnnexVII: Safety assessment of Titanium Dioxide (nano) and Zinc Oxide (nano)

2.2.1. Rationale for safety assessment of nano materials and its coatings in cosmetics

Recently, nanomaterial technology has advanced rapidly and has been applied to various products including cosmetics. Accordingly, ACSB has been having scientific discussions on Titanium Dioxide (nano) and Zinc Oxide (nano) (Figure 9). The 26th ACSB meeting focused on the safety assessment of TiO2 (nano) and ZnO (nano) coating materials, because the nanoforms of the core TiO2 and ZnO have already been evaluated as safe for cosmetic use in a SCCS Opinions (SCCS/1489/12 [39], SCCS/1518/13 [40], SCCS/1516/13 [41], SCCS/1539/14 [42], etc. 2012-16).

"Coating" differs from "surface treatments" such as metal vapor deposition and plating, which change the properties of a surface through processing (chemical reaction), in that it refers to covering the surface with another substance for decorative purposes and is a process of "blending" rather than chemical reaction (Figure 10). It suggests that if the coating material itself has been demonstrated to be safe as a cosmetic

ingredient, safe to use as coating (submited data to ACSB, including behavior and/or effects) (Figure 11).

Because of the above points, ACSB well discussed and approved a modification to the definition of the permitted coatings of TiO2 (nano) and ZnO (nano) detailed in EU 1143/2016 [43] and EU 621/2016 [44], respectively.

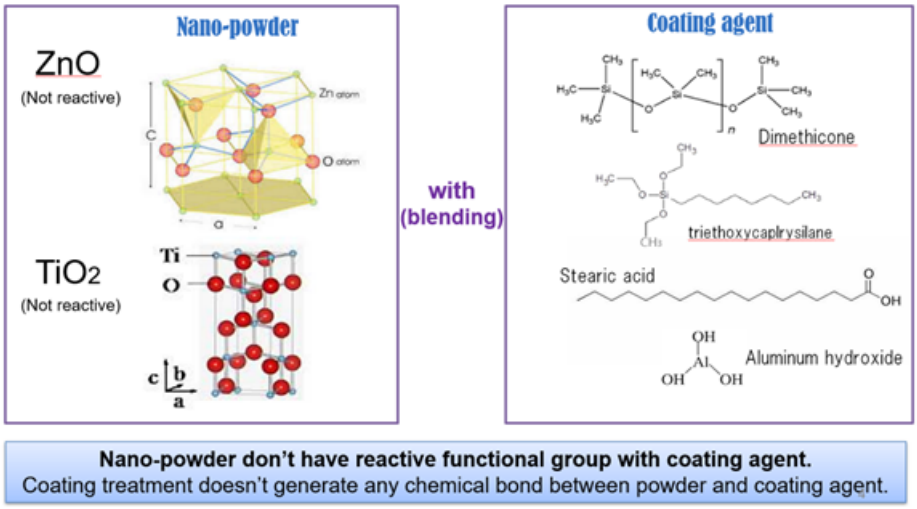


Figure 10: Safety Assessment of Coating agent (ref. Appendix of 26th ACSB)

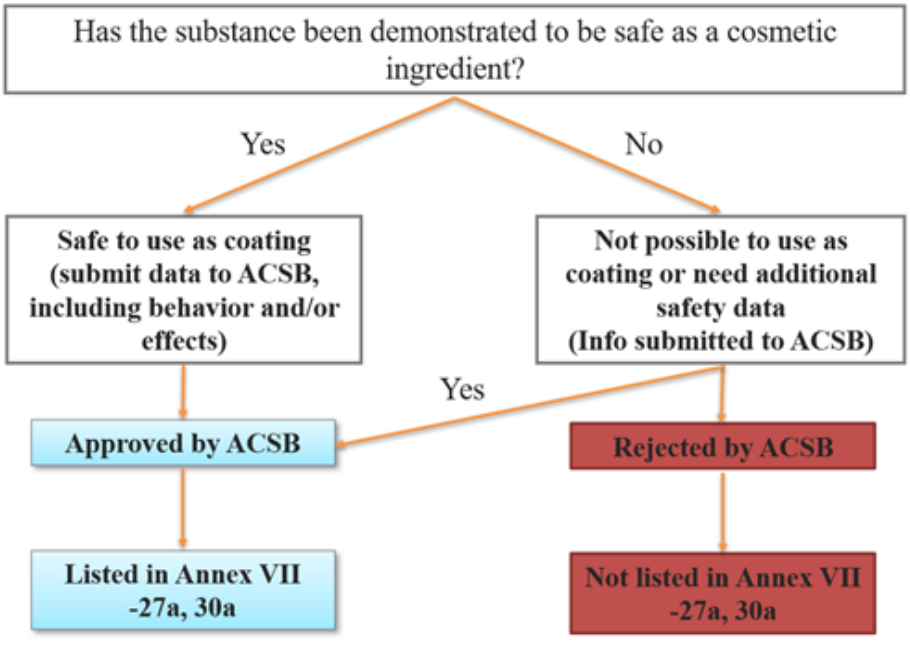


Figure 11: Decision tree for safety assessment of coatings (ref. Appendix of 26th ACSB)

2.2.2. List of current coating materials for nano - TiO2 (nano) & ZnO (nano) and overall safety assessment as a UV-filter in cosmetics

The 26th ACSB approved the safe use of TiO2 (nano) and ZnO (nano) with various coating blending mixture in cosmetics. Currently used coating materials for ZnO and TiO2 in Japan, Asian and ASEAN market are fully assessed in the Table 2 - 4 and concluded as safe for leave-on sunscreen products usage.

2.2.2.1. Safety Evaluation of Titanium dioxide (nano) as a UV-filter in Cosmetics

(1) Titanium dioxide is currently allowed as a UV-filter in cosmetic products, including in the form of nanomaterial. Titanium dioxide (nano) is listed in entry 27a of Annex VII to ASEAN Cosmetic Directive (ACD). It is allowed at a maximum concentration of 25 % in ready-for-use preparation, except in applications that may lead to exposure of the end user's lungs by inhalation and subject to the characteristics listed in the entry.

(2) The characteristics listed in entry 27a of Annex VII concern the allowed physico-chemical properties of titanium dioxide (nano) and the substances with which it can be coated. The ACSB concluded in the 26th meeting, that the use of the 26 forms of titanium dioxide (nano) under assessment, coated with silica, hydrated silica, alumina, aluminium hydroxide, aluminium stearate, stearic acid, trimethoxycaprylylsilane, glycerin, dimethicone, hydrogen dimethicone, simethicone (EU2019/1857) [45], or isostearic acid, magnesium hydroxide, distearyldimonium chloride, cetyl phosphate, manganese dioxide, methicone, alkyl methicone, lauroyl lysine, alkyl dimethicone, hydrated silica, stearic acid, trimethylsiloxysilicate, magnesium stearate, polymethylsilsesquioxane, dimethicone/vinyl dimethicone crosspolymer, can be considered safe for use in cosmetic products intended for application on healthy, intact or sunburnt skin. The ACSB added that this conclusion, however, does not apply to applications that might lead to exposure of the consumer's lungs to the titanium dioxide nanoparticles through the inhalation route (such as sprayable products). In light of the ACSB scientific review, these combinations of coatings as assessed should be allowed for use with titanium dioxide (nano) as a UV-filter, subject to the other conditions laid down in entry 27a of Annex VII to ACD.

	Coating Materials for TiO2 (INCI name)	Existing /New	Concentration in TiO2 (RM)	Concentration in Final Products	Safety Assessment (Safe limit)	Behavior/effect of TiO2/coating			Evaluation (Leave-on use)
						Coating Stability	Skin Penetration	Photo Stability	
1.	ISOSTEARIC ACID	Existing	1 - 20 %	0.25 - 5 %	10 % (CIR2005)	Stable	Not penetrate	Stable	Safe
2.	MAGNESIUM HYDROXIDE	Existing	1 - 2 %	0.25 - 0.5 %	Safe (CIR2015)	Stable	Not penetrate	Stable	Safe
3.	Distearyldimonium Chloride	Existing	1 - 2 %	0.25 - 0.5 %	1 % (Japan JCLS)	Stable	Not penetrate	Stable	Safe
4.	Cetyl Phosphate	Existing	1 - 6 %	0.25 - 1.5 %	Safe (SCCS2016) 2 % (CIR2014)	Stable	Not penetrate	Stable	Safe
5.	Manganese Dioxide	Existing	0.1 - 0.7 %	0.025 - 0.175 %	Safe (SCCS2016) 1272/2008 Annex VI	Stable	Not penetrate	Stable	Safe
6.	Triethoxycaprylylsilane	Existing	1 - 9 %	0.25 - 2.25 %	Safe (SCCS2016) 2.6 % (CIR2016)	Stable	Not penetrate	Stable	Safe
7.	Methicone	Existing	1 - 10 %	0.25 - 2.5 %	5 % (CIR2003)	Stable	Not penetrate	Stable	Safe
8.	Alkyl Methicone	Existing	1 - 10 %	0.25 - 2.5 %	5 % (CIR2003)	Stable	Not penetrate	Stable	Safe
9.	Lauroyl Lysine	Existing	1 - 10 %	0.25 - 2.5 %	14 % (CIR2014)	Stable	Not penetrate	Stable	Safe
10.	Alkyl Dimethicone	Existing	1 - 10 %	0.25 - 2.5 %	3 % (CIR2003)	Stable	Not penetrate	Stable	Safe

Table 2: Full review Table of Titanium Dioxide (nano) and its coatings in current cosmetics (ref. Appendix of 26th ACSB)

	Coating Materials for TiO2 (INCI name)	Existing /New	Concentration in TiO2 (RM)	Concentration in Final Products	Safety Assessment (Safe limit)	Behavior/effect of TiO2/coating			Evaluation (Leave-on use)
						Coating Stability	Skin Penetration	Photo Stability	
11.	Hydrated Silica	Existing	1 - 16 %	0.25 - 4 %	4 % (CIR2009)	Stable	Not penetrate	Stable	Safe
12.	Stearic Acid	Existing	1 - 10 %	0.25 - 2.5 %	16 % (CIR2006)	Stable	Not penetrate	Stable	Safe
13.	Trimethylsiloxysilicate	Existing	1 - 10 %	0.25 - 2.5 %	30 % (CIR2013)	Stable	Not penetrate	Stable	Safe
14.	Magnesium stearate	Existing	1 - 10 %	0.25 - 2.5 %	5 % (CIR2003)	Stable	Not penetrate	Stable	Safe
15.	Polymethylsilsesquioxane	Existing	1 - 10 %	0.25 - 2.5 %	3 % (CIR2003)	Stable	Not penetrate	Stable	Safe
16.	Dimethicone/ Vinyl Dimethicone Crosspolymer	Existing	1 - 20 %	0.25 - 5 %	46 % (CIR2014)	Stable	Not penetrate	Stable	Safe

Table 3: Full review Table of Titanium Dioxide (nano) and its coatings in current cosmetics (Continued) (ref. Appendix of 26th ACSB)

2.2.2.2. Safety Evaluation of Zinc Oxide (nano) as a UV-filter in Cosmetics

(1) Zinc Oxide is currently allowed as a UV-filter in cosmetic products, including in the form of nanomaterial. Zinc Oxide (nano) is listed in entry A29a of Annex VII to ASEAN Cosmetic Directive (ACD). It is allowed at a maximum concentration of 25 % in ready for use preparation, except in applications that may lead to exposure of the end user's lungs by inhalation and subject to the characteristics listed in the entry.

(2) The characteristics listed in entry A29a of Annex VII concern the allowed physico-chemical properties of Zinc Oxide (nano) and the substances with which it can be coated. The ACSB concluded in the 26th meeting, that the use of the 15 forms of Zinc Oxide (nano) under assessment, uncoated, or coated with triethoxycaprylylsilane, dimethicone, dimethoxydi phenylsilanetriethoxycaprylylsilane cross-polymer, or octyl triethoxy silane (EU2016/621) or hydrogen dimethicone, dextrin palmitate, hydrated silica, distearyldimonium chloride,

methicone, alkyl methicone, iron oxides, agar, glyceryl caprylate/caprate, caprylic/capric triglyceride can be considered safe for use in cosmetic products intended for application on healthy, intact or sunburnt skin. The ACSB added that this conclusion, however, does not apply to applications that might lead to exposure of the consumer's lungs to the Zinc Oxide nanoparticles through the inhalation route (such as sprayable products). In light of the ACSB scientific review, these combinations of coatings as assessed should be allowed for use with Zinc Oxide (nano) as a UV-filter, subject to the other conditions laid down in entry A29a of Annex VII to ACD.

Coating Materials for ZnO (INCI name)		Existing /New	Concentration in ZnO (RM)	Concentration in Final Products	Safety Assessment (Safe limit)	Behavior/effect of ZnO/coating			Evaluation (Leave-on use)
						Coating Stability	Skin Penetration	Photo Stability	
1.	Hydrogen Dimethicone	Existing	1 - 6.5 %	0.25 - 1.625 %	Safe as coating nano TiO2 (SCCS2013)	Stable	Not penetrate	Stable	Safe
2.	Dextrin Palmitate	Existing	1 - 10 %	0.25 - 2.5 %	16.8 % (CIR2015)	Stable	Not penetrate	Stable	Safe
3.	Hydrated Silica	Existing	1 - 16 %	0.25 - 4 %	4 % (CIR2009)	Stable	Not penetrate	Stable	Safe
4.	Distearyldimonium Chloride	Existing	1 - 3 %	0.25 - 0.75 %	1 % (Japan JCLS)	Stable	Not penetrate	Stable	Safe
5.	Methicone	Existing	1 - 10 %	0.25 - 2.5 %	5 % (CIR2003)	Stable	Not penetrate	Stable	Safe
6.	Alkyl Methicone	Existing	1 - 10 %	0.25 - 2.5 %	5 % (CIR2003)	Stable	Not penetrate	Stable	Safe
7.	Iron Oxides	Existing	1 - 4 %	0.25 - 1 %	No limit ACD Annex IV (colorant)	Stable	Not penetrate	Stable	Safe
8.	Agar	Existing	1 - 4 %	0.25 - 1 %	1 % (CIR2015)	Stable	Not penetrate	Stable	Safe
9.	Glyceryl caprylate/caprate	Existing	1 - 3 %	0.25 - 0.75 %	1 % (CIR2015)	Stable	Not penetrate	Stable	Safe
10.	Caprylic/Capric Triglyceride	Existing	1 - 10 %	0.25 - 2.5 %	45 % (CIR2003)	Stable	Not penetrate	Stable	Safe

Table 4: Full review Table of Zinc Oxide (nano) and its coatings in current cosmetics (ref. Appendix of 26th ACSB)

2.2.3. Conclusion on safety criteria of Nanomaterial with coatings

At the 26th ACSB meeting, silica, hydrated silica, alumina, aluminum hydroxide, aluminum stearate, stearic acid, trimethoxycaprylylsilane, glycerin, dimethicone, hydrogen dimethicone, simethicone, isostearic acid, magnesium hydroxide, distearyldimonium chloride, cetyl phosphate, manganese dioxide, methicone, alkyl methicone, lauroyl lysine, alkyl dimethicone, hydrated silica, stearic acid, trimethylsiloxysilicate, magnesium stearate, polymethylsilsesquioxane, dimethicone/ vinyl dimethicone crosspolymer, trimethicone/vinyl dimethicone crosspolymer, The use of liethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilane liethoxycaprylylsilane crosspolymer, octyltriethoxysilane, hydrogen dimethicone, dextrin palmitate, hydrated silica, distearyldimonium chloride, methicone, alkylmethicone, iron oxide, agar, glyceryl caprylate/caprate, and caprylic/capric triglyceride as a coating agent for

titanium dioxide (nano) or zinc oxide (nano) has been discussed safety assessment and approved. , . This has allowed ASEAN to increase flexibility in safety evaluations and realize the continued use of safe ingredients.

Based on the above, ACD Annex VI for ZnO(nano) and TiO2(nano) is represented as shown in Figures 12 and 13.

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
27a	Titanium dioxide (nano) CAS No. 13463-67-7/1317-70-0/1317-80-2	25 % (*)	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Only nanomaterials having the following characteristics are allowed: - Purity ≥ 99% - Rutile form, or rutile with up to 5% anatase, with crystalline structure and physical appearance as clusters of spherical, needle, or lanceolate shapes, - Median particle size based on number size distribution ≥ 30 nm, - Aspect ratio from 1 to 4.5 and volume specific surface area ≤ 460 m²/cm³ - Coating materials can be used that have been demonstrated to be safe and not to affect the nanoparticle properties related to the behaviour and/or effects, - Photocatalytic activity ≤ 10% compared with corresponding non-coated or non-doped reference, - Nanoparticles are photostable in the final formulation.	

26th ACSB approved the safe use of the Titanium dioxide (nano) coated with Silica, Hydrated Silica, Alumina, Aluminium Hydroxide, Aluminium Stearate, Stearic Acid, Trimethoxycaprylylsilane, Glycerin, Dimethicone, Hydrogen Dimethicone, Simethicone (EU2019/1857), or Isostearic Acid (5%, FP), Magnesium Hydroxide (0.175%, FP), Distearyldimonium Chloride (1%, FP), Cetyl Phosphate, Manganese Dioxide (0.175%), Methicone (5%, FP), Alkyl Methicone (5%, FP), Lauroyl Lysine (14%, FP), Alkyl Dimethicone (3%, FP), Hydrated Silica (4%, FP), Stearic Acid (16%, FP), Trimethylsiloxysilicate (30%, FP), Magnesium stearate (5%, FP), Polymethylsilsesquioxane (3%, FP), Dimethicone/Vinyl Dimethicone Crosspolymer (46%, FP), based on the safety review of their application as a blending mixture with Titanium dioxide (nano) in leave-on Sunscreen Cosmetics.

Figure 12: Annex VII List of permitted UVFs which cosmetic products may contain

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
A29a	Zinc Oxide (nano) CAS No.1314-13-2	25% (*)	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Only nanomaterials having the following characteristics are allowed: - purity ≥ 96% with wurtzite crystalline structure and physical appearance as clusters that are rod-like, star-like and/or isometric shapes, with impurities consisting only of carbon dioxide and water whilst other impurities are less than 1% in total. - Median diameter of the particle number size distribution D50 (50% of the number below this diameter) > 30 nm and D1 (1% below this size) >20nm. - Water solubility < 50 mg/l. Coating materials can be used that have been demonstrated to be safe and not to affect the nanoparticle properties related to the behaviour and/or effects	

26th ACSB approved the safe use of the Zinc Oxide (nano) with uncoated, or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilanetriethoxycaprylylsilane cross-polymer, or octyl triethoxy silane (EU2016/621) or Hydrogen Dimethicone (1.625%), Dextrin Palmitate (16.8%, FP), Hydrated Silica (4%, FP), Distearyldimonium Chloride (1%, FP), Methicone (5%, FP), Alkyl Methicone (5%, FP), Iron Oxides (1%, FP), Agar (1%, FP), Glyceryl caprylate/caprate (1%), Caprylic/Capric Triglyceride (45%, FP), based on the safety review of their application as a coating blending mixture with Zinc Oxide (nano) in leave-on Sunscreen Cosmetics.

Figure 13: Annex VII List of permitted UVFs which cosmetic products may contain

3. Concluding remarks

All matters related to ACD, including the thousands of substances listed in the Annex, are being discussed at the ACSB. Nanomaterials and CMR classification are one of the important issues and ACSB have been discussed in depth.

ACSB always takes into consideration the latest information, such as new findings and regulations, and conducts robust safety evaluations to ensure consumer safety.

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Overview of Toxicological Endpoint Evaluation of Skin Photosensitivity of Cosmetic Ingredients

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1. Definition

1.1 Skin Phototoxicity

As a special skin irritant reaction, skin Phototoxicity is a skin toxicity reaction (irritant) that occurs when the skin is exposed to ultraviolet radiation after a single contact or systemic application of chemical substances, such as erythema, edema, pigmentation, etc., which poses a potential threat to human skin health.

1.2 Definition and Biological Mechanism of Skin Photosensitivity

Skin Photosensitivity refers to the capacity of a chemical substance to cause Skin Photoallergy when the skin is exposed to ultraviolet (UV) radiation after repeated contact or application to that substance. Skin Photoallergy refers to a specific skin reaction when the skin is exposed to a test substance and exposed to UV radiation, which induces a photosensitive state in the body by acting on the immune system, and after a certain interval, the skin comes into contact with the same test substance again while being exposed to ultraviolet radiation. Its reaction forms include rash, erythema, edema, etc.

The occurrence of photoallergy mainly depends on light exposure as well as chemical properties and its ingestion methods. For the photosensitivity of chemical substances, they may have intrinsic photosensitivity, or they may not have photosensitivity themselves but their metabolites have photosensitivity. The intake of photosensitive substances can be divided into epidermal contact and systemic intake. For photoallergy caused by epidermal contact, it mainly depends on the transdermal absorption and skin metabolism of the substance, while for systemic ingestion, its absorption, distribution, and metabolism will have an impact on photoallergy.

The mechanism of photoallergy is similar to type IV skin sensitization reaction, and its key event is the combination of chemical substances or their metabolites with proteins under light conditions to form a complete photoantigen. In Skin Photoallergy, there are two modes of antigen formation: 1) chemical substances are modified by light to become photohaptens, which are conjugated with proteins; 2) chemical substances covalently bind with proteins and are then activated by light to form antigens with the potential to induce sensitization reactions.

The formation mechanism of photohaptens is similar to phototoxic reactions, both requiring the absorption of light energy and the production of Reactive Oxygen Species (ROS). After photosensitive molecules absorb light energy, the electrons of the relevant functional groups can be elevated from occupied orbitals (S0, ground state) to unoccupied orbitals (S1, S2). unpaired singlet electrons can be converted to

triplet states by absorbing energy. Molecular oxygen is the main acceptor of excitation energy, therefore, type II photochemical reactions can occur during the energy transfer from the excited triplet photosensitizer to oxygen, resulting in the production of excited Singlet Oxygen (SO); type I photochemical reactions can occur during the transfer of electrons or hydrogen, leading to the formation of superoxide anions (SA) and free radicals. These free radicals can react directly or in the presence of oxygen with biomolecules to form secondary free radicals. These directly or indirectly generated photohaptens can bind to proteins to form photoantigens.

After the formation of photoantigens, Langerhans cells recognize and uptake the antigen protein complex, which is then activated and expresses the corresponding cell surface markers. Meanwhile, Langerhans cells also acquired the ability to present allergens to the initial T cells. At this point, under the influence of relevant cytokines, Langerhans cells migrate to lymphoid tissue and present signals to the initial T cells, leading to their activation and formation of memory T cells, which then proliferate. Finally, once the individual's skin comes into contact with this photosensitive substance again and receives light exposure, it will enter the immune response stimulation stage, and memory T cells will be activated, leading to a skin allergic reaction. For photosensitive substances ingested by the system, they can diffuse through the blood to the epidermis, and under UV light, bind to various related signal proteins, thereby triggering the above allergic reactions.

Photoallergy is a delayed, cell-mediated allergic reaction with a lower incidence compared to phototoxic reactions. It is a specific sensitization reaction of a particular individual to photoactive photosensitizers.

The current in vitro methods for determining light safety include:

1. The test method for determining photoreactivity ROS (OECD TG 495, abbreviated as ROS test) detects whether a chemical substance has photoreactivity by detecting the chemical reaction caused by ROS generated by UV irradiation. It is the basis for determining whether a component has potential phototoxicity and photosensitivity;

2. The in vitro 3T3 neutral red uptake phototoxicity test (OECD TG 432, abbreviated as 3T3 NRU PT test) determines whether a chemical substance has phototoxicity by measuring the ability of 3T3 fibroblasts to absorb neutral red or the changes in cell toxicity after being exposed to a combination of chemical substances and UV radiation. After exposure to UV radiation, chemical substances can cause cell damage through the production of ROS or other mechanisms, leading to changes in cell surface or lysosomal membrane sensitivity and irreversible cytotoxic changes such as increased lysosomal fragility. According to the formation mechanism of photohaptens, ROS are necessary products in the process of converting chemical substances into photohaptens. Therefore, the 3T3 NRU PT test is also predictive of the photosensitivity of chemical substances.

2. Summary and Classification of Known Skin Photosensitizing Substances

No.	Name	CAS	Classification
1	3,4',5-Tribromosalicylanilide	87-10-5	Prohibited components in cosmetics
2	4-Methyl-7-ethoxycoumarin	87-05-8	
3	7-Methoxycoumarin	531-59-9	
4	8-Methoxypsoralen	298-81-7	
5	Benzophenone	119-61-9	
6	Bithionol	97-18-7	
7	Hexachlorophene	70-30-4	
8	Musk ambrette	83-66-9	
9	Sulfaniamide	63-74-1	
10	Isoniazid	54-85-3	
11	Omadine Na	3811-73-2	
12	Sulfasalazine	599-79-1	
13	5-methoxypsorale	484-20-8	
14	Anthracene	120-12-7	

No.	Name	CAS	Classification
15	Musk ketone	81-14-1	Restricted components in cosmetics
16	Musk xylene	81-15-2	
17	6-Methylcoumarin	92-48-8	
18	Dichlorophene	97-23-4	
19	p-Phenylenediamine	106-50-3	
20	Octyl dimethyl PABA	21245-02-3	Approved sunscreen for cosmetics
21	Ethylhexyl methoxycinnamate	5466-77-3	
22	Pyridoxine HCl	58-56-0	Vitamin
23	Fenticlor*	97-24-5	Antibacterial agents/ antibiotics(*Cosmetics ingredients)
24	Enoxacin	74011-58-8	
25	Griseofulvin	126-07-8	
26	Ofloxacin	82419-36-1	
27	Lomefloxacin HCl	98079-52-8	
28	Tetracycline HCl	64-75-5	
29	Diclofenac Na	15307-79-6	NSAIDs
30	Ketoprofen	22071-15-4	
31	Piroxicam	36322-90-4	
32	Promethazine HCl	58-33-3	Antihistamine
33	Mequitazine	29216-28-2	
34	Furosemide	54-31-9	Diuretic
35	Hydrochlorothiazide	58-93-5	
36	tetrachlorosalicylanilide	1154-59-2	Insecticide
37	Chlorpromazine HCI	69-09-0	Psychiatric drugs
38	Quinine	130-95-0	Malaria prevention drugs
39	Amiodarone HCL	19774-82-4	Cardiology drugs

Table 1 Summary and classification of photosensitive substances

Based on publicly available photosafety data, this article summarizes all 39 substances that can be retrieved and confirmed to have photosensitivity (refer to Table 1). These substances can be distinguished as cosmetic ingredients and non cosmetic ingredients.

In the category of cosmetic ingredients, it mainly includes prohibited components in cosmetics, restricted components in cosmetics, and approved sunscreen agents. Cosmetics contain very few photosensitive substances, which have undergone strict screening and restriction, and are under strict supervision.

In non cosmetic ingredients, they are mainly divided into antibacterial agents/ antibiotics, NSAIDs, antihistamines, diuretics, etc. The instructions for the use of such drugs have provided detailed descriptions of potential skin sensitization or photosensitivity reactions, and emphasized the importance of following medical advice to ensure patient safety.

3. Regulatory Requirements for Skin Photosensitivity

At present, mainstream authoritative institutions generally agree that for the light safety evaluation of cosmetic ingredients, further light safety evaluation is only necessary when the ingredient has an absorption peak in the UV visible spectrum and a molar extinction coefficient (MEC)>1000 L mol-1 cm-1.

The Scientific Committee on Consumer Safety (SCCS) of the European Commission believes that ingredients with skin photosensitivity are likely to show positive results in the skin photosensitivity test (3T3 NRU PT test), and therefore this test can be used as a pre screening method. If the result is positive, further experiments are needed to verify the risk of photosensitivity, such as exploratory in vitro experiments and clinical trials. In the previous introduction of the 3T3 NRU PT test principle, the scientific validity of this prediction was discussed. In addition, SCCS only considers the photosensitivity assessment of sunscreen category components when evaluating the listed substances (quasi banned and restricted substances).

The Personal Care Products Council (PCPC) suggests that ROS testing can be used as the first tier testing method for screening skin photostimulation and photosensitivity. The 3T3 NRU PT test can accurately predict skin photostimulation, but it may over predict skin photosensitivity. When the 3T3 NRU PT test result is negative, it can be considered that the chemical has no skin photostimulation in the human body, and the risk of photosensitivity can also be predicted to be low. But when the test result is positive, the component may have potential phototoxicity risks, and the photosensitivity needs further verification and cannot be directly determined.

Another physical characteristic that should be considered before conducting phototoxicity testing is the ability of the test substance to reach the target site (i.e. the subepidermal layer). If solid or non permeable photoreactive substances cannot reach the target site, they will not cause photostimulation or photosensitivity reactions. Similarly, compared to leave-on products, rinse-off products have a shorter contact time with the skin, so they can be exempted from light safety testing.

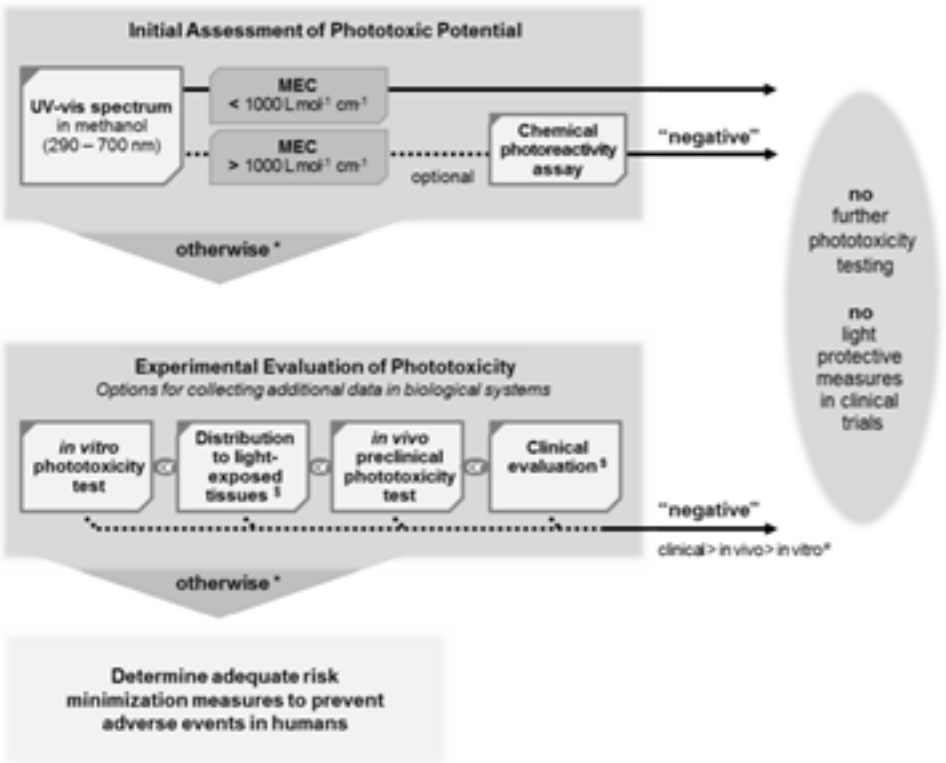

Fig 1 ICH Optical Safety Assessment Strategy

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) discusses the photosafety of drugs as a whole. When ingredients have absorption peaks in the UV visible spectrum in the wavelength range of 290-700 nm and MEC>1000 L mol-1 cm-1, ROS testing can be used as the preferred method for predicting photoreactivity. If the result of ROS testing is negative, the chemical can be considered non photoreactive and can be exempted from photosafety (including photosensitivity) evaluation and risk management measures. However, if the test result is positive, further confirmation through in vitro experiments, animal experiments, and clinical evaluations is required. For drugs exposed through the skin, clinical evaluation is usually conducted due to the lack of validated animal testing methods for photosensitivity.

The International Fragrance Association (IFRA) integrates the decision tree for phototoxicity and photosensitivity based on the UV visible spectrum and literature research. It also considers the MEC value of the substance and considers the exposure level of the substance in the human body as an important condition for exemption from evaluation. When any of the above exemption conditions are not met, due to the lack of validated photosensitivity test methods, the recommended evaluation test methods mainly focus on phototoxicity.

The Brazilian cosmetics regulations stipulate that photosensitivity testing is only necessary for special purpose products that claim certain efficacy, and can be exempted from submitting evaluations for this toxicological endpoint. The main recommended evaluation method is the repeated patch test under human illumination, which includes three stages: induction period, rest period, and stimulation period. According to the characteristics of the product to be evaluated, at least 25 volunteers will be subjected to closed or semi closed application, and the application site will be irradiated with energy standardized UV radiation to evaluate skin reactions.

According to the requirements of China's "Technical Specification for Safety of Cosmetics" (2015 edition), the safety assessment of ingredients in cosmetic formulas and the registration/notification of new ingredients need to evaluate their

photostimulation and photosensitivity. The currently accepted methods for determining the phototoxicity of cosmetic ingredients in China's "Technical Specification for Cosmetics Safety" (2015 edition) include the measurement of ROS, 3T3 NRU PT, and animal light exposure test.

4. Conclusion

The general skin photosafety includes photostimulation and photosensitivity. Regarding photostimulation, China has currently accepted the use of ROS assay and 3T3 NRU PT assay to evaluate this toxicological endpoint. However, for the evaluation of photosensitivity, due to the lack of validated in vitro testing methods and missing animal/human trial data, it is still a difficult point in the current safety assessment of ingredients.

Currently and internationally, substances without UV visible light absorption and substances used in rinse-off products can be exempted from photostimulation and photosensitivity. Regarding photosensitivity testing, SCCS believes that the 3T3 NRU PT test can cover most photosensitizing substances. PCPC recommends that among various phototoxicities, photosensitivity is relatively uncommon, and negative 3T3 NRU PT results can predict that the substance has no photosensitivity.

When evaluating the cosmetic ingredients in the "Catalogue of Used Cosmetic Ingredients", considering the recommendations of safety assessment guidelines from multiple authoritative international organizations and the long-term safe use history of cosmetic ingredients in the "Catalogue of Used Cosmetic Ingredients", the probability of photosensitivity occurrence is considered to be low. Therefore, in addition to in vitro methods, a comprehensive evaluation of the skin photosensitivity of ingredients can be conducted by combining document retrieval, QSAR model prediction, actual product application scenarios, and ingredients concentration.

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Sarcothalia circumcincta: the New Zealand Red Algae leaf extract. A novel cosmetic ingredient

Alain Khaiat, PhD

Dr. Khaiat was awarded the first in-cosmetics Lifetime Achievement Award in Paris in April 2010. With over 40 years of experience in the cosmetic industry having served as V.P. R&D and QA with Johnson & Johnson, Yves Rocher and Revlon; Alain Khaiat has created SEERS Consulting in 2006. Dr. Khaiat is Chairman of the CTFA of Singapore, Past-Chairman (2014-2019) of the ISO TC 217 (cosmetics), Past- Chairman ASEAN Cosmetic Association (2009-2011 and 2017-2019), member of the ASEAN Cosmetic Scientific Body, member of the International Dialogue for the Evaluation of Allergens (IDEA) Supervisory Group, a joint project between IFRA and the EU commission. Dr Khaiat is behind some of the most successful "beauty from within" products. He has several patents and publications in his name.

Andrea Taimana

Founder & CSO, Organic Bioactives New Zealand

Andrea Taimana is an accomplished researcher, cosmetic ingredients developer, innovator, and award-winning cosmetic chemist. Her unique combination of expertise has positioned her at the forefront of research on innovative skincare bioactives derived from New Zealand's native marine and land botanicals. In addition, Andrea has studied Te Reo Māori (the Māori language) and Rongoā Māori (traditional Māori medicine), integrating this knowledge into her business practices. This fusion of cultural tradition and advanced cosmeceutical innovation distinguishes her work in the global skincare industry.

Introduction

In recent years there has been an increased interest in algae source of new ingredients for cosmetic products as cosmetic companies are looking for new ingredients, that are multi-functional, sustainable and of plant origin.

We would like to introduce here, a novel cosmetic ingredient, an extract of the New Zealand unique red algae, Sarcothalia circumcincta.

Global demand for Marine Actives

The skincare industry is witnessing a notable rise in the utilization of algae-based ingredients, driven by their abundant nutrient content, sustainability, and versatile applications[1]. Various algae types provide a rich array of vitamins, minerals, amino acids, and micronutrients, making them highly desirable in beauty formulations. This trend aligns with the increasing consumer preference for sustainable, naturally-derived skincare solutions that offer both effectiveness and ecological responsibility.

Algae are known to contain bioactive compounds such as astaxanthin, fucoxanthin, and phlorotannins, which exhibit anti-inflammatory, antioxidative, and cell-protective properties. These compounds are incredibly important for skin health and also provide protection against UV damage. Additionally, algae are rich in vitamins, minerals, omega-3 fatty acids, and amino acids, making them valuable ingredients for skincare products. Their nourishing and antioxidative properties cater to various skin types and needs. The growing awareness of the nutrient-rich nature of algae and its positive impact on skin health is expected to drive the future demand for algae-based skincare products.

Increase in Macroalgae Trend

Macroalgae dominated the market share in 2023, largely driven by the rising demand for natural ingredients in cosmetics, cosmeceuticals, and nutricosmetics. Marine-sourced red algae offers a multitude of benefits, including photoprotective, moisturizing, antioxidant, anti-melanogenic, anti-allergic, anti-inflammatory, anti-acne, anti-wrinkling, antimicrobial,

anti-aging, and whitening properties, which has led to its increasing use in skincare products.

France is a global leader in the cosmetic industry, known for its innovation and commitment to natural ingredients. The French cosmetic market has embraced algae-based ingredients, particularly red macroalgae, for their proven efficacy and alignment with the demand for sustainable and natural products.

Pioneering Algae-Based Formulations

Several French cosmetic brands have pioneered the use of algae in their formulations and have developed extensive ranges of skincare products leveraging the benefits of marine actives. These brands emphasize the anti-aging, moisturizing, and protective properties of red macroalgae, creating products that cater to the sophisticated preferences of consumers seeking high-performance skincare solutions.

New Zealand Algae: A Superior Source

New Zealand's unique geographic and environmental conditions contribute to the superior quality of its marine algae. The pristine waters surrounding New Zealand along with a strong and vibrant subantarctic water streams are among the world's purest and richest in minerals, creating an ideal environment for algae growth.

Purity and Potency

The isolation of New Zealand's waters from industrial pollutants ensures that the algae harvested from this region are of exceptional purity. The high mineral content of these waters enhances the nutritional profile of the algae, making them particularly potent in bioactive compounds. This purity and potency translate into more effective cosmetic ingredients, capable of delivering multitasking skin benefits.

New Zealand ‘s unique biodiversity and elevated UVB exposure

New Zealand's early geographic isolation in the southwestern Pacific Ocean has fostered the evolution of abundant and unique flora and fauna.

More than 70 percent of New Zealand's land and marine botanicals are endemic, existing nowhere else on Earth.

Addtionally, the higher levels of UVB light in New Zealand cause these botanicals to produce bioactive compounds with potential skin and health benefits. In response to the UVB stress, New Zealand's land and marine botanicals increase their production of these bioactive compounds, including plant phenolics.

These natural actives exhibit potent antioxidant and other functional properties, and are known as nature’s own SPF factors.

Novel marine actives from New Zealand

Algae have been used for many years, with red algae being a time-proven medicine, known to the Māori, indigenous people of New Zealand, for its vast benefits for health, skin and hair.

We introduce here a novel cosmetic ingredient: an extract from the New Zealand endemic red algae, *Sarcothalia circumcincta*.

This red algae, characterized by its large, leathery, crimson-colored blades, thrives in the low intertidal and subtidal rocky shores of New Zealand. Utilizing solar energy for photosynthesis in intertidal waters, Sarcothalia circumcincta exhibits unique properties valuable for cosmetic applications.

Red seaweed “Rhodophyta” are an important group of macro algae, rich in diverse bioactive constituents. The most important ones are sulfated polysaccharides (S-PS), proteins, phenolic compounds, vitamins and minerals, most of these are hydrophilic. They also contain unsaturated fatty acids.

S-PS are the main component of the cell walls of red algae, representing about 50% of the dry weight. S-PS possess several biological activities including anticoagulant,

antiviral, antitumor, anti-inflammatory and immune-stimulating activity[2]. They are approved by the US FDA as food additive.

The S-PS of S. circumcincta are reported to be carrageenan κ and λ[3].

Certain photosynthetic marine organisms have evolved mechanisms to counteract UV radiation, synthesizing UV- absorbing molecules like mycosporine-like amino-acids (MAA)[4] .

TPT Xtraction® - an innovative "Clean Beauty " extraction method

An extract from the New Zealand endemic red algae, Sarcothalia circumcincta, has been developed using a pioneering green extraction technology, TPT Xtraction® (Tripartite Extraction). This method is an innovative, three-layered, cold-processed, and chemical-free bio-liquefaction approach, utilizing ultra-distilled water as a single solvent.

TPT Xtraction® is a proprietary, patent-pending method, resulting from eight years of comprehensive research and development. The primary focus is to obtain the highest quality and quantity of bioactive compunds derived from fresh, raw red algae while creating multifunctionality and elevating a sensorial profile of red algae extract. The extract obtained is odourless.

Properties

Moisturizing

Polysaccharides form a film on the skin surface. This film, highly hygroscopic, will hold water and enhance skin moisturization.

Lifting

Upon evaporation of the formula water, the film will contract and tighten the skin, creating a unique "lifting effect".

UV Protection

The water extract of the Sarcothalia circumcincta absorbs in the UV B and UVA with a peak at 324nm (UVA II region). The absorption continues into the UVA I (mainly 240 -360nm). This is consistent with the reported absorption of the MAA[5].

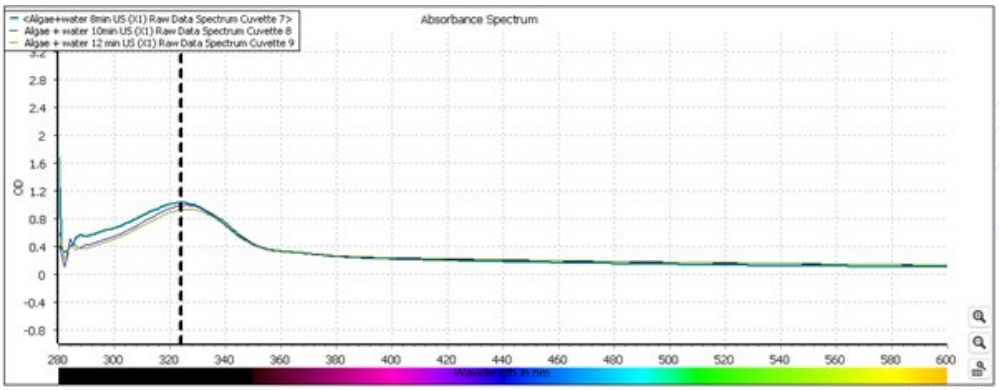

Fig 1: Spectrum of a 10% dilution of the algae extract.

UV protection is particularly important to prevent skin aging, preventing the formation of free radicals (ROS) and, as such, protecting the skin.

This property was confirmed by the protection of HaCaT cells when exposed to UVA. The viability is close to the control (no exposure), i.e., 100% protection.

The UV protection also confers anti-inflammatory activity.

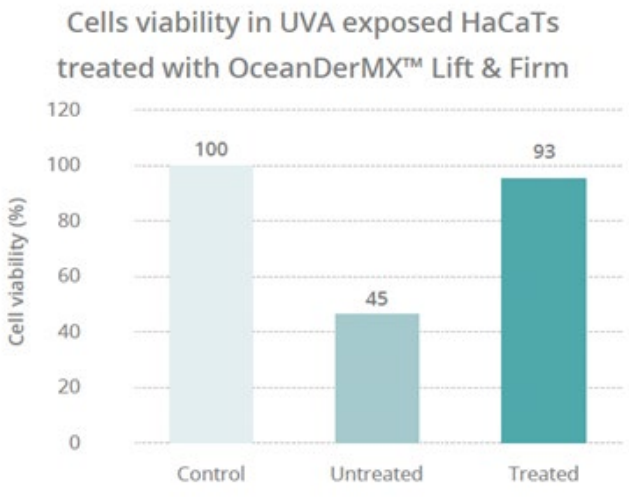

Fig 2: Cell viability protection

Antioxidant

Thanks to the high level of polyphenols, the extract is also directly protecting cells from reactive oxygen species (ROS). The protection is close to no exposure, while non-treated cells have significant damage.

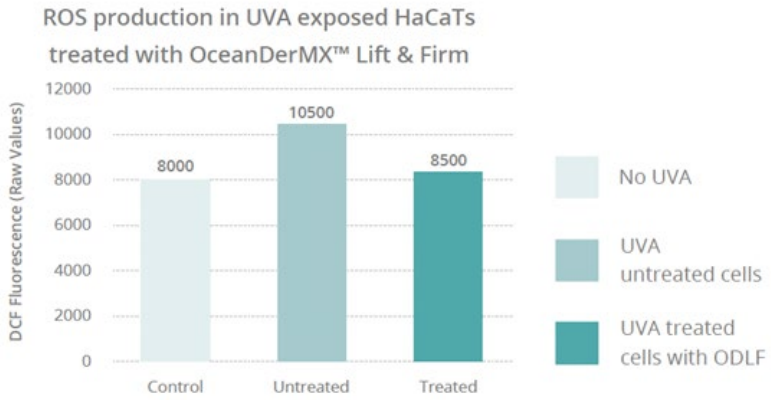

Fig 3: antioxidant activity

MMP inhibition

Collagen and elastin fibers in the dermis are destroyed by Matrix Metallo Proteases (MMPs) like collagenases, elastases, gelatinases, etc.

Sarcothalia circumcincta extract has been shown to chelate metal ions (85% of the chelation activity of EDTA).

Fig 4: metal chelation activity

Since MMPs require the presence of a divalent metal ion to activate their active site, chelation of the metal ion will reduce the MMP activity, thus protecting the dermis structure and reducing wrinkles.

Additionally, there is published data showing an increase in pro-collagen . This would contribute to the anti-aging activity, especially anti-wrinkles.

Collection

The algae are collected by hand, following Māori tradition, in mid-tidal level. Only broken algae are collected, there is no destruction of, and total respect for, the environment. The extract is produced by a proprietary triple step manufacturing process to get the highest possible yield and to protect the properties.

Conclusion

Sarcothalia circumcincta, the New Zealand native red algae, extract will have the following main cosmetic activities in addition to moisturizing the skin:

Anti-aging / Anti-wrinkles

due to MMP inhibition ((chelation of metal ions), UV protection, antioxidant, anti-inflammatory, increase in pro-collagen, moisturizing and lifting.

Anti-aging / Whitening

due to the lifting effect (reduction of the light scattering), antioxidant and anti-inflammatory (two of the causes of pigmentation) activity, UV protection (main cause of pigmentation).

UV protection booster

the addition of the extract into a sunscreen will increase the SPF, the UVA -PF and the Cw.

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New Regulations Empower Ingredients Innovation: Analysis on Dynamics of Notification of New Cosmetics Ingredients

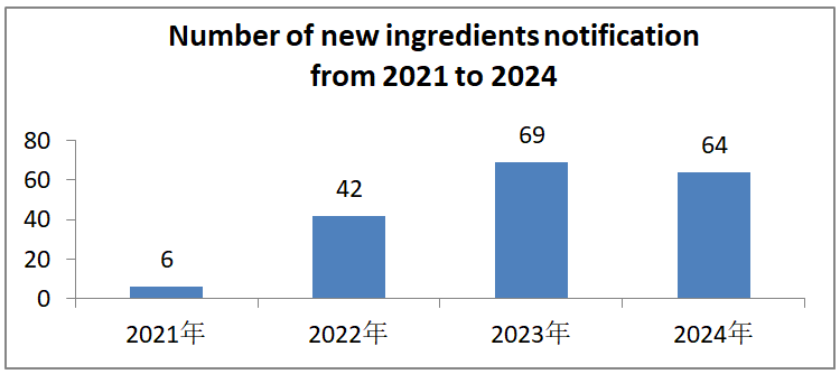
SINO - EUROPEAN YIHONG CONSULTING LTD.

With the official implementation of new regulatory documents such as the "Cosmetics Supervision and Administration Regulations (CSAR)" and the "Administration Regulations on Registration and Notification Materials for New Ingredients of Cosmetics", the cosmetics industry in China has entered a new stage of development, and the notification of new ingredients has ushered in an unprecedented period of prosperity. These new regulations not only provide clear regulatory basis for notification process of new cosmetic ingredients in China, but also inject new impetus into the innovative development and market prosperity of the entire industry. This article will delve into the current status of the notification of new ingredients in China based on the notification data after the implementation of new regulations, providing a reference for readers both within and outside the industry.

1. Overview of the Current Status of Notification of New Ingredients

(1) The number of notification has been increasing year by year

Since the implementation of the new regulations, notification of new ingredients for cosmetics has continued to gain momentum, and the number of notification has increased significantly year by year. Currently, a total of 181 new ingredients have been notified. As of the end of August 2024, the number has reached 64, accounting for one-third of the



total notification, an increase of 106% compared to the same period in 2023. Based on the current trend of high notification, it is expected to exceed the 100 mark in 2024.

(2) Notifying popular ingredients

Upon statistical analysis, we have found that "Nicotinamide Mononucleotide" has become a popular new ingredient, with a high number of notification cases reaching 11 times. In addition, there are cases where new ingredients have been notified multiple times by different enterprises. For instance, 7 new ingredients including Pterostilbene, Sodium Lauroyl Methyl Isethionate and Fucosyllactose, which have been notified twice; Acetylneuraminic Acid and Pyrroloquinoline quinone disodium (PQQ) salt have been notified three times; Bakuchiol has been notified six times; And Nicotinamide Mononucleotide has an astonishing number of notification, as high as 11 times! In January 2022, Yuyao Lifespan Health Technology Co., Ltd. was the first to complete the notification of Nicotinamide Mononucleotide. Eight companies, including RubyBerries (Zhongshan) Biotechnology Co., Ltd., Shenzhen Winkey Pharmaceutical R&D Co., Ltd., Jiangxi Haven Biotechnology Co., Ltd., and Harbin Voolga Technology Co., Ltd., have subsequently notified the ingredient. As of August 2024, there are still companies joining the notification ranks for this ingredient, which indicates its broad market potential.

(3) Notification enterprises

181 newly notified new ingredients are distributed among 112 enterprises, among which Yunnan Botanee Group has the highest number of notifications and has obtained 10 new ingredients notification numbers; Next is Shenzhen Winkey Pharmaceutical R&D Co., Ltd., which has been approved 8 times, Bloomage Biotech Co., Ltd., which has been approved 6 times, and Dow (Zhangjiagang) Investment Co., Ltd., which has been approved 5 times.

2. Analysis of Notification Situation

(1) The momentum of notifying new plant ingredients is strong, and Chinese specialty plant resources have become a hot spot.

Article 9 of CSAR clearly states that the use of modern science and technology, combined with China's traditional advantageous projects and specialty plant resources, is encouraged and supported in the research and development of cosmetics. According to statistics, since March 2022, TCI Group (Shanghai) has successfully notified for the first plant new ingredient Chenopodium formosanum extract, marking the beginning of the plant new ingredients notification process. From 2022 to 2024, the proportion of new plant ingredient notification to the total annual was 7%, 15% and 37%, respectively, showing a significant upward trend. This data reflects that Chinese local enterprises are actively exploring Chinese specialty plant resources, committed to developing cosmetics with Chinese characteristics, and providing consumers with more choices of green and natural cosmetics. This not only demonstrates the innovation capability and market potential of cosmetics industry in China, but also brings new vitality and opportunities to the cosmetics market.

(2) The status of 4 new ingredients is "cancelled," and enterprises' understanding of new ingredients has been further strengthened.

According to data from National Medical Products Administration (NMPA), currently, there are four new ingredients on the market completing the cancellation procedures. They are Zinc hydrolyzed hyaluronate, Asivatrep, Alpha-Glucan Polysaccharide, and Bakuchiol. Some of the reasons include "avoiding confusion in the use of new ingredients, rather than safety factors"; others are "managed as already used cosmetic ingredients", which clarifies the public's doubts about the cancellation after the notification of new ingredients.

These situations reflect that the notifiers of new cosmetic ingredients are actively responding to the call of NMPA, fulfilling their corporate responsibilities, conducting self-inspections of new ingredients notification, strengthening research on new ingredients, and ensuring the quality and safety of ingredients and final products.

(3) The trend of declaring usage purposes driven by the market

Data from the cosmetic new ingredients notification shows that the usage purpose

of functional ingredients such as skin protectants, moisturizers and antioxidants accounts for about 50% of the proportion, highlighting the increasing market demand for functional ingredients. As consumers' attention to product ingredients and effects continues to increase, in order for brands to stand out in the market, they need to provide "differentiated products" with unique selling points and establish consumer identification with ingredients and categories to attract and retain consumers. This not only meets consumers' expectations for product performance, but also helps brands gain advantages in fierce market competition and meet consumers' expectations for high-quality cosmetics.

(4) The inclusion of new ingredients that have reached the end of the monitoring period in the catalog urgently needs to be standardized.

According to Article 14 of CSAR, new cosmetic ingredients that have not had any safety issues after the expiration of 3 years shall be included in the list of used cosmetic ingredients formulated by the NMPA department of the State Council. So far, with the implementation of the new regulations, the newly notified ingredients have exceeded the monitoring period of 3 years. Specifically, it includes:

1. Acetylneuraminic Acid (Wuhan CASOV Green Biotechnology Co.,Ltd.)
2. Lauroyl Alanine (Suzhou Weimei Biotechnology Co., Ltd.)
3. β-Alanyl Hydroxyprolyldiaminobutyroyl Benzylamide (Shenzhen Winkey Pharmaceutical R&D Co., Ltd.)
4. Tissue Culture of Saussurea Involucrata (Dalian Practical Biotechnology Co., Ltd.)

As time goes by, more new ingredients will complete their the monitoring period. How these ingredients can be smoothly included in the standards and procedures of the list of used ingredients requires further clarification and regulation by regulatory authorities to ensure safety and compliance.

3. Conclusion

With the implementation of new regulations on cosmetics, the research and application of new cosmetic ingredients in China have received strong policy support. Driven by

both policy guidance and market demand, the Chinese cosmetics industry is entering a phase of steady growth of new ingredients notification. Innovation in ingredients will be certain to become a key driving force for industry development and is crucial for enhancing the competitiveness of Chinese brands in the global market.

We will continue to focus on the frontier trends of the industry, committed to supporting its innovation and healthy development. We believe that through the joint efforts of the entire industry, China's cosmetics industry will move towards a more prosperous and sustainable future, bringing safer and higher-quality product experiences to consumers worldwide.

Sustainable Development of Cosmetics

- Insights Into the Evolving and Emerging Regulations Globally Surrounding Green Claims
- Introduction to the Sustainable Development Working Group of CACHCA
- Towards Sustainability: The Impact and Reflections of the European Green Deal and Its Legislation on the Cosmetics Industry

Insights Into the Evolving and Emerging Regulations Globally Surrounding Green Claims

Dr Mark Smith

Director General of NATRUE AISBL, the International Natural and Organic Cosmetics Association

Dr Mark Smith graduated with a M.Chem (Hons.) degree in chemistry and an interdisciplinary PhD. between chemistry and genetics. Before joining NATRUE in 2014, he worked in research covering biotechnology (Leeds, UK) and the biomedical/pharmaceutical sector (Montréal, Canada). In July 2016 Mark was appointed by the NATRUE Board to Director General of NATRUE where he is in charge of the day-to-day running of NATRUE, and plays lead role in all political, regulatory and scientific affairs of the association – advocacy, research and label.

Around the globe increasing emphasis is being placed by regulators on greenwashing. This trend reflects the growing strength of consumer responses to environmental protection, and the rising interest of investors in sustainability.

When it comes to cosmetics, it is no longer purely the impact of vertical regulation. As the transition towards a greater sustainable footprint continues to take hold, cosmetic manufacturers must adapt to an increasingly intricate and complex web of regulatory compliance outside cosmetics. However, many of these regulatory adaptations show how some brands today are increasingly formulating with naturals to defossilise, as well as sourcing ethically and sustainably, protecting biodiversity and guaranteeing transparency throughout the chain of custody.

Europe

During the last European political mandate, a wave of proposed initiatives and

legislation appeared as a result of the European Green Deal, which is leading change across multiple sectors. For cosmetics, although the proposed targeted revision of the European Cosmetics Regulation has not yet materialised, the impacts from evolving and emerging horizontal legislation up- or downstream within the value chain are set to become applicable during the current political mandate by the mid-2020s. Moreover, it is not only amendments to the framework itself, but any subsequent delegated acts for specific product categories that will present regulatory challenges. Industry-wide collective management and closer pre-competitive collaboration will be essential for seizing opportunities through standardised best-practices and initiatives that lower entry barriers – particularly for SMEs.

The interplay between the zero-pollution ambition and the circular economy are at the heart of the strategies and legislative proposals set to impact cosmetics, and how sustainability will be measured. For some time now, ethical and sustainable sourcing has quickly become a cornerstone for raw material selection, considering both the environmental and social impact of raw materials, or their production using green chemistry, biotechnology, or upcycling of industrial waste stream and by-products.

In the last 12-months, we have already seen three legal Acts published covering rules for raw materials resulting from deforestation (Regulation (EU) 2023/1115), as well as corporate due diligence (Directive (EU) 2024/1760) and reporting (Directive (EU) 2022/2464) enter into force. Whilst the scope of these three examples only affects certain raw materials (e.g., palm oil and its derivatives) or larger companies (e.g., over 1000 employees and a net global turnover of €450k), it is undeniable that these regulations are a turning point for mandating company responsibility for the potential impact of their operations and supply chains on the environment and human rights. Furthermore, these practices promote traceability in the supply chain, which is crucial for consumer transparency.

If we consider circularity as a focal point of a future economy, we must evaluate how to improve product design and environmental impact. These aspects

have been addressed holistically in the published eco-design for sustainable product (ESPR - Regulation (EU) 2024/1781) and the provisional agreement for packaging and packaging waste regulation (PPWR). The ESPR guarantees product sustainability throughout the EU single market via uniform requirements across all Member States. It also encourages waste reduction by preventing the destruction of unsold consumer products, accounting for recycled content and reusability, and setting restrictions for substances of concern that impact a product's sustainability.

On 27 March 2024, Directive (EU) 2024/825 came into force amending the existing Unfair Commercial Practices Directive (UCPD). Whilst the UCPD can already be used to address greenwashing, the targeted amendments in Articles 6 and 7 (misleading actions and omissions respectively), along with additional bans in Annex I ("blacklist"), aim to facilitate enforcement and level the playing field. Articles 6 and 7 cover the main characteristics of a product, including environmental or social aspects, ban unverified environmental claims related to future performance, and establish criteria necessary for product comparisons. For natural and organic cosmetics (NOCs) in particular, the Annex I "blacklist" is perhaps the most interesting since it bans generic environmental claims (e.g., biodegradable, biobased), claims about the entire product only a specific aspect is concerned, and the use of voluntary sustainability labels unless based on third-party certification scheme or established by public. Although neither "natural" (nor "organic") appears on Annex I, it remains to be seen precisely how Member States may eventually interpret such claims. Member States have two years to integrate this Directive national law, with application from 27 September 2026. Since the Directive's regulatory scope is horizontal, all sectors are covered although the directionality is business-to-consumer (B2C) only.

The companion to Directive (EU) 2024/825 is the proposed Green Claims Directive (GCD), which sets specific rules for explicit environmental claims and labels, with the same scope and B2C application. To-date, the European Parliament and Council have adopted their negotiating positions, and the process is expected to enter the final institutional negotiation phase with the Commission later this year, following the

European Elections. Whilst robust pre-verification of claims and labels remains a focus, the Council position introduces the concept of a simplified procedure to exempt certain types of explicit environmental claims for eligible operators. For NOCs, there is support for existing private label schemes, even if these will need to ensure compliance with the framework of these Directives to ensure continued use after their application.

As environmental claims increasingly play an important role in consumer orientation, a robust and complementary framework will be essential to support informed decision making based on reliable, verifiable and comparable information. Ultimately, with two interconnecting anti-greenwashing Directives, consistency between the final texts is crucial to avoid potential conflicts that could derail their joint objective. Additionally, harmony with other legislative acts is important, and, as with all the Green Deal initiatives, a clear balance needs to be struck between the expectations of the environmental and social sustainability objectives and the reality of the economic sustainability and capacities of the market. To this end, it appears that compliance with regulatory requirements upstream of B2C will support compliance with the GCD without additional regulatory measures. Such a framework is essential for promoting sustainable innovation, fostering consumer empowerment and confidence, and ensuring that natural and organic cosmetics manufacturers can continue to make substantiated environmental claims through long-term trusted label schemes.

UK

Historically, the UK had general consumer protection requirements through the Consumer Protection from Unfair Trade Regulations from 2008. Potential sanctions related to unfair practices had involved court proceedings by the Competition and Markets Authority (CMA) or Trade Standard Services, and could also include action against misleading advertisements by the Advertising Standards Authority (ASA).

In recent years, two significant developments have occurred:

1. the CMA has developed and published its Green Claims Code and begun investigating market compliance with the Code. Recently, this has included a high-profile

investigation into a multinational cosmetic manufacturer as part of the fastmoving consumer goods focus. Whilst this case is yet unresolved, the CMA's investigation spotlighted statements and claims related to vague language about the environmental impact of products, exaggerated natural cosmetic product claims (focusing on single aspects of a product to suggest they reflect the product as a whole), and used colours and imagery to create an impression of a positive environmental impact.

2. the UK Government passed the Digital Markets, Competition and Consumers ("DMCC") Act, where the CMA is set to gain a range of new enforcement powers. Nevertheless, with certain exceptions, the Act's provisions will not come into force until secondary legislation is passed. The CMA initially expected its new responsibilities to become operational in the Q3 2024, but this timeline may be delayed due to the UK's election on 4 July. On the same day as the DMCC Act became law, the CMA published for consultation its new Digital Markets Competition Regime Guidance. A key aspect of this Act for greenwashing is that the DMCC replaces the 2008 Regulations and empowers the CMA to impose fines of up to 10% of worldwide group turnover for non-compliance with single market status conduct requirements or "pro-competition orders".

Given that the UK maintained some EU laws post-Brexit, it is interesting to note that the differences between the UK and EU approaches to green claims. For example, generic claims that are now prohibited under Directive (EU) 2024/825 are permitted in the UK if they are supported by robust substantiation. Similarly, whilst the EU is more in favour of third-party certification to substantiate sustainability (environmental and/or social) claims and labels – including validation of both before placing the product on the market (ex-ante) – the UK still provides flexibility for self-declarations if (again) robust substantiation is provided and does not require any ex-ante verification by an accredited third-party control body. Lastly, in terms of penalties, although the EU GCD remains under discussion the initial proposal referred to 4% of national turnover in the European Member State that raised the non-compliance.

In general, the existing UK approach is more flexible, as it is associated with guidance based on principles, recommendations and examples with less precision

and prescriptive requirements. By comparison, the EU approach focuses on binding legislation and prescriptive requirements for verification.

USA and Canada

The most famous aspect of the US regulatory framework to counter greenwashing are the Federal Trade Commission (FTC) Green Guides. These guides, first introduced in 1992were last reviewed in 2012, and a new review closed for public comments in April 2023.

The Green Guides can inform companies in their supply chain decision-making. The FTC designed the Green Guides to provide guidance to marketers and companies on (1) general principles for all environmental marketing claims; (2) how consumers are likely to interpret particular claims and how marketers can substantiate these claims; and (3) how marketers can qualify their claims to avoid deceiving consumers.

The current 2012 revision covers claims such as degradability and free-from, whilst also highlighting certifications and seals of approval. To-date, the newest update to the Guide has not been made available, but the FTC will likely have to update provisions pertaining to "sustainability," "recyclability," "environmentally friendly," and other ESG-relevant marketing claims given the increasing prevalence of such claims and significant concerns expressed by stakeholders about these types of claims. Whether and how the FTC will tackle environmental marketing claims that it declined to address in 2012, particularly climate change-related marketing claims or organic claims outside of foodstuffs, is less certain.

Although stickly guidance, the FTC Guide's actions and penalties can still be brought against operators. To this end, a fundamental trigger is whether the practice is deceptive in a way that would involve a material representation, omission, or practice that is likely to mislead an average consumer. As such the FTC requires all marketing claims to be substantiated before they are made, and marketers must have a reasonable basis for the claim, which is often established through competent and reliable scientific evidence. Such scientific evidence to substantiate that each

of the marketing claims is true should be based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence. If we consider this concept within the context of environmental marketing claims, this “reasonable basis” often requires competent and reliable scientific evidence, which consists of tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.

In June 2024, Canada has passed Bill C-59, which lays down legislation aimed at curbing 'greenwashing' by corporations. The new law will prohibit certain environmental representations that are not based on adequate and proper substantiation in accordance with international methodologies. Companies found in violation of the law may face finds up to the greater of $10 million, or $15 million for subsequent orders, or three times the value of the benefit derived from the deceptive conduct, or 3% of annual revenues. Moreover, from June 2025, the changes could allow private litigants to initiate legal proceedings against businesses over green claims.

India

In early 2024, the Advertising Standards Council of India (ASCI) issued guidelines to take down misleading green claims in advertising. The guidelines have been subject to public consultation since mid-November 2023 and took effect from 15 February 2024. Overall, the guidelines reflect the same themes seen in the EU approach; namely, prohibiting the use of vague terms or generic claims (e.g., green, eco-friendly), ensuring all environmental claims or communications are full disclosed (communication via QR codes, weblinks etc.), and confirming claims are verified, comparative, transparent, and present a clearly defined scope. Moreover, just like in the EU approach, the substantiation of specific claims (e.g., sustainability, degradability, 100% natural) must be verified by independent third-party certification or supported by reliable scientific evidence. However, unlike the EU GCD proposal, the Indian approach does not require the claims to be ex-ante verified by a nationally accredited control body.

Conclusion

Sustainability is a broad topic covering environmental issues (e.g., water usage, waste, biodiversity impact), social concerns (fair compensation, labour rights), as well as economics and governance policies. Nevertheless, whilst the specificity of the approach may vary, many key markets internationally are implementing regulatory models to combat greenwashing, protect consumers, and assist the green transition towards net zero and a circular economy. Given the global marketplace for cosmetics, the need for manufacturers to account for a whole life cycle model when it comes to their products whilst ensuring specificity, justification and verification for the social and environmental claims they make will become increasingly important to ensure compliance and mitigate risk. A key component of these new rules is that every industrial sector will be subject to them, even if some sectors may see more enforcement action than others. The business risks of inaction are real and significant. Impact factors related to penalties, litigation and reputational damage, as well as negative impacts to the environment and increased scrutiny from consumers, NGOs, competitors, and investors alike can only be expected to rise as the crackdown on greenwashing continues. To this end, futureproofing existing products and operations, reviewing standard operating procedures, identifying the methods used for substantiation, and ensuring preparedness will be essential for regulatory compliance and to safeguard commercial and consumer interests.

Introduction to the Sustainable Development Working Group of CACHCA

CACHCA

The Sustainable Development Working Group of Cosmetics Advancement Committee of China Health Care Association (CACHCA), shortened as the Working Group, has been committed to promoting the sustainable development of cosmetics industry since its establishment in September 2022. The Working Group helps the industry move towards a green, healthy, and sustainable future by strengthening communication with government agencies, building databases and standards, monitoring and analyzing China domestic and international policy trends, and establishing platforms for communication and cooperation.

1. Background of Establishment

Currently, the world is facing a series of severe challenges, such as climate change, loss of biodiversity, worsening desertification and frequent extreme weather events. These challenges have brought unprecedented challenges to human survival and development. The 2030 Agenda for Sustainable Development, as a grand blueprint jointly promoted by the world, aims to enhance human well-being, protect the health of the planet, promote prosperity and peace, and foster global partnerships. More than 100 countries and regions around the world have formulated sustainable development goals based on their respective development status and integrated them into their national development strategies.

The European Commission (EU) has launched the European Green Deal, aimed at achieving a more sustainable transformation of the EU economy and society. The deal proposes the goals of "promoting the transformation of the industry towards a clean and circular economy" and "creating a pollution-free and non-toxic environment", as well as a series of legislative amendments to achieve these goals, which will undoubtedly have a profound impact on the cosmetics industry.

China has also formed a "1+N" policy framework for socioeconomic and green transformation at the top-level design level, and has committed to striving to achieve carbon peak before 2030 and carbon neutrality before 2060. The Action Plan on Controlling New Pollutants specifically includes chemicals such as cosmetics for dispersed use as a key focus of environmental and health risk assessment.

The introduction of these policies has not only had a profound impact on the cosmetics industry, but also prompted more enterprises to pay attention to and implement sustainable development strategies, regarding them as an important component of fulfilling corporate social responsibility. In the wave of global green development, the cosmetics industry is at the forefront of change, facing unprecedented opportunities and challenges.

2. Purpose

The Working Group brings together the forces of the industry to jointly explore and cultivate the green advantages of the industry, and transform them into momentum and competitive edges that promote the sustainable development of the cosmetics industry, contributing to the achievement of global sustainable development goals.

3. Core Responsibilities and Work Achievements

In recent years, the Working Group has been committed to promoting exchanges and cooperation at home and abroad, conducting in-depth analysis and research, timely proposing policy recommendations, and actively participating in database and standard construction. The main work carried out is as follows:

(1) Promoting China domestic and international exchanges and cooperation

The Working Group strengthens the exchange and sharing of relevant policies and technologies at home and abroad, establishes cooperative relationships with relevant government agencies, international government organizations, and industry associations, builds an international information sharing platform, in order to jointly promote the global sustainable development of the cosmetics industry.

a. CACHCA has successfully held two National-level Forums including the first and the second International Forum on Beauty Economy and Sustainability (BEST Forum), one of Zhongguancun Forum Regular Activities (ZGC Forum)

b. At the ESG's Promotion to Carbon Reduction, Pollution Reduction, and Green Growth Seminar and Beauty Economy and Sustainability Forum, CACHCA organized in-depth discussions among Department of Solid Wastes and Chemicals of China MEE, Foreign Environmental Cooperation Center of China MEE, and Cosmetics Europe (CE) on guiding green consumption, tracing sustainable palm oil, transparent supply chains, green substitution of ingredients, sustainable product standards, and sustainable packaging standards, as well as building communication bridges between China domestic and foreign governments, associations and enterprises to share our views. Meanwhile, the China-Europe Sustainable Development Alliance has been established.

c. The above-mentioned Alliance held a seminar based on the above platform on July 25, 2024, to explore the impact of the European Green Deal and Sustainable Chemicals Strategy on the cosmetics industry.

(2) Analysis and research

The Working Group organizes research on sustainable development policies and practices both China domestically and internationally, analyzes the impact of policies on China's cosmetics industry, and releases the latest research, data and trends related to sustainable development in cosmetics industry.

a. An article "ESG and Sustainable Development: The Inevitable Choice and New Path for the Cosmetics Industry" was published in the electronic journal "China Cosmetics Regulations and Development" (CNCRDJ) of CACHCA, analyzing the policy background and industry status at home and abroad. The article was not only published in China Medical News, but also reprinted by multiple media outlets such as Sina Finance and China Food and Drug Network.

b. Another article “Towards Sustainability: The Impact and Reflections of the European Green Deal and Its Legislation on the Cosmetics Industry” was published on CNCRDJ, which provides a detailed analysis and summary of the European Green Deal and a series of legislative changes closely related to the cosmetics industry, exploring the profound impact of these changes on the cosmetics industry and providing useful insights for the industry.

(3) Policy recommendations

The Working Group collects and analyses opinions from enterprises through various forms such as organizing seminars and symposiums, communicates with relevant government agencies, and provides suggestions to assist in the formulation and implementation of relevant policies, and promotes the sustainable development of cosmetics industry.

The Working Group have organized and participated in multiple symposiums with relevant departments of the Ministry of Ecology and Environment of China (China MEE), discussing with industry experts and decision-makers, and contributing wisdom and strength to promoting the green development of the cosmetics industry.

(4) Database and standard construction

The Working Group collaborates with relevant government agencies, industry experts and enterprises to build an authoritative database of cosmetic ingredients, research and formulate standards related to the sustainable development of cosmetics industry, aiming to provide clear guidance and norms, and lay a solid foundation for the long-term development of the cosmetics industry.

On June 6, 2024, the Solid Waste and Chemicals Management Center (SCC) of China MEE, the China Health Care Association (CHCA), and China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE) signed a strategic agreement aimed at comprehensively promoting the construction of a beautiful China, accelerating the industry's green and low-carbon transformation, promoting industrial

green technology innovation and high-quality development.

a. Establishment of a database for cosmetic ingredients. The Working Group plan to launch version 1.0 of the cosmetics ingredients database on May 1, 2025, to further strengthen the industry's infrastructure.

b. Construction of sustainable standards. The standard project of "Sustainable Packaging Guidelines - Cosmetics" has been approved by CHCA and is steadily progressing. It is expected to be released before the end of 2024.

Towards Sustainability: The Impact and Reflections of the European Green Deal and Its Legislation on the Cosmetics Industry

Susan Sun CACHCA

With the increasing global emphasis on environmental protection and sustainable development, the cosmetics industry is also facing unprecedented challenges and opportunities. In the past five years, the EU's European Green Deal and a series of legislative changes it has triggered have had a profound regulatory impact on the cosmetics industry, affecting various levels of the industry.

On July 25, 2024, at the invitation of Cosmetic Advancement Committee of China Health Care Association (CACHCA), Cosmetics Europe, based on the China-Europe International Communication, Exchange and Cooperation Platform on Sustainable Development, shared the report entitled "The European Green Deal and its Chemicals Strategy for Sustainability" with colleagues from the Division of Chemicals of the Solid Waste and Chemicals Department of the Ministry of Ecology and Environment (China MEE), the Solid Waste and Chemicals Management Center(SCC) of China MEE, the Cosmetic, Toiletry and Perfumery Association (CTPA) and relevant industry associations in China. This paper will provide in-depth sharing for readers based on the report and relevant information.

1. Introduction to the European Green Deal

The European Green Deal was launched in December 2019 and is the focus of the legislative work of the "von der Leyen" European Commission government during the five-year period (2019-2024). It is the most important programmatic document issued by the European Union (EU) in the field of climate change. It is not only a major cross disciplinary policy of the EU, but also a comprehensive blueprint covering multiple dimensions of the economy, society, and environment. The European Green Deal sets ambitious goals to enhance the EU's 2030 and 2050 climate goals, aiming to provide

clean, affordable, and secure energy, mobilize industry for a clean and circular economy, achieve efficient use of resources, build a zero pollution and non-toxic environment, protect and restore ecosystems and their biodiversity, establish a fair, healthy, and environmentally friendly food system, and accelerate the shift to sustainable and smart mobility [1, 2] . It aims to transform climate and environmental challenges into opportunities in the policy domain, in order to achieve a more sustainable development of the EU economic society.

Fig 1 Key points of the European Green Deal

As a highly integrated regional organization, the laws formulated by EU apply to all of its members [3] , so regulating policy implementation from a legislative perspective is a powerful guarantee for promoting policy implementation. Under the goal of the European Green Deal, EU has successively introduced a series of relevant legal revisions, inevitably affecting the cosmetics industry.

2. Policies Closely Related to the Cosmetics Industry

The goals of "mobilizing industry for a clean and circular economy" and "creating a zero pollution and non-toxic environment" proposed in the European Green Deal, as well as the "Circular Economy Action Plan" and "Chemicals Strategy for Sustainability"

issued to address these two goals, are particularly relevant to the cosmetics industry.

(1) The Circular Economy Action Plan

In March 2020, EU released a new Circular Economy Action Plan, which is not only an important component of the European Green Deal, but also a guiding document for the development of the circular economy in the EU. Its main content includes [4, 5] :

① To develop a sustainable policy framework for products. The concept of circular economy shall be integrated throughout the entire product lifespan, developing a sustainable product policy framework that covers design, consumption, manufacturing, and other aspects.

② To build a key product value chain. It identifies seven key areas, including packaging, for specific implementation and the development of mandatory requirements.

③ To promote waste reduction and value increasing. By controlling the total amount of waste, reducing and controlling harmful substances in waste, establishing an EU market for recycled ingredients, and strengthening waste export management, it aims to achieve the goals of significantly reducing total waste generation and halving non recyclable urban waste by 2030.

These measures have had a specific impact on the cosmetics industry, particularly in establishing standards and requirements related to product sustainability. These standards cover the product's lifespan, repairability, reusability, and recyclability, as well as its environmental footprint, recycled content, management of unsold products, and digital product passport. These standards and requirements not only provide regulatory basis for environmental claims of products and packaging, but also provide consumers with easily understandable information labeling, helping them make more environmentally friendly choices, and providing evidence-based methods and frameworks for green claims.

(2) The Chemicals Strategy for Sustainability (CSS)

The Chemicals Strategy for Sustainability(CSS), released by the European Commission on October 14, 2020, aims to completely reshape chemical policies, involving over

50 measures, including: to shift paradigm from risk-based action to hazard-based preventive action on “most harmful substances”; to simplify and integrate Chemicals Legislation across all sectors; to link to Circular Economy (safe and sustainable by design); to improve data transparency; to make partial revision of the REACH Regulation and other measures [6, 7] .

3. Regulations May Affect the Cosmetics Industry

(1) Revision of CLP Regulation

① Objectives

The objective is to establish the central position of the CLP Regulation in chemical legislation, simplify and accelerate the classification process, enhance the regulatory role of CLP in relevant downstream legislation, and ensure the clarity and comprehensibility of hazard labels.

② Achievements

The initial CLP revision plan considered bringing industries that currently use risk-based management rather than hazard-based management, such as the cosmetics industry, into CLP's regulatory scope, but this plan was ultimately not implemented. The EU passed the revised CLP regulation on April 23, 2024, which includes the following:

a. Create hazard categories: To introduce substance categories such as endocrine disruptors, persistent/bioaccumulation, and toxic substances, and enhance hazard-based restrictive measures for downstream legislation.

b. Classification of natural mixtures to be based on mixture calculation rules, no possibility to use test data on the mixture.

c. Group classification: It refers to the classification of substances with similar chemical structures or properties as a whole for hazard classification, and allows for the classification of substance groups based on data from one individual substance.

d. ECHA can trigger CLP classifications.

e. Introduction of digital labelling.

(2) Revision of REACH Regulation

① Objectives

The objective is to streamline the REACH authorisation/restriction process; Using grouping approach for restrictions and bans; The plan is to prohibit the use of Generic Risk Management Approach (GRA) in existing CMR Cat 1 substances; Prohibition of PFAs; Exemptions only granted for "essential use" substances (exemption cannot be granted for safe use); Introduce additional Mixture Assessment Factor (MAF) for human and environmental risk assessment; Clarify registration requirements for certain polymers; And extend registration requirements to low tonnage substances, etc.

② Achievements

The above revision process has been put on hold. The new European Commission government is committed to simplifying the REACH authorization/restriction process and clarifying the PFAs.

(3) Targeted Revision of Cosmetic Products Regulation

① Objectives

The original plan was to implement hazard based bans for Generic Risk Management Approach (GRA) substances, and only provide exemptions in cases of "essential use"; To introduce MAF and update the definition of nanomaterials based on the EU's horizontal recommendations; To adjust the organizational structure of SCCS under the EU and move it to the European Chemicals Agency (ECHA) organization; To consider introducing digital labelling that allow ingredient lists to be displayed through digital labels rather than just on the packaging (for allergen information, clear labelling is still required on the packaging).

② Achievements

The revision plan has been put on hold, and the European Commission is evaluating the next steps of its work. This indicates that while promoting regulatory updates, the European Commission also carefully considers the impact of revisions on various aspects to ensure that the final revision can achieve a balance between industry demand, consumer protection, and environmental sustainability. The new European Commission has not yet decided whether and how to proceed with these revisions.

(4) Revision of the Urban Wastewater Treatment Directive (UWWTD)

① Objectives

The original goal of revision was to enhance the minimum treatment standards and performance requirements for wastewater treatment plants within the EU, including expanding the “Extended Producer Responsibility scheme (EPR)” to provide funding for upgrading wastewater treatment plants, to ensure the removal of "micro-pollutants" (a broad, hazard-based definition of "micro pollutants" that includes substances unrelated to wastewater treatment).

② Achievements

The European Commission has released a proposal and concluded discussions in November 2022, reaching compromises including joint funding (which may only apply to specific industries), exemptions for biodegradable substances, and cost calculations based on the amount of micro pollutants rather than the entire product. The Directive may be released in the fourth quarter of 2024, while the establishment and implementation of the “Extended Producer Responsibility (EPR)” scheme is expected to take some time, with a gradual start anticipated by 2027.

(5) Packaging and Packaging Waste Directive (PPWD)

① Objectives

To promote reuse and recycling, increase the recycling content in packaging, address the issue of excessive packaging, and reduce packaging waste.

② Specific Items Involved

By 2030, all packaging will be recyclable; Defining recyclability (degree of recyclability) through future secondary legislation; Set different minimum percentage requirements for the content of recyclable materials across various industries, with varying implementation timelines for these requirements; Establish EPR fees related to recyclability and recycling content (for plastic packaging); Manufacturers are obliged to minimize packaging as much as possible; Establish reuse targets (not yet applicable to cosmetics); Restrict the use of certain packaging forms (such as single-use hotel miniature packaging).

③ Achievements

The European Commission has released a proposal in November 2022, but there is still significant controversy. If officially approved, the Directive may be released in the fourth quarter of 2024. The Directive sets the time frame for achieving recyclability/content recycling goals between 2030 and 2040; At present, the transition period for other items is still under discussion, and the proposed transition period is 12 months after the promulgation of the Directive, which is considered insufficient and may not be sufficient to complete the necessary changes.

(6) Ecodesign for Sustainable Products Regulation (ESPR)

① Objectives

The ESPR aims to significantly improve the circularity and environmental sustainability aspects of products placed on the EU market. It provides a regulatory framework that lays the foundation for future industry-specific regulations.

② Specific Items Involved

The ESPR provides a "catalogue" of requirements on sustainability, which includes: product durability, reusability, upgradability, and reparability; the presence of substances of concern (based on the definition of harm); energy and resource efficiency; recycled content; remanufacturing and recycling; carbon and environmental footprint; and environmental footprint information requirements. The ESPR also includes restrictions on the destruction of unsold goods and introduces the concept of a Digital Product Passport (DPP).

③ Achievements

The ESPR has entered into force in the second quarter of 2024. Restrictions and/or reporting on the destruction of unsold goods by large companies may come into effect by mid-2026, while for SMEs it will be effective by 2030. Specific requirements for the cosmetics industry are unlikely to be introduced before 2028.

(7) Directive of Empowering Consumers for the Green Transition

① Objectives

The Directive aims to help consumers make circular and ecological choices; protecting consumers from being misled by so-called "green" claims (including: prohibiting the use of general environmental claims without clear, objective and verifiable conditions; sustainability labels should be based on independent verification; prohibiting the promotion of a common practice or a mandatory requirement by law as a prominent feature of the product; when comparing products, information on the comparison method must be provided, etc.).

② Expected Implementation Time

The "Directive of Empowering Consumers for the Green Transition" has come into effect and been issued, and member states must translate it into member state law and immediately begin implementing it by September 2026.

(8) Green Claims Directive

① Objectives

The objective is to combat "greenwashing"; require environmental claims to be supported by scientific evidence; certify green claims before sale; prohibit environmental claims if the product contains hazardous substances (regardless of whether it is related to the actual safety of the product), etc.

② Expected Implementation Time

The "Green Claims Directive" is expected to be released before the end of 2024.

(9) Deforestation-Free Products Act

① Objectives and Requirements

The "Act" aims to ensure that specific commodities entering the EU market, such as soy, beef, palm oil, timber, cocoa, coffee and rubber, as well as their derivatives, do not contribute to deforestation or forest degradation. It requires businesses operating or trading in these commodities within the EU market to prove that their products do not originate from lands where recent deforestation has occurred and have not negatively impacted forest health. To this end, relevant parties must conduct thorough due diligence and submit corresponding reports to demonstrate the sustainability of their

supply chains. These requirements primarily target ingredients suppliers to ensure they adhere to environmental protection standards.

② Expected Implementation Time

The legislative work for the act has been completed, and it is expected to be implemented by the end of 2024.

4. Conclusion

The “European Green Deal” under the 2019-2024 term of the European Commission, led by von der Leyen, has implemented significant regulatory initiatives, with most legislation either passed or in the final stages of passing. These legislative actions have had a wide-ranging impact on the cosmetics industry and its supply chains, including the classification of chemical hazards, environmental claims, packaging sustainability (recycled content/recyclability), and the industry's contribution to urban wastewater treatment. However, the extreme shift from "risk management" to "hazard management" in the field of chemical management has been put on hold. The focus of the new European Commission (2024-2029) will undoubtedly become a focal point of attention in the industry.

5. Reflections

The European Union has established a comprehensive framework for the green transformation of its economic and social systems based on the “European Green Deal”, while China has also formed a "1+N" policy framework for the green transformation of its economy and society at the top-level design. The cosmetics industry both domestically and internationally is at the forefront of the green development trend. In order to further promote the sustainable development of the industry, it is recommended to take actions in the following areas:

First, to deepen international cooperation and exchange. We should actively understand the latest technological advancements and industry trends in the global green field, and participate in the formulation of international standards, which will enhance our influence and voice on the global stage.

Second, to promote green technological innovation. This includes innovation in cosmetic ingredients, production technology, packaging and standards, incentivizing innovative activities within the industry, and making innovation the core driving force for green development.

Third, to build a data platform of cosmetic ingredients information. By accumulating and improving information and data related to cosmetic ingredients, we can provide a solid data support for product development, human and environmental health risk assessment, standard establishment and risk management.

Fourth, to raise consumer awareness. We can enhance consumers' understanding of environmentally friendly products, guide them to make more environmentally friendly consumption choices through education and publicity activities, and thus promote the entire market to shift towards a green consumption model.

The green transformation of the cosmetics industry will be a long-term and complex process. We believe that through the concerted efforts of the government, enterprises, relevant institutions and consumers, we will definitely be able to achieve this goal and move towards a sustainable future together.

Special Acknowledgement: We would like to extend our sincere gratitude to Cosmetics Europe (CE) for sharing updates on the European Green Deal and the Chemicals Strategy for Sustainability (CSS) as of July 2024!

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Industry Insights

- Export Value Increased by 8.7% Year-on-Year and Trade Deficit Continuing to Narrow
  ——Analysis of Foreign Trade Situation of China's Cosmetics in the First Half of This Year

Export Value Increased by 8.7% Year-on-Year and Trade Deficit Continuing to Narrow
——Analysis of Foreign Trade Situation of China's Cosmetics in the First Half of This Year

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Focusing on industry policies and regulations, market access and international collaboration research, Liu Yan was responsible for the initiation and establishment of RCEP International Cooperation and Exchange Platform on Cosmetics, as well as the initiation and establishment of SCO Traditional Medicine Industry Alliance. She led the review project of the National Traditional Chinese Medicine Service Export Base, and participated in various ministerial-level projects such as the project of international cooperation on the Belt and Road Initiative by the State Administration of Traditional Chinese Medicine. She has also organized multiple international seminars and maintained close cooperation with foreign industry organizations.

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On July 15th, the National Bureau of Statistics released data showing that in the first half of this year, the total retail sales of consumer goods reached CNY 2.3596 trillion, a year-on-year increase of 3.7%. Among them, the retail sales of cosmetics for units above designated size reached CNY 216.8 billion, a year-on-year increase of 1%, lower than the growth rate of total retail sales of consumer goods in the same period, and further decreased from the 3.4% growth rate in the first quarter of this year. The gap between the growth rate and the 5.1% growth rate for the whole year of 2023 continues to widen, and the growth rate of China domestic cosmetics market has further slowed down.

In terms of import and export, according to customs data statistics, the China Chamber of Commerce for Import and Export of Medicines and Health Products (shorted as CCCMHPIE) showed that in the first half of the year, the total import and export volume of cosmetics in China was USD$11.63 billion, a year-on-year decrease of 7.2%, and a significant slowdown from the 12.9% decline in the first quarter. Among them, the import value was USD$8.36 billion, a year-on-year decrease of 12.3%. Although the downward trend continues, it has slowed down compared to the 14.5% decline in the same period last year and the 19.9% decline in the first quarter of this year; In terms of export, the total export volume of cosmetics in China in the first half of the year was USD$3.27 billion, a year-on-year increase of 8.7%, and the trade deficit of cosmetics import and export further narrowed. It is evident that as the market scale of China domestic cosmetics tends to stabilize, local cosmetics companies continue to expand overseas and seek breakthroughs in emerging markets.

Import: The sources of origin are relatively concentrated, continuing the down cycle.

With the stabilization of China domestic cosmetics market and the rise of local cosmetics brands, the growth trend of cosmetics imports continues to slow down, and it has started a sustained negative growth cycle since 2022 - the import value of cosmetics in 2022, 2023 and the first quarter of this year decreased by 10.6%, 19.4% and 19.9% year-on-year, respectively. In the first half of this year, the total import value of cosmetics in China was USD$8.36 billion, a year-on-year decrease of 12.3%, with a slight decline narrowing.

Main Sources of Import

In the first half of the year, China's cosmetics imports were concentrated in Europe, America, Japan and South Korea, with the top five being France, Japan, South Korea, the United States and the United Kingdom, accounting for 80.7% of the total imports.

France is the largest source of cosmetics imports in China, but imports from France have maintained a negative growth trend since 2022, with a year-on-year decrease of 12.1% in the first half of this year, a significant improvement from the 23.2% decline in the first quarter of this year. Despite a 34.7% decline in exports to China in the first quarter of this year, Japan, ranked second, still experienced a 29.8% decline in the first half of the year, which is not optimistic. South Korea, ranked third, has seen a relatively small decline in exports to China, but the trend is accelerating. The decrease was 6% in the first half of this year, further declining from the 2.2% drop in the first quarter. Since 2020, the USA and the UK have been the fourth and fifth largest cosmetics import markets in China. In the first quarter of this year, China's imports from the USA and the UK decreased by 13.1% and 7.9% respectively, but this trend showed a significant rebound in the second quarter of this year. In the first half of the year, the decline in

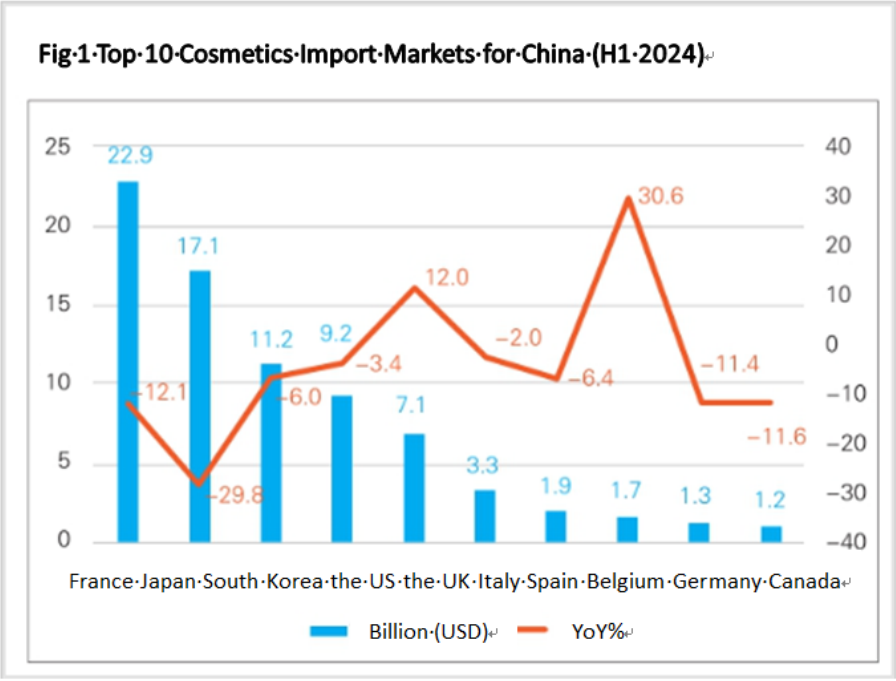

Fig 1

China's imports from the USA narrowed to 3.4%; The import value from the UK has achieved a positive growth of 12%. According to relevant data, the UK is one of only two countries among the top ten import markets in the first half of this year to achieve positive growth in exports to China, with the other country being Belgium ranked eighth. (Fig 1)

The import sources ranked sixth to tenth are Italy, Spain, Belgium, Germany and Canada, accounting for 11.2% of the total import volume. Canada has replaced Poland, which was in the tenth place in the first quarter, to become the tenth largest source of cosmetic imports in China. Meanwhile, Poland has seen a year-on-year decline of 15.2%, falling to the fourteenth position, which is a stark contrast to its first-quarter growth of 9.4%. It is noteworthy that Belgium achieved a positive growth of 30.6% in the first half of this year, completely reversing the decline of 18% in the first quarter.

From the perspective of the proportion of various import markets, the top ten import markets account for 91.9% of China's total cosmetics imports, with a high degree of concentration. Among the top five import markets, except for South Korea, whose proportion has decreased from 21.4% in 2019 to 13.5% in the first half of this year, showing a continuous downward trend, the proportion of imports in other markets has remained relatively stable. In recent years, despite the increasingly fierce competition in China's cosmetics market, established cosmetics industry giants such as France and Japan have maintained their market share in Chinese cosmetics market by relying on highly renowned cosmetics brands, long-term accumulated technological advantages and diverse product matrices.

Overall, in the first half of the year, the cosmetics imports in China continued to show a trend of overall reduction. Among the top ten import sources, only two achieved positive growth, while the rest showed negative growth; However, the rate of decline in imports from most sources has slowed down, and there is still room for recovery. In the increasingly saturated cosmetics market in China, a group of China domestic cosmetics companies that have gradually accumulated brand influence and excellent reputation

have emerged, competing with international brands to some extent, squeezing the survival space of imported cosmetics. It can be foreseen that the challenges faced by imported cosmetics will become increasingly severe in the future.

Main Imported Products

In terms of imported product categories, in the first half of the year, the cosmetic category with the highest import value in China was beauty and skincare products, with an import value of USD$6.75 billion, accounting for 80.8% of the total import value, a year-on-year decrease of 12.6%, with a slower decline rate compared to the first quarter. Body care products are the second largest category of imported cosmetics in China, with an import value of USD$620 million, a year-on-year decrease of 17.4%. The import volume of perfume products ranked third, reaching USD$500 million. It was the only category of imported products that achieved positive growth, with an increase of 0.8% year on year. The import value of hair care and oral care products ranked fourth and fifth respectively, at USD$390 million and USD$100 million, with a significant decline compared to the first quarter's value of over 20%. (Fig 2)

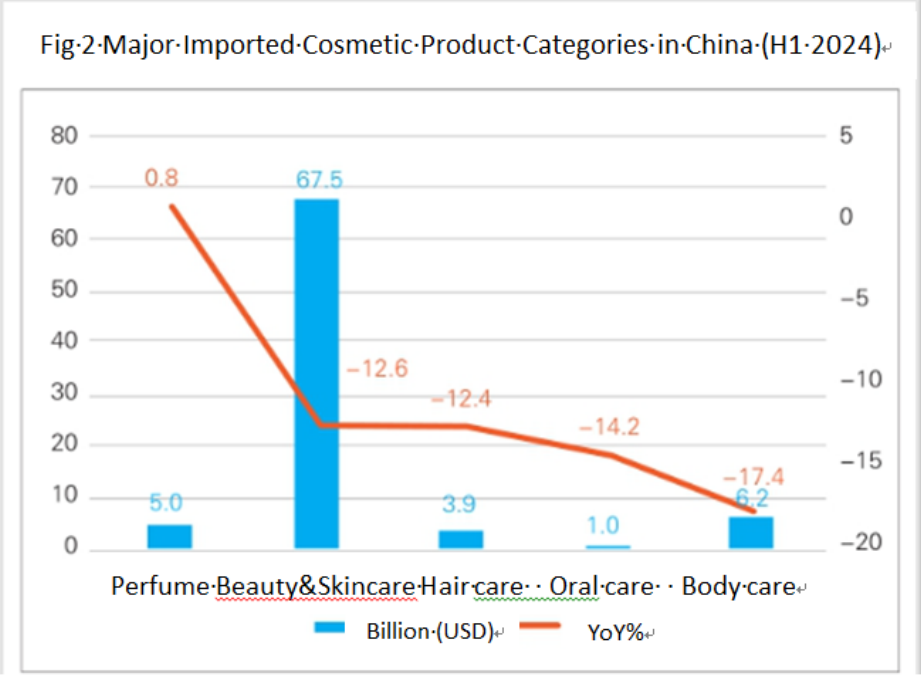

Fig 2

Among all the subcategories of imported cosmetics, only four types of products achieved positive growth in import value in the first half of the year, namely, perfume, lip cosmetics, hair styling agents and other oral and dental cleansers. Among them, the import value of other oral and dental cleaners increased by 19.4%; lip cosmetics grew by 8.1%; The growth rate of the other two types of products were both around 1%.

Export: Relatively dispersed destinations, achieving positive growth in major markets

In the first half of the year, against the backdrop of slowing growth in China domestic cosmetics market and continuous reduction in the scale of cosmetics imports, China's cosmetics exports showed a growth trend, with an export value of USD$3.27 billion, a year-on-year increase of 8.7%, achieving positive growth for major export destinations, further demonstrating that the international competitiveness of China domestic cosmetics is gradually improving.

Main Export Markets

The export market for cosmetics in China is relatively scattered. In the first half of the year, the top five export markets were the United States, Hong Kong, the UK, Japan and the Netherlands. The United States and Hong Kong have always been the first and second largest export markets for cosmetics in China, with export volumes of USD$640 million and USD$440 million respectively in the first half of the year, with year-on-year growth rates of around 9%. In the past five years, the UK and Japan have consistently ranked as the third and fourth largest cosmetics export markets in China, with export volumes reaching USD$220 million and USD$160 million respectively in the first half of the year. Among them, China's exports to the UK have performed outstandingly, with an overall high-speed growth of 21.5% in the first half of the year, following a 28.3% increase in exports in the first quarter; Unlike the 4.4% growth in the first quarter, exports to Japan experienced a 2.4% decline. The Netherlands surpassed South Korea in the first quarter and entered China's fifth largest cosmetics export market in the first half of the year with a growth rate of 34%. (Fig 3)

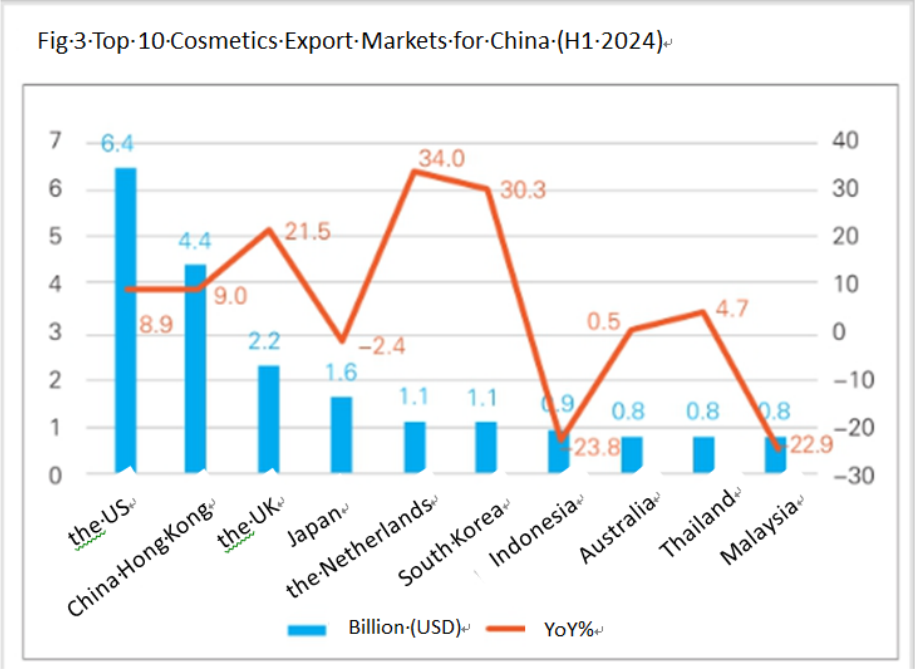

Fig 3

The sixth to tenth ranked export markets are South Korea, Indonesia, Australia, Thailand and Malaysia. South Korea rapidly climbed from 15th place in 2022 to 6th place with a growth rate of 108.5% in 2023. In the first half of this year, the exports to South Korea still achieved a growth rate of 30.3%. Although the growth rate has significantly declined from 61.3% in the first quarter, the growth momentum is still evident, reflecting the competitiveness of China's cosmetics in the South Korean market. Indonesia and Malaysia have been strong export markets for cosmetics in Southeast Asia in recent years, ranking fifth and ninth in China with growth rates of 67.7% and 12.0% respectively in 2023. But in the first half of this year, the situation took a sharp turn for the worse, with a decline of over 20%. Upon investigation, Indonesia and Malaysia, as popular emerging markets for cosmetics with large populations and rapid economic growth, have attracted numerous international brands to enter the market. However, due to limited purchasing power of local consumers and strong performance of Korean brands, the influence of Chinese cosmetics brands has declined. China's exports of cosmetics to Australia have maintained a continuous growth trend since 2022, but the export products are mainly ingredients and cleaning products with low technical barriers and strong substitutability, which do not have a

stable growth foundation, resulting in a significant slowdown in growth rate in the past two years; With the rapid reduction of exports of oral and body cleaning products, China's export growth rate to Australia has dropped from 52.0% in 2022 to 0.5% in the first half of this year. The export value to Thailand has fluctuated significantly since 2022, with alternating periods of high-speed growth and negative growth. It decreased by 10.4% in the first quarter of this year, but achieved an overall growth of 4.7%.

In terms of the proportion of export value, the top five export markets account for 48.0% of China's total cosmetics exports, with the United States and Hong Kong accounting for much higher proportions than other markets, at 22.7% and 13.3% respectively. The sixth to tenth largest export markets account for a total of 12.4%, and there is not much difference in export value between each market.

Main Export Products

In the first half of the year, the largest category of cosmetics exports in China was beauty and skincare products, with an export value of USD$1.86 billion, a year-on-year increase of 8.5%, which was slightly lower than the 15.7% in the first quarter. The top five export markets for this product category are the United States, Hong Kong, the UK, South Korea and the Netherlands, all of which have achieved positive growth, with exports to South Korea and the Netherlands growing by 36.1% and 42.2% respectively. The second largest product category in terms of export value is body care products, with an export value of USD$520 million, a year-on-year decrease of 11.4%, continuing the downward trend in the first quarter. The top five export markets for this product category are the United States, Japan, Hong Kong, the UK and Malaysia, with only 15.5% growth in exports to the UK, while other markets have experienced varying degrees of contraction. Oral care products and hair care products are the third and fourth largest export categories, with export values of USD$400 million and USD$260 million respectively, both increasing by 20.5% year-on-year, with little difference from the first quarter. It is worth noting that in recent years, the export of perfume has repeatedly achieved good results, with the export volume growing rapidly from USD$150 million in 2020 to USD$370 million in 2023, and the year-on-year growth rate

also climbed from 21.5% in 2021 to 49.6% in 2023. In the first quarter of this year, the export growth of perfume reached 60.8%, while in the first half of this year, the growth rate also reached 46.8%, still maintaining a strong growth momentum. (Fig 4)

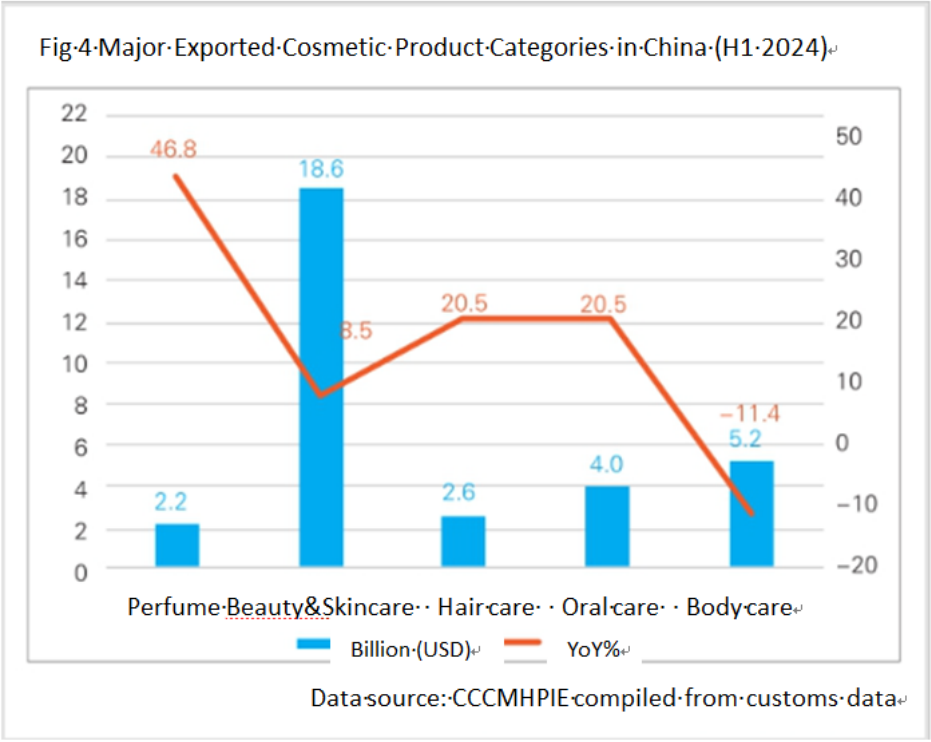

Fig 4

From the perspective of segmented fields, the exported cosmetics in China were mainly skincare and makeup products in the first half of the year. Among them, the export of lip cosmetics grew rapidly, with a year-on-year increase of 43.5%, and the export value reached USD$340 million, accounting for 18.3% of the total export value of beauty and skincare products. The export value of body care products has decreased, mainly due to a decline in the export value of toiletries, which accounts for the largest proportion. The export value of oral care products has increased comprehensively, with toothpaste accounting for 65.4% of the total export value. In hair care products, except for a year-on-year decrease of 22.0% in the export value of perm agents, the export value of other products has achieved varying degrees of growth compared to the same period last year.

Main Export Provinces (cities)

In recent years, China's cosmetics industry has been booming and showing a distinct

trend of clustered development. In terms of export value, the top five exporting provinces (cities) in the first half of the year were Guangdong, Zhejiang, Shanghai, Jiangsu and Fujian, accounting for 86% of the total cosmetics exports.

Specifically, Guangdong Province and Zhejiang Province ranked first and second respectively in the export volume of cosmetics in the first half of the year, and were much higher than other provinces (cities). As a major province in China's cosmetics industry, cosmetics exports in Guangdong accounted for 35.6% of the total exports in the first half of the year, reaching USD$1.17 billion, a year-on-year increase of 11.3%, further increasing the growth rate from 9.5% in the first quarter. The export value of cosmetics in Zhejiang Province reached USD$850 million, a year-on-year increase of 12.8%, showing overall stability and progress. It is worth noting that the export value of cosmetics in Hainan Province has grown significantly, ranking 14th in 2023. However, it became the tenth largest cosmetics exporting province with a growth rate of 385.7% in the first half of this year.

From the perspective of cosmetics sub categories, the top three provinces in terms of export value for beauty and skincare products are Guangdong, Zhejiang and Shanghai City, all of which have export values in the billions of US dollars. The export values of Guangdong Province and Zhejiang Province both exceed USD$600 million, while Shanghai's export value is USD$260 million. The top three provinces in terms of hair care product exports are Guangdong Province, Jiangsu Province and Zhejiang Province. Guangdong Province still ranks first with an export value of USD$150 million; The export value of Jiangsu Province and Zhejiang Province is less than one-third of that of Guangdong Province, but Zhejiang Province has grown rapidly, with a growth rate of up to 66.5%. The top three provinces in terms of export value of oral care products are Guangdong Province, Jiangsu Province, and Shanghai City. Guangdong Province's export value is USD$170 million, which is about USD$100 million higher than the second place Jiangsu Province; The export value of Shanghai was USD$44.79 million, but the growth was impressive with a year-on-year increase of 30%. In terms

of body care products, Guangdong Province still ranks first with an export value of USD$150 million, while Zhejiang Province, Fujian Province and Jiangsu Province rank second, third, and fourth respectively, with export values all at the level of USD$80 million. However, Zhejiang Province is showing a downward trend, with a year-on-year decrease of 29.0%. The distribution of major export provinces of perfume is quite different from other categories. The export volume of perfume in Zhejiang Province is far higher than that of other provinces, reaching USD$100 million, up 54% year on year; Guangdong Province and Shanghai ranked second and third respectively, with export values of around USD$30 million.

Overall, in the first half of this year, China's foreign trade in cosmetics showed a trend of declining import volume, increasing export volume, and further narrowing trade deficit.

Products take the lead, fueling the international development of brands.

At present, it has become an undeniable fact that the growth of cosmetics market in China is slowing down. Faced with an increasingly competitive China domestic market, both local and foreign companies find it quite challenging to get a share of this big cake. Against this backdrop, capable local cosmetics companies are striving to adopt a dual approach, trying to consolidate their domestic market share while looking globally for new blue oceans.

This trend is also becoming increasingly evident in the import and export trade of cosmetics. On the import side, the scale of China's cosmetics imports has been shrinking for several consecutive years, with many international big brands frequently expressing that their business growth in China is facing bottlenecks and challenges. On the export side, the situation is quite the opposite; in recent years, the scale of China's cosmetics exports has maintained a continuous and robust growth, and breakthroughs have been made in many emerging markets. The reasons for this include not only the weak global economic growth leading to insufficient demand and decreased purchasing power but also the strong rise of China domestic cosmetics industry.

After years of development, the cosmetics industry in China has already possessed technology and quality comparable to or even surpassing imported products in some fields. Meanwhile, the cosmetics industry chain and supply chain have a solid foundation. From ingredients to intermediates, packaging materials and finished products, there are many enterprise layouts in every link, which makes China domestic cosmetics more cost-effective and diverse compared to imported cosmetics. Moreover, in recent years, Chinese cosmetics companies have actively explored the application of Chinese special plant ingredients in the field of cosmetics, and successfully filed a batch of new cosmetic ingredients with clear efficacy and natural sources. On the one hand, this conforms to the global trend of advocating green and natural products; On the other hand, it endows the brand and product with cultural value, further enhancing the competitiveness of the brand and product in domestic and international markets.

Despite the increasingly fierce competition in China domestic cosmetics market, the path for companies to "go global" is by no means smooth sailing. However, more and more local cosmetics companies are focusing on research and development and actively innovating, beginning to seek a transformation to high-end, which injects strong confidence into the future development of China's cosmetics industry. It is foreseeable that the engine of the "beauty economy" has been ignited, and the pursuit of beauty is endless. There is still huge development space in the global cosmetics market. Local cosmetics companies in China need to strengthen their internal skills, be down-to-earth, perceive the potential needs of consumers, and provide safe and high-quality products and services in a targeted manner. Based on this, explore and excavate product and brand positioning, take the product as the forefront, and ultimately achieve the international development of the brand.

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