

BUILDING ON THE PAST AND SHAPING THE FUTURE:  
THE DEVELOPMENT AND FUTURE PROSPECTS OF CHINA'S  
COSMETICS SAFETY ASSESSMENT SYSTEM

EFFCI AND THE GLOBAL EXCELLENCE IN COSMETIC  
INGREDIENT MANUFACTURING: A STRATEGIC AND TECHNICAL  
OVERVIEW OF THE EFFCI GMP STANDARD

RECENT KEY DEVELOPMENTS IN COSMETIC REGULATIONS  
IN THE REPUBLIC OF KOREA

RESEARCH ON INTERNATIONAL TOOTHPASTE REGULATORY  
LAWS AND REGULATIONS (PART II) - EU AND U.S.

# CHINA COSMETICS REGULATIONS AND DEVELOPMENT

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## Chinese Policies and Regulations

- ◆ Building on the Past and Shaping the Future: The Development and Future Prospects of China's Cosmetics Safety Assessment System

## Building on the Past and Shaping the Future: The Development and Future Prospects of China's Cosmetics Safety Assessment System

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Since May 1, 2025, the submission of full-version cosmetic safety assessment reports has become mandatory, marking a significant milestone in China's cosmetics regulatory system. This reform, initiated in June 2020 with the promulgation of the *Cosmetic Supervision and Administration Regulation (CSAR)*, has undergone a five-year phased rollout, ultimately establishing a scientific and international safety assessment framework. By systematically reviewing the development and implementation effects of relevant policies at home and abroad, and identifying the pain points and development needs of industrial transformation, this article aims to provide references for further improving the cosmetic safety assessment system and advancing industrial upgrading.

### I. Progress and Trends in International Cosmetic Safety Assessment

Cosmetic safety assessment is a regulatory priority worldwide. The European Union (EU) and the United States have developed mature systems and established a model where ingredient safety assessment replaces traditional animal testing. In the EU, the Scientific Committee on Consumer Safety (SCCS) is responsible for providing scientific opinions, conducting risk assessments, and updating guidelines. Its *Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation* issued in 2003 systematically standardized assessment methods, with the latest 12<sup>th</sup> edition released in 2023. While the U.S. Cosmetic Ingredient Review (CIR), composed of scientists from multiple fields, focuses on the safety assessment of ingredients. To date, the CIR has assessed over 6,000 ingredients, and its reports have important reference value for the industry<sup>[1, 2]</sup>.

Traditional animal testing is gradually being phased out due to its long cycle, high cost, species differences, and ethical concerns. With the interdisciplinary integration, in vitro and predictive toxicology technologies are advancing rapidly, enabling more

efficient and accurate toxicity testing. Regulatory authorities in many countries have strengthened the recognition and application of these technologies. For example, the U.S. Food and Drug Administration (FDA) has clearly stated in relevant documents that it will enhance the use of in vitro and predictive toxicology technologies to reduce animal testings<sup>[3]</sup>.

China has developed nearly 50 cosmetic toxicology methods referencing standards from the Organization for Economic Cooperation and Development (OECD), covering a number of animal testing alternatives and computational toxicology tools. Based on scientific consensus, these measures ensure the scientificity and international mutual recognition of assessment results. The European Chemicals Agency (ECHA) database consolidates toxicological data of thousands of ingredients, which, by harmonizing with OECD methods, unifies standards, reduces repetitive tests, and promotes the standardization of assessments and global regulatory coordination.

## **II. Development of China's Cosmetic Safety Assessment System**

China's cosmetic safety assessment system is gradually aligning with international standards. In 1987, the former Ministry of Health issued GB 7919-1987 *Procedures and Methods for Safety Evaluation of Cosmetics*, laying the foundation for safety evaluation. In 2010, the former State Food and Drug Administration issued relevant guidelines to provide guidance for the assessment of potential risk substances.

In 2014, the notification-based filing system for domestic non-special-purpose cosmetics was implemented, requiring the submission of risk substance assessment reports. This marked the beginning of systematic assessment of ingredient risks in the industry. In 2015, relevant draft for comments clarified the qualifications and procedures for assessors, laying the foundation for the subsequent system building.

In June 2020, the CSAR was released and implemented in January 2021, initiating the reconstruction of the industry's regulatory and technical systems. In April 2021, the *Technical Guidelines for Cosmetic Safety Assessment* (hereinafter referred to as the

Guidelines) was released and implemented in January 2022. It clarified requirements for “simplified version” and “full version” reports, with the Inventory of Existing Cosmetic Ingredients in China (2021 Edition) (IECIC) providing the basis for simplified version assessment.

In April 2024, the Announcement on Several Measures for Optimizing Cosmetic Safety Assessment Administration (hereinafter referred to as the Optimization Measures) was implemented. It allowed some general cosmetics to submit only basic conclusions and extended the transition period for the simplified version to May 2025. During the same period, the National Institutes for Food and Drug Control (NIFDC) intensively released technical guidelines to enhance data support and systematically address gap in ingredient assessment data.

This process marks the transition of the China's system from initial adaptation to scientization and internationalization, establishing a three-in-one framework of "regulatory requirements - method guidelines - data support" and laying a long-term mechanism for the standardized development of safety assessment.

### **III. Collaborative Efforts for Effective Safety Assessment**

The implementation of cosmetic safety assessment relies on collaboration among government agencies, industry associations, enterprises, and other stakeholders. The National Medical Products Administration (NMPA) and NIFDC have played a leading role, establishing institutional and technical foundations through the CSAR, the Guidelines, the Optimization Measures, etc. They have extensively solicited opinions, incorporated reasonable suggestions, and promoted high-quality development of the industry.

Industry associations have played an important role in promoting policy implementation. As an industry representative, the Cosmetics Advancement Committee of China Health Care Association (CACHCA) has actively participated in building the cosmetic safety assessment system. In 2023, CACHCA established a Cosmetic Safety Assessment Group, which deeply engaged in policy formulation, actively attended over ten safety

assessment-related meetings held by the Administration Department and NIFDC, submitted three proposals to relevant authorities and voiced enterprise perspectives to inform policy improvement. At the Parallel Forum on Cosmetic Safety Assessment Technology and Development Trends, successfully hosted by CACHCA during the 2023 BEST Forum, the industry deepened its understanding of key safety assessment points and accumulated practical experience. In February 2024, CACHCA, on behalf of the industry for the first time, proposed to the NMPA to postpone the implementation of the full-version safety assessment by one year, gaining valuable preparation time for the industry and effectively ensuring the smooth implementation of key policies.

Enterprises and experts have actively responded to regulatory requirements, contributing ideas to address industry issues such as lack of assessment data. CACHCA has also collaborated with the Solid Waste and Chemicals Management Center (SCC) of the Ministry of Ecology and Environment (MEE) to build a cosmetic ingredient database, exploring the integration and application of computational toxicology prediction method data to provide data support for safety assessment.

With multi-stakeholder collaboration, the industry's awareness of primary responsibility has been enhanced, assessment work has gradually been standardized, and the "administration-method-data" framework has effectively supported the sustainable advancement of safety assessment. This has prevented product quality and safety risks at the source and facilitated industrial upgrading.

#### **IV. Reflections on Cosmetic Safety Assessment**

As the system advances, while achieving significant results, we also pay attention to the following aspects that need continuous optimization and improvement:

##### **1. Gaps in Data Foundation Scientificity Compared with International Standards**

The historical usage data in IECIC has, to a certain extent, lowered the threshold for initial industry safety assessments. However, as "empirical data" rather than "professional assessment conclusions", it lacks toxicological data support and

professional assessment, making it difficult to gain widespread international recognition. Long-term reliance on such data may weaken the scientificity and rigor of assessments, fail to meet regulatory requirements in international markets such as the EU and the United States, hinder domestic cosmetics from "going global", and undermine the international competitiveness of China's cosmetics industry.

## **2. Urgent Need to Improve Integrity of Ingredient Safety Information**

Safety of ingredients is the foundation and prerequisite for ensuring product safety. However, most ingredients in China currently have significant shortcomings in safety information, specifically manifested as: non-standard or inaccurate naming, incomplete source information, vague description of production processes, lack of chemical property data, unclear types and limits of residual impurities, and insufficient disclosure of environmental safety information, etc. In addition, relevant technical requirements and testing methods are poorly standardized. These information defects directly create loopholes in the "input end" of safety assessment, making it difficult to support scientific and comprehensive risk assessment and control.

Furthermore, cosmetics do not undergo metabolic transformation during their entire service life and generally enter the ecological environment through sewage discharge systems after use, with potential hazards that cannot be ignored<sup>[4]</sup>. Drawing on experience of chemical management processes and technical methods globally, major developed countries and regions are strengthening the risk screening, assessment, and management of chemicals, continuously restricting or eliminating "problematic" chemicals, and addressing new pollutant issues at the source. China's New Pollutant Action Plan has also clearly stated that it will conduct environmental and health hazard testing and risk screening for chemicals used in decentralized applications (including in cosmetics)<sup>[5]</sup>.

## **3. Urgent Need to Address Safety Assessment Challenges for Plant-derived Ingredients**

The safety assessment of plant-derived ingredients is a common technical challenge in the global cosmetics industry. Currently, most of the approximately 3,600 plant-derived

ingredients included in IECIC lack systematic authoritative safety assessment conclusions. This has significantly restricted the widespread application and innovative development of plant ingredients in cosmetics. Therefore, accelerating solutions to plant ingredient safety assessment has become a key priority for promoting the high-quality development of China's cosmetics industry.

#### **4. Imperative for Industry and Cross-departmental Collaboration**

At present, toxicological data on used ingredients remains weak. For small and medium-sized enterprises, independently undertaking comprehensive assessments often faces high cost pressure. Moreover, cosmetic safety assessment involves multiple disciplines such as toxicology, chemistry, and medicine, making it difficult for enterprises or individuals alone to conduct scientific assessments.

#### **5. Need to Balance Tool Development and Professional Capability Building**

On the one hand, although intelligent assessment tools can improve efficiency, yet over-reliance may weaken assessors' professional judgment. On the other hand, as data gaps gradually narrow, opportunities for the industry to deeply learn practical assessment skills may decrease, requiring vigilance against the risk of capability degradation due to "tool dependence".

### **V. Future Prospects**

Based on the aforementioned reflections, to further align China's cosmetic safety assessment system with international standards and advance safety assessment work, the following prospects are proposed:

#### **1. Establish a Collaborative Mechanism to Facilitate Data Circulation and Sharing**

In the era of deep integration of globalization and informatization, cross-enterprise, interdisciplinary, and cross-departmental collaboration has become an inevitable choice for advancing the cosmetics industry. An all-round and multi-level collaborative model should be actively built to strengthen in-depth communication and close cooperation among enterprises, research institutions, industry associations,

and government agencies. Special attention should be paid to data sharing and collaboration with relevant departments of the MEE, which will help improve the overall development level of China's cosmetics industry and promote its green transformation. By breaking down data barriers between departments, deepening cross-departmental data circulation and collaboration, optimal allocation and efficient utilization of resources can be achieved. This will inject new impetus into the sustainable and stable development of China's cosmetics industry, thus achieving a win-win situation in improving industry safety, promoting green transformation, and ensuring sustainable development.

## **2. Strengthen Research and Support for Animal Testing Alternatives to Drive Assessment Technology Innovation**

In-depth research and support for animal testing alternatives should continue, with a focus on cutting-edge fields such as computational toxicology. Efforts to research and exchange ideas on animal testing alternatives like computational toxicology should be intensified, and research institutions and enterprises should be encouraged to pursue technological innovation. This will reduce reliance on animal testings, improve assessment efficiency, and align with ethical and sustainable development requirements. As a key alternative to animal testing, computational toxicology can provide new ideas and technical means for cosmetic ingredient safety assessment, driving innovation in assessment technologies and enhancing China's scientific and technological level and international competitiveness in this field.

## **3. Build a Complete Database to Lay a Solid Foundation for Safety Assessment**

Data is the core of cosmetic safety assessment, and its quality and integrity directly determine the scientificity and reliability of assessment results. A systematic and complete cosmetic ingredient database should be established, integrating various industrial data resources, including basic ingredient information, toxicological data, and environmental impact data, etc. While focusing on human safety, full consideration should be given to cosmetics' environmental impact, providing comprehensive, accurate, and reliable data support for safety assessment, and laying a solid foundation for the healthy and

sustainable development of the cosmetics industry. In this regard, CACHCA has carried out a series of work and achieved certain phased results. However, data establishment is a long-term and arduous systematic project requiring continuous investment and improvement. CACHCA will continue to strengthen cooperation and exchanges with all stakeholders, promote continuous upgrading and optimization of the database, and provide better and more efficient data services for cosmetic safety assessment work.

#### **4. Enhance Safety Assessment of Plant Ingredients: Increase Scientific Research Investment and Standard Formulation**

China has rich and diverse plant resources. The CSAR clearly proposes to apply "characteristic plant resources" to the cosmetics industry, which points out the direction for the development of China's plant ingredients. To address challenges of safety assessment for plant ingredients, future efforts should focus on two key dimensions: scientific research investment and standard formulation. In terms of scientific research investment, support should be increased to encourage in-depth cooperation between research institutions, universities, and enterprises. In terms of standard formulation, relevant standards and norms for the safety assessment of plant ingredients should be accelerated and improved. The assessment process should be clarified and clear guidance for the industry should be provided, to promote the standardized and scientific development of safety assessment work for plant ingredients. By encouraging scientific research investment and standard formulation, we can provide strong support for the widespread application and innovative development of plant ingredients in cosmetics, fostering a unique competitive advantage in China's cosmetics industry.

In general, China's cosmetic safety assessment has achieved a leap from "policy adaptation" to "system building". However, it is still necessary to focus on existing challenges, sustain efforts in enhancing data scientificity, improve integrity of ingredient information, balance capacity building, and establish industry and cross-departmental collaboration mechanisms. These efforts will drive the assessment system towards the goal of "international recognition, scientific rigor, efficient sharing, and green sustainability".

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# International Regulatory Exchange

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## **EFfCI and the Global Excellence in Cosmetic Ingredient Manufacturing: a Strategic and Technical Overview of the EFfCI GMP Standard**



### **Andrea Maltagliati**

#### **EFfCI Secretary-General**

Andrea Maltagliati is a 51-year-old professional with a strong technical foundation and over two decades of experience in the cosmetics industry. A graduate in Chemistry from the University of Milan, he has built a versatile international career that spans roles in Research & Development, Regulatory Affairs, and Global Business Development within both SMEs and multinational corporations.

A natural communicator and strategic thinker, he is known for his ability to lead teams, foster collaboration, and build consensus across diverse stakeholders. His professional journey is marked by a deep understanding of both the scientific and business dimensions of cosmetic ingredient development.

He currently serves as the Secretary General of the European Federation for Cosmetic Ingredients (EFfCI), where he oversees and coordinates the Federation's technical, regulatory, and strategic activities. In this role, he manages ten specialised Working Groups, advocates for the European ingredient industry in global forums, and represents EFfCI in dialogues with international associations and regulatory authorities. His leadership ensures that EFfCI remains at the forefront of global policy, science, and quality standards in the field of cosmetic ingredients.

Keywords: **EFfCI, GMP, Standard, Quality, Cosmetic**

### **EFfCI as a global beacon of Cosmetic Ingredient standards**

The European Federation for Cosmetic Ingredients (EFfCI) stands as a unique and authoritative voice representing the collective interests of cosmetic ingredient manufacturers in Europe. Founded in 2000, EFfCI has developed into the central platform for the scientific and regulatory dialogue that shapes the future of the cosmetic ingredient sector. What differentiates EFfCI on the global stage is its exclusive focus on ingredients for cosmetics, positioning it as a singular association of its kind worldwide.

In recent years, EFfCI has revised its statutes to extend membership eligibility beyond Europe, thus responding to the globalisation of the cosmetics industry and the growing need for harmonised standards. This strategic evolution underscores EFfCI's commitment to global collaboration and excellence, enhancing its impact on the worldwide stage.

### **Structure and Governance: Working Groups and strategic leadership**

At the heart of EFfCI lies a network of ten specialised technical Working Groups (WGs), each focusing on key scientific and regulatory domains crucial to the cosmetic ingredients industry. These WGs include:

- **RAPS (Regulatory Affairs and Product Safety)**
- **Sustainability**
- **INO (Ingredients of Natural Origin)**
- **Toxicology**
- **China Hub**
- **GMP (Good Manufacturing Practices)**
- **Preservatives**
- **Colorants**
- **International Relations**
- **Polymers**

These groups provide expert analysis, develop guidance documents, and foster consensus within the industry. Their technical input is translated into strategic direction by the EFfCI Board of Directors, a governing body that ensures coherent policy implementation and industry alignment. This bidirectional flow between operational expertise and strategic oversight guarantees that EFfCI remains responsive, informed, and aligned with both regulatory and market dynamics.

### **EFfCI's global network and strategic collaborations**

EFfCI's strength is amplified by its extensive global network. Through robust partnerships and sustained dialogues with international associations such as Cosmetics Europe, Cosmetics Alliance Canada, CAFFCI and CACHCA in China, EFfCI continuously fosters alignment on regulatory and safety standards. The Federation also engages in regular discussions with global regulatory authorities, including the European Commission, the Chinese NMPA (National Medical Products Administration), and NIFDC (National Institutes for Food and Drug Control).

As an active participant in key international cooperation platforms such as the International Collaboration on Cosmetic Safety (ICCS) and the International Cooperation on Cosmetics Regulation (ICCR), EFfCI contributes significantly to the global harmonisation of safety and quality standards for cosmetic ingredients.

### **The EFfCI GMP Standard: a pillar of technical excellence**

One of EFfCI's flagship contributions to the industry is its Good Manufacturing Practice (GMP) Guide for Cosmetic Ingredients, first issued in 2005. In 2025, this industry cornerstone celebrates its 20th anniversary. The EFfCI GMP Standard was developed as a sector-specific adaptation of ISO 9001 principles, tailored specifically to the complexities and specificities of cosmetic ingredient manufacturing.

The EFfCI GMP Guide, aligned with C-ISO 9001, outlines a comprehensive Quality Management System (QMS) approach, integrating risk-based thinking and a process-oriented methodology. It goes beyond the generic ISO framework by including sector-specific GMP

requirements, particularly in areas such as:

- Establishment of an independent Quality Unit
- Risk assessment protocols
- Management of outsourced quality-critical activities
- Process validation adapted to cosmetic manufacturing
- Robust documentation and traceability systems
- Environmental and contamination control measures
- Personnel hygiene and training controls
- Equipment and infrastructure qualification

#### **Quality unit and organizational oversight**

A cornerstone of the Efficacy Good Manufacturing Practice (Efficacy GMP) system is the requirement to establish an independent Quality Unit with defined authority and responsibility. This ensures that quality-critical decisions, including raw material approval, product release, deviation investigation, and supplier qualification, are conducted free of commercial conflicts. The Quality Unit also oversees the implementation and effectiveness of the Quality Management System (QMS) and ensures that training programs are maintained and documented across departments.

This structure is vital for risk mitigation and compliance monitoring. In practice, Efficacy-certified facilities implement internal dashboards linking quality Key Performance Indicators (KPIs) such as deviation trends, audit non-conformities, and product return rates to strategic planning activities.

#### **Risk assessment and technical controls**

Risk-based thinking is embedded in the Efficacy GMP philosophy. The guide requires the systematic use of tools such as HACCP (Hazard Analysis and Critical Control Points) and FMEA (Failure Mode and Effects Analysis) to identify and address risks to product quality.

For example, in the management of outsourced activities, Efficacy GMP mandates a documented assessment of the service provider's capabilities, including GMP compliance history, technical infrastructure, and traceability systems. Mitigations may include contractual agreements defining GMP responsibilities, periodic on-site audits,

and analytical cross-checks of delivered goods.

Another critical technical area involves infrastructure controls. Manufacturers must conduct risk assessments on the design, maintenance, and cleaning procedures of their buildings and utilities (e.g., air handling units, water systems). These assessments determine the control measures necessary to prevent microbial, chemical, and particulate contamination.

Figure 1: Example of risk matrix for ingredient contamination risk assessment

Severity	Likelihood	Risk Rating	Mitigation Action
High	High	Critical	Install automated CIP system
Medium	High	Major	Increase frequency of monitoring
Low	High	Moderate	Conduct additional staff training

### **Audit procedures and continuous improvement**

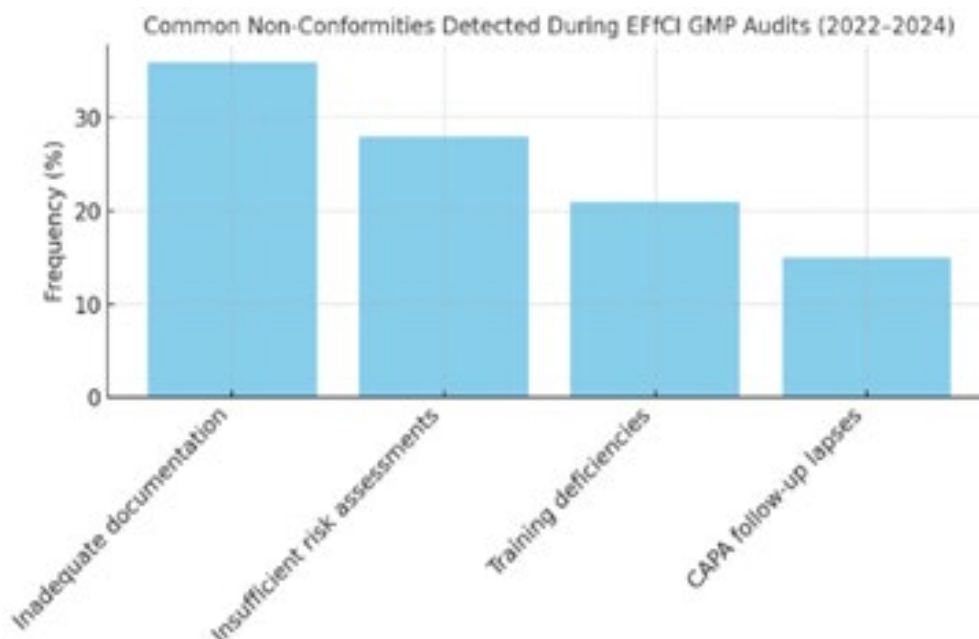
The EffCI GMP Certification Scheme includes rigorous auditing protocols. Audits are conducted by third-party Certification Bodies approved by EffCI, and they include both desk reviews and on-site evaluations. Auditors assess conformity across documentation, facility operations, and personnel competency.

An audit cycle typically includes:

- Initial certification audit (Stage 1: document review, Stage 2: on-site inspection)
- Annual surveillance audits
- Recertification every three years

Audit procedures focus particularly on critical process controls, change management, and complaint handling. For example, auditors may review how a facility manages deviations in raw material specifications, whether these are captured in deviation reports, investigated thoroughly, and followed by CAPA (Corrective and Preventive Actions). They will also verify the effectiveness of internal audits, training records, and whether key performance indicators (KPIs) such as "batch rejection rate" are tracked and acted upon.

Figure 2: common non-conformities detected during EFfCI GMP audits (2022-2024)



EFfCI encourages facilities to view audits not as a compliance exercise, but as a tool for continuous improvement. Findings and observations should be translated into systematic changes, feeding into the facility's management review process and long-term quality planning.

### **Advanced technical aspects of EFfCI GMP implementation**

To provide manufacturers with practical tools to meet the standard's requirements, the EFfCI GMP Guide includes detailed guidelines on numerous critical areas. These technical elements are essential in establishing a consistent and reproducible manufacturing environment that upholds product safety and quality.

#### **Documentation control and record retention**

Documentation forms the backbone of any GMP system. The EFfCI GMP Guide stipulates that all documentation, including procedures, specifications, manufacturing records, and quality reports, must be controlled through a document management system that ensures version traceability, approval workflows, and change control.

Key requirements include:

- Each document must be uniquely identified and carry a version number and date.
- Obsolete documents must be withdrawn promptly from operational areas to prevent unintended use.
- Records must be legible, readily retrievable, and retained for a minimum of five years, or longer if national regulations require it.

A best practice example involves the integration of electronic document management systems (EDMS) with audit trail capabilities, which can log all changes made to critical quality documents, including who made them and when.

#### **Process validation and qualification**

Process validation is central to confirming that manufacturing operations are capable of consistently producing ingredients that meet predetermined specifications. According to EFfCI GMP, process validation must be performed for all quality-critical processes, with particular attention to those where product variability cannot be fully verified through final testing.

Validation typically involves three consecutive, successful production runs under normal operating conditions, with comprehensive data analysis covering:

- In-process controls (e.g., temperature, pH, mixing time)
- Critical material attributes (e.g., raw material purity)
- Output consistency (e.g., yield, assay results, impurity profiles)

The guide also specifies the need for cleaning validation of shared equipment. This includes:

- Selection of worst-case scenarios
- Establishment of acceptance criteria for residue limits
- Use of analytical methods (e.g., TOC, HPLC)

### **Supplier qualification and incoming material control**

A robust supplier qualification process is essential to ensure the quality of raw materials and packaging components. EFfCI GMP requires that all suppliers of quality-critical materials be evaluated through a combination of questionnaires, audits, and material testing.

Evaluation criteria include:

- Supplier's GMP certification status
- Historical performance (e.g., rejection rates, complaint trends)
- Analytical results of delivered batches

Incoming material testing must be risk-based. For example, materials from certified and qualified suppliers with a proven track record may undergo reduced testing (e.g., identity only), whereas new suppliers must undergo full analytical verification for at least the first three deliveries.

### **Change control and deviation management**

Change control is critical for managing modifications to processes, equipment, materials, and documentation. EFfCI GMP requires that all changes be evaluated for their potential impact on product quality, approved by the Quality Unit, and documented through a formal change control system.

Typical changes include:

- Introduction of new equipment
- Change in raw material supplier
- Modification of manufacturing parameters

Each change must be assessed through risk analysis, and where necessary, require re-validation. In parallel, deviation management processes ensure that unexpected events (e.g., process deviations, out-of-spec results) are promptly investigated.

Corrective and Preventive Actions (CAPA) must be defined, tracked to completion, and reviewed for effectiveness.

### **Environmental monitoring and contamination control**

Contamination control is a cornerstone of EFfCI GMP. Environmental monitoring programs must be defined based on a risk assessment of potential contamination sources, including:

- Air quality (e.g., microbial and particulate load)
- Surface hygiene (e.g., swab testing of workstations)
- Water systems (e.g., TOC, conductivity, microbial counts)

Cleanliness classifications of manufacturing areas must be based on the type of product handled and its sensitivity. The frequency of cleaning and disinfection must be defined, validated, and documented. Use of colour-coded cleaning equipment, dedicated utensils for different zones, and validated cleaning agents are considered best practices.

### **Personnel qualification and training**

Human error is a significant risk in manufacturing. EFfCI mandates that all personnel involved in quality-critical activities receive initial and periodic training appropriate to their responsibilities.

Training must include:

- GMP principles and company-specific procedures
- Hygiene requirements
- Hazard and risk awareness
- Data integrity and documentation practices

Training records must be maintained, and effectiveness must be evaluated, for instance through post-training assessments or observation during operations.

### **Data integrity and IT systems (Integrated across multiple sections)**

Although not a standalone clause, EFfCI GMP reinforces the importance of data integrity, particularly when electronic records are used. Key principles include:

- ALCOA+ attributes (Attributable, Legible, Contemporaneous, Original, Accurate, plus Complete, Consistent, Enduring, and Available)
- Use of validated software systems
- Access control and user-based permissions
- Regular system backups and audit trails

Examples of risk include manipulation of analytical data, unauthorized changes to electronic records, or loss of traceability in batch records. To mitigate such risks, manufacturers are encouraged to perform periodic reviews of electronic systems and establish policies for electronic signature management.

### **Certification and global reach**

As of 2025, more than 400 manufacturing sites around the world have achieved EFfCI GMP Certification. This certification has become a globally recognised benchmark and a prerequisite for cosmetic ingredient suppliers operating at the highest levels of the industry.

### **PCS360: a dedicated entity for GMP services**

In a strategic move to enhance the accessibility and implementation of its GMP framework, EFfCI launched Personal Care Services 360 (PCS360) in 2025. PCS360 is a dedicated entity that commercialises EFfCI services, with its first offering centred on the EFfCI GMP Standard.

PCS360 facilitates:

- Licensing of the EFfCI GMP Certification trademark
- Coordination with Certification Bodies worldwide
- Delivery of EFfCI GMP training programmes, both in-person and digital

Training is conducted by EFfCI-approved trainers and focuses on the practical application of the GMP Standard, including risk-based approaches, QMS integration, documentation practices, and audit readiness.

These training modules include case studies on issues such as cleaning validation, change control management, and mock audits. Attendees engage in interactive exercises such as preparing a risk assessment for a fictitious manufacturing deviation, or drafting a CAPA plan for a simulated audit finding. This ensures not only theoretical understanding but also applied competence.

#### **EFfCI's vision for a global industry**

EFfCI has not only pioneered regulatory and quality frameworks for cosmetic ingredients in Europe but has also actively shaped global expectations and benchmarks. Through its GMP Standard and its extensive network of stakeholders, EFfCI fosters a culture of excellence, transparency, and innovation.

With the establishment of PCS360 and the expansion of its membership base, EFfCI reinforces its role as the global reference for quality in cosmetic ingredient manufacturing. As the industry continues to evolve in complexity and scope, EFfCI remains firmly positioned at the forefront, guiding manufacturers toward regulatory compliance, sustainable growth, and consumer trust through technical and scientific leadership.

## Navigating Regulatory Changes for Naturals in the Cosmetics Industry



**Dr Mark Smith**

### **Director General of the International Natural & Organic Cosmetics Association (NATRUE)**

Dr Mark Smith holds an MChem (Hons) in Chemistry and an interdisciplinary PhD in chemistry and genetics. Before joining NATRUE in 2014, he gained research experience in biotechnology (UK) and the biomedical/pharmaceutical sector (Canada). Director General since 2016, he oversees NATRUE's operations and leads its political, regulatory and scientific work. A published researcher and sought-after speaker, Dr Smith has delivered talks worldwide, from New York to India and across Europe.

The cosmetics industry has seen an accelerated shift toward natural and organic formulations over the past two decades, driven by increasing consumer demand for naturals, sustainability, and supply chain transparency. However, formulating with natural ingredients is far from straightforward—especially in a global context where regulations vary widely and are frequently updated. For cosmetic brands and manufacturers, keeping up with these evolving regulatory landscapes requires vigilance, adaptability, and a proactive compliance strategy.

## Evaluating frameworks: EU

In February 2025, the European Commission (EC) opened the call for evidence<sup>1</sup> to evaluate and assesses whether the EU Cosmetics Regulation (EC) No. 1223/2009 (CPR) remains fit for purpose more than a decade after entering into force. The evaluation comes at a time when discussions related to the joint green and digital transitions persist and aims to assess how the CPR works in today's regulatory and social environment. It addresses aspects such as online and bulk sales, digital labelling, professional use of cosmetic products, as well as international competitiveness<sup>2</sup> and trade - now key topics under the new EU political mandate.

The criteria for the evaluation are closely linked to the Better Regulation Guidelines<sup>3</sup> and cover aspects such as effectiveness, efficiency, relevance, coherence, and added value of the CPR. A potent aspect of this review is how the CPR aligns with broader legislation affecting chemicals (e.g., the simplification of EU REACH and updates to CLP<sup>4</sup>), sustainability integration (PPWR<sup>5</sup>, ESPR<sup>6</sup>, CS3D<sup>7</sup>, CSRD<sup>8</sup>) and green claims (e.g., ECGT<sup>9</sup> and Green Claims Directive<sup>10</sup>)

Whilst the process is on-going, with a public consultation open until the end of July 2025, the work is expected to continue through mid-2026. It remains clear that the joint successes of the CPR -setting strict safety requirements to ensure high protection for consumer health and supporting the functioning of the internal market - must be

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<sup>1</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14433-Cosmetic-Products-Regulation-evaluation\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14433-Cosmetic-Products-Regulation-evaluation_en)

<sup>2</sup> [https://commission.europa.eu/topics/eu-competitiveness/competitiveness-compass\\_en](https://commission.europa.eu/topics/eu-competitiveness/competitiveness-compass_en)

<sup>3</sup> [https://commission.europa.eu/law/law-making-process/better-regulation\\_en](https://commission.europa.eu/law/law-making-process/better-regulation_en)

<sup>4</sup> <https://eur-lex.europa.eu/eli/reg/2024/2865/oj/eng>

<sup>5</sup> [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L\\_202500040&pk\\_campaign=todays\\_OJ&pk\\_source=EUR-Lex&pk\\_medium=X&pk\\_content=Environment&pk\\_keyword=Regulation](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202500040&pk_campaign=todays_OJ&pk_source=EUR-Lex&pk_medium=X&pk_content=Environment&pk_keyword=Regulation)

<sup>6</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32024R1781&qid=1719580391746>

<sup>7</sup> <https://eur-lex.europa.eu/eli/dir/2024/1760/oj>

<sup>8</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022L2464>

<sup>9</sup> [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L\\_202400825](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202400825)

<sup>10</sup> [https://environment.ec.europa.eu/topics/circular-economy/green-claims\\_en](https://environment.ec.europa.eu/topics/circular-economy/green-claims_en)

maintained. To this end, simplification does not mean deregulation; rather, it offers an opportunity to clarify the regulatory framework, correct outstanding issues and reduce the potential burden affecting operators, particularly SMEs.

### **Embracing the bioeconomy**

A key touchstone to measure the success of naturals is the access to a wide palette of raw materials. However, the biobased sector faces notable challenges in reaching its full potential and in supporting the movement to defossilise raw material feedstocks. Primarily, these challenges are commonly associated with higher production costs for naturals compared with fossil fuels alternatives, which are commonly subsidised and therefore their price can distort the playing field. Equally, as with any product, naturals would have to achieve economies of scale to reduce the unit cost. Additional obstacles include regulatory uncertainty and/or inconsistencies, lack of harmonised definitions and/or certifications, scale-up limitations, maturity of technologies and the integration of new approaches into existing chemical infrastructure. These barriers risk slowing marketing access and destabilising demand and investment in innovation. To tackle these issues, the EC has launched a public consultation aimed to ensure a competitive and circular bioeconomy in the EU<sup>11</sup>.

Amid these larger changes, naturals - in particular natural complex substances (NCSs), such as essential oils and other plant extracts - are increasingly facing regulatory scrutiny. Notable examples include how substances, such as tea tree oil (TTO), or constituents of NCSs (e.g., p-cymene) will be regulated under Article 15 of the CPR.

TTO, for instance, contains more than 100 composites and is a substance with more than one constituent (MOCS), which are themselves subject to further examination as per Article 54a(1) of amended CLP Regulation (EU) 2024/2865. In 2023, following

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<sup>11</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14555-Towards-a-circular-regenerative-and-competitive-bioeconomy\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14555-Towards-a-circular-regenerative-and-competitive-bioeconomy_en)

ECHA review on a harmonised classification, ECHA's Risk Assessment Committee (RAC<sup>12</sup>) recommended classifying TTO as CMR 1B – a stricter classification than the original category 2 proposed by Poland. In response, in order to defend TTO, industry stakeholders submitted a dossier to defend its safe use in cosmetics. In June 2025, the Scientific Committee on Consumer Safety (SCCS) presented their preliminary Opinion<sup>13</sup> supporting the safe use of TTO in cosmetics under defined conditions: (a) used at or below 2.0% in shampoos; (b) 1.0% in shower gels and face washes; (c) 0.1% in face creams. The SCCS also emphasised the need to conform to ISO 4730:2017 and to ensure its chemical stability in formulations to prevent degradation. Following the finalisation of the SCCS opinion, the EC will continue with risk management provisions.

Besides the individual NCSs, an overarching risk to a multitude of NCSs is the case where a constituent would be classified as a CMR. This is already the case for **p-cymene**, a component found in numerous essential oils (e.g., cumin, thyme oil, tea tree, oregano). In 2022, Sweden proposed classifying this substance as a CMR 1B<sup>14</sup>. Similar to the case of TTO, according to Article 15(2) of the CPR, the impact for cosmetics of such classification would trigger a ban, potentially requiring reformulation or removal of a vast number of “natural” and essential-oil-based products. Yet, in practice, removing a single constituent from NCS without altering the substance's overall properties is often technically and economically unfeasible. Equally, one constituent can impact multiple NCSs, amplifying the regulatory impact; and for naturals especially, suitable alternatives may not exist. Current discussions among stakeholders aim to resolve this matter to avoid any regrettable restrictions, where the safety of NCSs can be adequately assessed. If unresolved, a domino effect may limit the palette of naturals, reduce the diversity of natural cosmetics on the market, go against a global consumer trend for natural products, and run contrary to the EU's ambitions concerning the bioeconomy and sustainable substance use in the future.

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<sup>12</sup><https://echa.europa.eu/fr/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18571231a>

<sup>13</sup>[https://health.ec.europa.eu/publications/sccs-scientific-opinion-tea-tree-oil-case-no-68647-73-4-285-377-1\\_en](https://health.ec.europa.eu/publications/sccs-scientific-opinion-tea-tree-oil-case-no-68647-73-4-285-377-1_en)

<sup>14</sup><https://echa.europa.eu/pl/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e188d24acd>

### **A natural future?**

The coming years will support further discussions between stakeholders concerning how to ensure the continuity of existing formulations, while fostering innovation for new natural product development. Although global harmonization is unlikely in the short term, trends such as sustainability, ingredient traceability, and data-driven safety assessments are becoming universal. Brands that invest in robust regulatory systems, ethical sourcing, and transparent communication will be best positioned to lead in the natural cosmetics space.

In the short-term, upholding a strong science-based, risk assessment approach to consumer protection and safety remains essential. Looking forward, the scope to support the needs of natural cosmetics sector, enhance the capabilities of the European bioeconomy, foster sustainable innovation, and accommodate digitalisation will remain essential to meeting evolving consumer expectations.

There are various key elements where manufacturers should stay ahead, including ingredient traceability, environmental claims and certifications, new allergen labelling<sup>15</sup>, intellectual property, and biodiversity<sup>16,17</sup>. As such, operators in the natural sector must prioritise ingredient vigilance and greater sustainability awareness across the lifecycle of a product - particularly in light of the expected conclusion of institutional trilogue on the Green Claims Directive file in 2024.

Therefore, while the path to global compliance for natural cosmetic products is fraught with complexity, it also offers immense opportunity. Natural brands that can successfully manage to align innovation with regulatory rigor are not just meeting compliance but contributing to building the future of beauty.

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<sup>15</sup><https://eur-lex.europa.eu/eli/reg/2023/1545/oj/eng>

<sup>16</sup><https://www.cbd.int/dsi-gr>

<sup>17</sup><https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0511>

## Recent Key Developments in Cosmetic Regulations in the Republic of Korea



**Jun-ki, Jang ( 张俊基 )**

**Executive Vice President, Korea Cosmetic Association**

He is an expert in several key areas, including the research, analysis, and review of both domestic and international cosmetic regulations. He also specializes in new product planning and marketing within the cosmetics industry, as well as conducting cosmetic safety assessments. Additionally, he is experienced in CGMP (Cosmetic Good Manufacturing Practice) audits and oversees the manufacturing and distribution of cosmetics.

The regulatory framework governing cosmetics in the Republic of Korea has undergone significant improvements aimed at enhancing consumer protection and reinforcing industry autonomy. The key developments are summarized as follows.

In alignment with the digital transformation of information delivery methods, the Ministry of Food and Drug Safety (hereinafter referred to as MFDS) has officially launched a pilot project for e-labeling of cosmetics starting in 2024. This initiative is

designed to reduce environmental costs and improve user accessibility by replacing full ingredient labeling on paper packaging with a QR code system that enables consumers to access information via mobile devices. While similar discussions have taken place in the European Union, the United States, and Japan, Korea is the first to implement such a pilot program at the government level.

Legislative improvements have also been made in the area of ingredient and safety management. Previously, applications were permitted only for the designation or modification of restricted ingredients; however, as of 2024, a legal basis has been established to allow applications for the removal of prohibitions on banned ingredients as well. The scope and format of the required documentation for such applications have been specified through an official notification.

The MFDS conducts risk assessments of cosmetic ingredients regularly and takes necessary measures based on the results, such as prohibition or restriction of specific substances. In 2024, 1,2,4-Trihydroxybenzene (THB) was newly designated as a prohibited ingredient.

In addition, improvements to the custom cosmetics system are ongoing. Custom cosmetics sellers are now allowed to report products with identical contents under a unified “product group name,” streamlining administrative procedures and improving operational efficiency. Furthermore, the organization responsible for administering the qualifying examination for custom cosmetics compounders has been changed to the Korea Chamber of Commerce and Industry.

With regard to labeling and advertising regulations, requirements have been strengthened for small packages (50 mL(g) or less), which are now mandated to display all essential information. Specifically, eyelash permanent wave products and external genital cleansers (feminine washes) are no longer exempt from labeling obligations and are subject to the same information disclosure standards as other products.

Additionally, the scope of prohibited expressions in cosmetic advertising that may mislead consumers has been expanded. This includes: expressions implying recommendation or designation by medical professionals (e.g., “for hospital use”), emphasizing human-derived ingredients such as exosomes, quantitative improvement claims such as reducing skin age, and misleading descriptions of application methods, such as microneedling effects.

Regulations pertaining to the advertisement of private certifications have been revised to permit such representations under defined conditions. Certifications including, but not limited to, those related to Halal, vegan, and natural or organic cosmetics may now be referenced in promotional materials, provided such certifications are issued by recognized institutions based on objectively verifiable standards. This amendment is intended to support the advancement and diversification of the associated industry sectors.

Provisions governing air-handling systems under the Good Manufacturing Practice (GMP) standards for cosmetics have been revised to more accurately reflect actual manufacturing conditions, thereby narrowing the gap between practical operations and legal compliance requirements. In addition, the required retention period for reserve samples has been amended to extend only through the product’s labeled expiration date, reducing the burden associated with prolonged storage obligations.

Going forward, cosmetic companies are expected to actively respond to regulatory changes in pursuit of three strategic directions: enhancement of consumer safety, harmonization with international standards, and the promotion of industry development. Through these efforts, the dual goals of protecting consumers and strengthening the competitiveness of Korea’s cosmetics industry will continue to be achieved.

## **Research on International Toothpaste Regulatory Laws and Regulations (Part II) - EU and U.S.**

**Emily Ji Minghua, CACHCA**

### **I. Introduction**

In the previous study *Research on International Toothpaste Regulatory Laws and Regulations*, we discussed the regulatory frameworks in Japan and South Korea. This report focuses on the EU and the U.S. - two key markets characterized by large scale, strong consumption capacity, and growing demand for oral care products such as toothpaste. As a birthplace of modern cosmetic regulations, the EU has a mature and far-reaching regulatory system. The U.S. adopts a dual regulatory framework for toothpaste, classifying it as either a cosmetic or an OTC drug, with differentiated supervision for each category. These characteristics are worthy of in-depth research and reference.

This report continues to use a sub-item review method, covering regulatory approaches, registration and filing requirements, efficacy claims, labeling requirements, safety assessment, production quality management, and post-marketing supervision. The research materials mainly come from official government websites of the EU and the U.S., as well as regulatory research literatures.

### **II. Toothpaste Regulation in the EU**

#### **1. Regulatory Approach**

In the EU, “cosmetics” is defined as any substance or mixture intended to be applied to any external part of the human body (e.g., epidermis, hair, nails, lips, external genitalia, etc.) or in contact with teeth and oral mucosa, for purposes such as cleaning, altering odor or appearance, protecting, conditioning, or correcting body odors. Toothpaste, which is used on teeth and oral mucosa primarily for cleaning and cosmetic purposes, falls under the EU’s definition of cosmetics and is explicitly classified as a cosmetic product. Its supervision is mainly based on the EU Cosmetics

Regulation (EC) No. 1223/2009, which establishes unified rules to ensure consumer safety and facilitate the free circulation of products within the EU internal market through simplified procedures and standardized terminology.

However, not all toothpastes in the EU are classified as cosmetics. Depending on the product's intended use, mechanism of action, as well as formulation, usage method, mode of action, claims, appearance, packaging, and promotional materials, toothpaste may also be classified as a medicinal product or medical device. *Manual of the Working Group on Cosmetic Products (Sub-Group on Borderline Products) on the Scope of Application of the Cosmetics Regulation (EC) NO. 1223/2009 (ART. 2(1)(A))* issued by the European Commission serves as a reference for such classification. If a product is intended to treat, prevent, or diagnose diseases, or to restore, correct, or modify physiological functions through pharmacological, immunological, or metabolic actions (e.g., products claiming "anti-inflammation, pain relief, or hemostasis"), it is classified as a medicinal product. If a product achieves medical purposes through physical or physiological effects (e.g., anti-sensitive toothpastes that relieve sensitivity by physically blocking dentinal tubules), it is generally regarded as a medical device, which must comply with the *EU Medical Device Regulation (EU) 2017/745 (MDR)* and bear the CE certification label before marketing.

A core element of the EU regulatory framework is the "Responsible Person" system. Every cosmetic product marketed in the EU must designate a legal or natural person within the EU as the Responsible Person, who is liable for the product's compliance and safety.

## **2. Registration and Filing Requirements**

For toothpastes classified as cosmetics, the EU implements a pre-market notification system. Before marketing, the Responsible Person must submit product-related information through the Cosmetic Products Notification Portal (CPNP), including product category, formulation, original label, and packaging photos. The notification aims to provide product information to competent authorities and toxicology centers of member states for effective market supervision.

In addition to CPNP notification, the Responsible Person must compile a Product Information File (PIF) and update it in a timely manner. Enterprises are not required to actively submit the PIF but must keep it at the Responsible Person's address, ready for inspection by competent authorities at any time. The PIF must include product description, Cosmetic Product Safety Report (CPSR), description of production methods and Good Manufacturing Practice (GMP) compliance statement, supporting materials for efficacy claims, and data on animal testing, etc.

Toothpastes claiming to treat gingival diseases (regulated as medicinal products) and anti-sensitive toothpastes classified as medical devices must be registered in accordance with relevant requirements.

### **3. Efficacy Claims**

The EU's management of cosmetic efficacy claims follows the six common criteria specified in Regulation (EU) No. 655/2013: legality, truthfulness, evidence support, honesty, fairness, and facilitation of consumer decision-making. These criteria establish a clear regulatory framework for cosmetic claims. Under these criteria, toothpastes may generally claim effects such as "effectively cleaning teeth," "long-lasting fresh breath," "whitening teeth," "inhibiting plaque," and "helping prevent dental caries."

Toothpastes classified as cosmetics must not claim therapeutic or disease-curing effects, as such claims may lead to reclassification as medicinal products or medical devices, subject to stricter supervision. For "borderline products" between cosmetics, medicinal products, medical devices, and disinfectants, classification is determined based on claims and a comprehensive assessment of multiple factors. For example, if a product's main purpose is oral cleaning with antibacterial effects as a secondary claim, it remains classified as a cosmetic. While claims of treating or repairing dental caries are prohibited, preventive claims such as "helping prevent dental caries" are allowed.

### **4. Labeling Requirements**

In accordance with Regulation (EC) No. 1223/2009, toothpaste labels must clearly

indicate: the name and address of the Responsible Person (if multiple addresses exist, highlight the one where the PIF is accessible), country of origin, net content, ingredient list, shelf life (if  $\leq 30$  months, indicate the expiration date; if  $> 30$  months, indicate the post-opening use period), usage precautions and warnings, batch number or product identification number, and product functions.

Additionally, Regulation (EC) No. 1223/2009 imposes special requirements for nanomaterials: cosmetics containing nanomaterials must be labeled with "nano". Specific precautions and warnings are also required. For example, toothpastes containing sodium fluoride must be labeled with "contains sodium fluoride"; for toothpastes with 0.1%-0.15% fluoride, unless marked as "for adults only", they must include: "Children under 6 years: use a pea-sized amount and brush under supervision to reduce swallowing. If fluoride is ingested from other sources, please consult a dentist or doctor."

## 5. Safety Assessment

Before marketing, the Responsible Person must ensure the product has undergone professional safety assessment and a detailed CPSR has been completed. The report does not require government approval but must be retained in the PIF, available for inspection by competent authorities at any time, and continuously updated based on the latest scientific evidence and monitoring data. The CPSR consists of two parts: Part A (Cosmetic Safety Information) includes quantitative and qualitative components, physical/chemical properties and stability, microbial quality, impurities, packaging materials, normal and foreseeable usage, and exposure information; Part B (Cosmetic Safety Assessment) includes the final conclusion on product safety issued by a qualified safety assessor.

The *Notes of Guidance for Testing of Cosmetic Ingredients for Their Safety Evaluation* issued by the EU Scientific Committee on Consumer Safety (SCCS) is a key technical document for cosmetic safety assessment. It details principles and methods for toxicological and safety assessment of cosmetic ingredients, including hazard

identification, exposure assessment, and risk characterization, and applies to toothpaste and other oral care products. Notably, the SCCS stipulates that for general cosmetics without absorption rate data, a default 50% absorption rate is applied; for toothpaste, due to unavoidable ingestion during use, a conservative 100% absorption rate is applied if no absorption data is available.

#### **6. Production Quality Management**

Toothpaste produced in the EU must comply with GMP. Enterprises may refer to the International Organization for Standardization (ISO)'s cosmetic GMP guideline ISO 22716, the GMP standards of Cosmetics Europe, or other equivalent or higher standards. ISO 22716 is a harmonized standard published in the EU Official Journal and serves as the primary means to demonstrate compliance with GMP requirements. EU member states supervise enterprises' compliance with GMP principles.

#### **7. Post-Marketing Supervision**

Post-marketing supervision in the EU centers on the Responsible Person, emphasizing cosmetic product vigilance to continuously monitor product safety after marketing and promptly identify, assess, and manage potential risks. The Responsible Person is obligated to collect, record, and evaluate adverse reactions and serious adverse reactions reported by consumers. In case of serious adverse reactions, the Responsible Person or distributor must immediately report to the competent authority of the member state where the incident occurred. This data is used to continuously update product safety assessments, inform market supervision and necessary risk management measures by competent authorities, and support product recalls.

### **III. Toothpaste Regulation in the U.S.**

#### **1. Regulatory Approach**

In the U.S., toothpaste is classified as an oral product and regulated by the Food and Drug Administration (FDA) under the Department of Health and Human Services. The FDA supervises toothpaste in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) enacted in 1938. Toothpaste is classified as a cosmetic, OTC drug, or a

combination of both, based on its functions, claims, and active ingredients.

Since the *Modernization of Cosmetics Regulation Act of 2022* (MoCRA) took effect in July 2024, regulatory requirements for toothpastes classified as cosmetics have undergone significant adjustments. These include: designating a cosmetic responsible person, implementing manufacturer registration and product filing, complying with FDA's GMP requirements and adverse event record inspections, and facing recall requirements for non-compliance.

Toothpastes regulated as OTC drugs are subject to pharmaceutical regulations and OTC Monograph requirements. The OTC Monograph, equivalent to China's mandatory national standards, specifies approved active ingredients, their concentrations, uses, indications, dosage forms, formulations, labeling, and testing requirements.

Toothpastes with cleaning and beautifying functions (e.g., cleaning, tartar reduction, whitening, and fresh breath) are classified as cosmetics and require product filing. However, small enterprises with an average annual sales volume of less than USD\$ 1 million over three years are eligible for exemptions, including exemptions from cosmetic GMP, manufacturer registration, and product filing.

Toothpastes claiming specific therapeutic effects (e.g., anti-caries, anti-gingivitis/plaque, anti-sensitivity) with active ingredients listed in the FDA OTC Monograph are classified as OTC drugs and require drug information registration in accordance with regulatory procedures. Toothpastes claiming specific effects with active ingredients not listed in the FDA Monograph are regarded as new drugs and must be registered with the FDA before marketing.

## **2. Registration and filing Requirements**

For toothpastes classified as cosmetics with cleaning and beautifying functions, MoCRA requires manufacturers to complete product filing with basic information within 120 days after marketing. This includes: the manufacturer's registration number, name and contact information of the responsible person (manufacturer, packer, or distributor

indicated on the packaging), product name, product category, ingredient list (as labeled), and product filing number (if previously filed). Updated information can be submitted annually if changes occur after filing. Filing is flexible: a single filing can include multiple products with the same basic formulation but differences in color, fragrance, taste, or ingredient concentrations.

For toothpastes classified as OTC drugs, there are two scenarios: (1) Products complying with the OTC Monograph can be marketed directly after completing drug information filing with the FDA. However, adding new active ingredients, uses, or dosage forms beyond the monograph requires FDA review for monograph modification or the establishment of a new monograph. (2) New drugs must be registered before marketing. New drug registration is based on formulations, and any changes to registered content require re-evaluation.

### **3. Efficacy Claims**

The U.S. imposes principled requirements for toothpaste claims: all efficacy claims must be true and valid; false or misleading claims are prohibited, and explicit or implied claims of non-existent effects are strictly forbidden. Efficacy claims must be clearly labeled in prominent positions such as product labels and instructions.

Toothpastes regulated as cosmetics can claim: whitening-related effects (e.g., "whiten teeth," "restore whiteness," "naturally whiten and brighten"); breath-related effects (e.g., "kill microbes/bacteria that cause bad breath," "freshen the mouth," "refreshing taste," "keep breath feeling fresh"); and cleaning-related effects (e.g., "gently remove surface stains," "inhibit tartar," "make teeth feel clean," "help prevent tartar," "make teeth feel smooth").

Toothpastes regulated as OTC drugs can claim: anti-caries effects (e.g., "prevent dental caries," "remineralize tooth enamel," "prevent caries on teeth and tooth roots"); oral discomfort relief effects (e.g., "prevent tooth sensitivity," "prevent sensitive tooth pain"); gum health protection effects (e.g., "control gum-harmful bacteria," "help relieve plaque-related gingivitis," "anti-plaque and anti-gingivitis"); and other effects such as "sterilization."

#### **4. Labeling Requirements**

The U.S. requires toothpaste labels to be clear and non-misleading. Labels must include basic information such as: product name, net content, company name and address, ingredient list, product characteristics and uses, usage instructions, warnings, and country of origin (as required by customs laws). Additionally, MoCRA mandates the inclusion of contact information for reporting adverse reactions (the U.S. domestic address, phone number, and email address).

For OTC drug toothpastes, labels must include: product attribute descriptions, uses, net content, active ingredients of the OTC product (concentration per unit dose and functions), usage instructions, warnings, and a list of inactive ingredients. For example, fluoride toothpastes must indicate fluoride concentration (in ppm or percentage) and efficacy claims such as "helps prevent dental caries," as well as safety prompts like "Children under 6 years of age should use under adult supervision."

#### **5. Safety Assessment**

The safety of cosmetic toothpastes in the U.S. is guaranteed by manufacturers' self-regulation and primary responsibility. MoCRA stipulates that each cosmetic product must have sufficient evidence to support its safety, and records of the necessary safety evidence must be retained. The FDA will only review safety evidence data if there is reasonable cause to believe that the toothpaste or its ingredients may be adulterated or cause serious adverse health consequences.

For OTC drug toothpastes, active ingredients listed in the OTC Monograph have sufficient evidence to support their safety and efficacy under specified usage conditions. However, enterprises must fully evaluate and verify the overall safety of the toothpaste in accordance with pharmaceutical regulations.

#### **6. Production Quality Management**

For toothpastes classified as cosmetics, MoCRA requires the establishment of reasonable and operable GMP standards that are consistent with internationally accepted standards, where appropriate and feasible.

For toothpastes regulated as OTC drugs, compliance with Pharmaceutical GMP guidelines is mandatory, though there is no mandatory GMP certification requirement. Factories must complete FDA registration, and the FDA may inspect factories at any time to verify GMP compliance.

### **7. Post-Marketing Supervision**

The U.S. has established a comprehensive post-marketing supervision system for toothpastes, with the FDA playing a core role. Market supervision and inspection methods include: regular inspections of manufacturers (covering production facilities, processes, and quality management systems) to ensure compliance, as well as irregular inspections based on consumer complaints, monitoring of public comments in the market, and other risk signals. Non-compliant toothpastes may be subject to measures such as ordered recall, sales prohibition, and fines.

The FDA also collects and analyzes adverse reaction reports submitted by consumers and medical institutions to identify potential safety issues through market supervision. For cosmetic toothpastes, MoCRA mandates monitoring of serious adverse events, requiring enterprises to report them to the FDA within 15 working days of becoming aware of such events. The FDA is authorized to investigate adverse event records during inspections. For OTC drug toothpastes, reporting of serious and unexpected adverse reactions is mandatory.

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# COSMETICAL

## Overview of ASEAN Market

- ◆ Promising Future: Sustained Growth in China-Malaysia Cosmetics Trade

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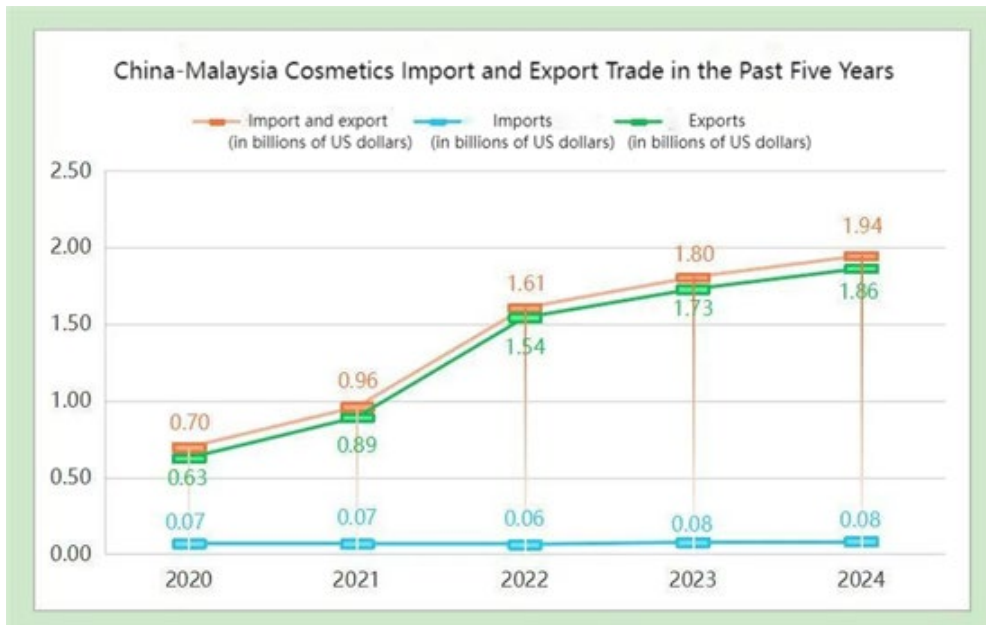
### China Chamber of Commerce for Import & Export of Medicines & Health Products

As Malaysia's economy surged in the 1990s, it became one of the "Four Asian Tigers" and a prominent diversified emerging industrial nation and global emerging market economy. In 2024, Malaysia's economy outperformed expectations, with GDP growing by 5.1% year-on-year, up from 3.6% in 2023. Its per capita GDP reached USD\$13,310, ranked 68th globally—slightly higher than China's. As Malaysia's economy continues to develop, rising disposable incomes and consumers' escalating pursuit of beauty have driven sustained growth in cosmetics market demand, with an expected compound annual growth rate (CAGR) of 3.05% from 2024 to 2028.

#### Overview of China-Malaysia Cosmetics Import and Export Trade

Over the past five years (2019–2024), the total import-export volume of cosmetics between China and Malaysia grew from USD\$70 million to USD\$194 million, with a CAGR of 29.0%. China's cosmetics exports to Malaysia dominated, surging from USD\$63 million to USD\$186 million over five years, a CAGR of 31.1%. For three consecutive years (2022–2024), Malaysia has remained among China's top 10 cosmetics export markets, demonstrating the growing competitiveness of Chinese cosmetics in Malaysia. Additionally, China has overtaken France as Malaysia's largest source of cosmetics imports.

In 2024, Malaysia was China's third-largest cosmetics trading partner in ASEAN, with a total trade volume of USD\$194 million, up 7.8% year-on-year. In exports, Malaysia was China's second-largest cosmetics market in ASEAN after Indonesia, with export value reaching USD\$186 million, a 7.8% year-on-year increase. In imports, China's cosmetics purchases from Malaysia totaled USD\$8.31 million in 2024, up 7.7% year-on-year.



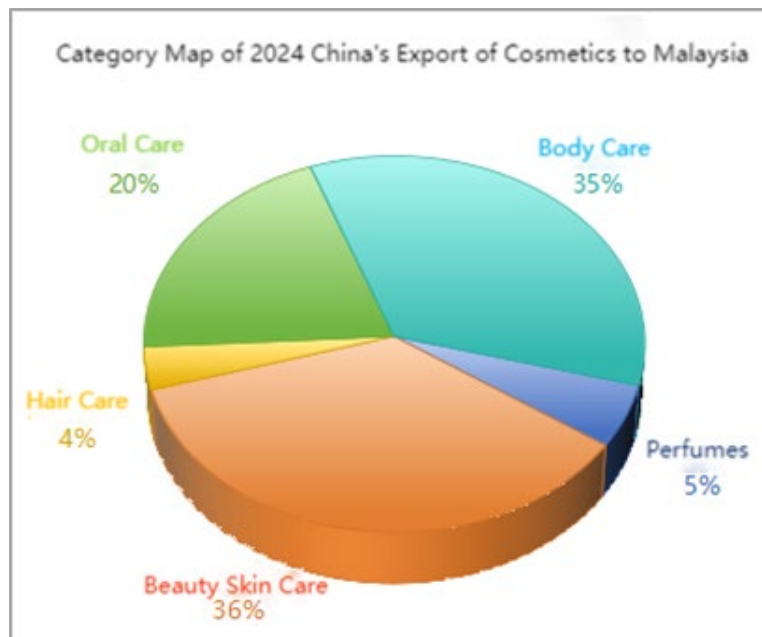
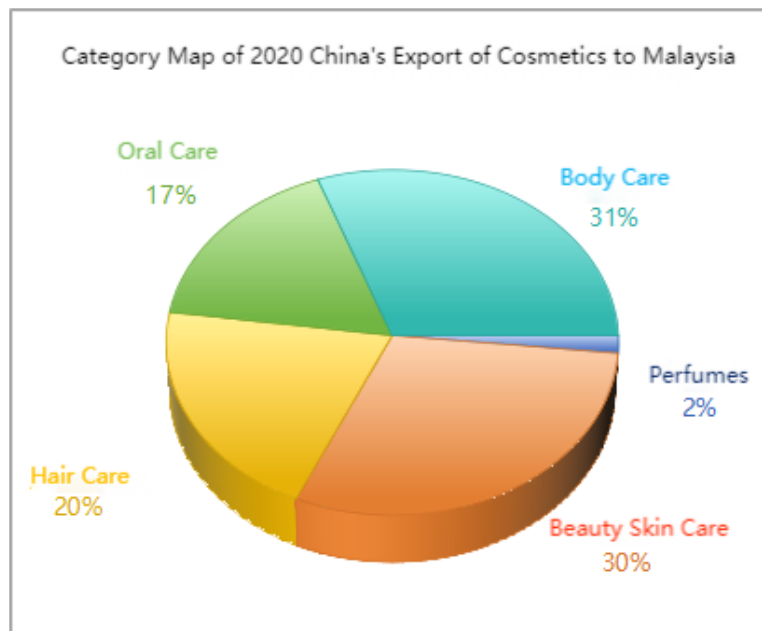
By CCCMHPIE, Based on Customs Data Statistics

### Export Overview

Currently, China's cosmetics exports to Malaysia are dominated by beauty skin care and body care products, accounting for 71% of exports in 2024. As shown in the following figures, in 2020, the top three categories of Chinese cosmetics exports to Malaysia were body care, beauty skin care, and hair care products. By 2024, beauty skin care exports grew from USD\$18.86 million to USD\$66.76 million, a CAGR of 37.2%, becoming the largest export category. Body care products rose from USD\$19.15 million to USD\$64.82 million, a CAGR of 35.6%, ranking second. Oral care and perfumes grew from USD\$10.83 million and USD\$1.03 million to USD\$37.66 million and USD\$10.09 million, ranking third and fourth respectively, with perfumes showing the most significant growth at a CAGR of 76.9%.

In contrast, hair care product exports shrank significantly over five years (2020-2024), dropping from USD\$12.81 million to USD\$6.84 million, with their share falling from 20% to 4%. This is due to two main factors: first, Malaysia's rapid economic growth has boosted cosmetics purchasing power, with international brands like Kerastase, L'Oréal,

and Clairol occupying a large share of the hair care market through technology, brand influence, and extensive distribution channels; second, local Malaysian hair care brands such as Enliven Hair Care Malaysia and BF1, which focus on natural, organic, and halal ingredients to meet consumer preferences, have enhanced their competitiveness.



By CCCMHPIE, Based on Customs Data Statistics

### **Malaysia's Halal Certification for Cosmetics**

Halal certification is a system for certifying products like food, pharmaceuticals, cosmetics, and additives that comply with Muslim lifestyle and needs. It is implemented according to halal regulations, and upon certification, qualified products receive official certificates and labels to confirm that no forbidden substances or non-compliant processes were used in manufacturing or processing—e.g., no pork products, alcohol (ethanol content in non-alcohol products must not exceed 0.5%), or ingredients from animals not slaughtered according to Islamic rites. This comprehensive review extends to all aspects of production to ensure no cross-contamination occurs, even at the level of processing equipment and facilities. Additionally, Halal-certified product names must not include words violating Islamic teachings. For cosmetics, certification covers ingredients, production processes, and packaging to ensure they are free of alcohol, pork-derived raw materials, and harmful substances.

Malaysia is a key global hub for Halal certification, with its system enjoying high international influence and recognition. Official certifying bodies include the Department of Islamic Development Malaysia (JAKIM), the State Islamic Religious Affairs Department (JAIS), and the Halal Development Corporation Berhad (HDC). JAKIM is the core certifying authority, responsible for formulating and implementing halal standards and procedures, certifying products such as food, beverages, cosmetics, pharmaceuticals, and personal care items, accrediting and managing international halal certification bodies, conducting regular audits of certified enterprises, and updating Malaysia's halal standards to cover the entire process from raw material procurement to production, packaging, and transportation. JAIS primarily handles local halal affairs management and supervision to ensure compliance with Islamic law, cooperating with JAKIM to provide religious guidance and support in the certification process. HDC focuses on promoting the overall development of Malaysia's halal industry—including food, cosmetics, and pharmaceuticals—and enhancing Malaysia's global halal market influence through international cooperation.

Malaysia's cosmetics market is distinct: as Islam is the state religion, most citizens are Muslims (approximately 22.147 million, accounting for 63.7% of the population), so halal cosmetics that contain no alcohol or animal-derived ingredients and are produced in processes completely isolated from substances considered "unclean" by Islamic teachings are widely popular. However, according to public information, few Chinese cosmetics enterprises have obtained Malaysia's halal certification—only TCI Co.,Ltd. is known to have received JAKIM's halal certification, with its halal facial masks performing well in Malaysia and Indonesia. As the Southeast Asian halal market grows and Indonesia enforces halal certification, its importance will continue to rise, prompting more enterprises to enter this field.

Notably, in August 2023, Indonesia and Malaysia formally signed a Halal Certificate Mutual Recognition Cooperation Agreement (MoC) to strengthen halal trade ties. Under MoC, the two governments mutually recognize each other's halal certificates, though specific implementations require meeting certain conditions. For example, Indonesia recognizes halal certificates issued by JAKIM, but imported products must still be registered in Indonesia's BPJPH system; Malaysia recognizes halal certificates issued by Indonesia's MUI, but specific products entering the Malaysian market must still meet JAKIM's requirements. Under MoC, enterprises with Indonesian halal certification can leverage the mutual recognition mechanism to further expand into the Malaysian market.

### **Market Outlook**

Multiple authoritative institutions predict that Malaysia's cosmetics market will continue to grow in the next five years. On the one hand, demand for personalized, high-quality cosmetics is strong, and the rise of young consumers willing to try new brands and products will sustain market growth. On the other hand, high internet penetration will further boost e-commerce, providing cosmetics enterprises with broader market reach and more convenient sales channels. Additionally, product innovation driven by natural, organic, and environmental concepts will become a new industry trend.



In recent years, China's cosmetics innovation and R&D have flourished, particularly in the development of Chinese characteristic plant-based ingredients. Ingredients like *Centella asiatica*, *Portulaca oleracea*, licorice (*Glycyrrhiza glabra*), *Dendrobium officinale*, *ganoderma lucidum*, ginseng, matsutake mushroom, aloe vera, rose, and peony have been widely researched and applied, giving rise to a number of outstanding China domestic brands. Examples include "GUYU," which focuses on glabridin for whitening; "SHE LOG," which uses matsutake extract; "Pechoin," a major domestic brand with aloe vera; and "Inoherb," which contains rhodiola extract. This trend is also reflected in new ingredient notifications: in 2024, China's National Medical Products Administration (NMPA) approved 90 new cosmetics ingredients, of which 42 were plant-derived—an explosive growth, marking the first time plant-based ingredients exceeded chemical ingredients in notification quantity and becoming the fastest-growing ingredient type.

It is clear that China's cosmetics industry development direction aligns with Malaysia's market trend of favoring green, natural, and pure products. As the quality of Chinese cosmetics continues to improve and brand power strengthens, China's market share in Malaysia will further increase, and the future of China-Malaysia cosmetics trade looks promising.

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## Enterprise Highlights

- ◆ Dr. Wolff Group: Heritage & Innovation Path of a Century-Old German Pharmaceutical Enterprise
- ◆ Youthretain Bio-Tech: Innovative Technology, Exceptional Service

## **Dr. Wolff Group: Heritage & Innovation Path of a Century-Old German Pharmaceutical Enterprise**

In Bielefeld, Germany, a century-old pharmaceutical enterprise has become a leader in the global health and beauty sector with its exceptional pharmaceutical and cosmetic R&D capabilities, as well as its unremitting pursuit of quality and innovation. This is the Dr. Wolff Group. Since its establishment in 1905, Dr. Wolff Group has become a highly regarded enterprise in the international market, relying on its rigorous German craftsmanship, strong scientific research strength, and global strategic layout.

### **From Pharmacist to Global Brand: A Century of Heritage and Innovation**

The history of Dr. Wolff Group began in 1905 when pharmacist Dr. August Wolff founded the company in Bielefeld. From the initial pharmaceutical R&D to a diversified enterprise covering both pharmaceutical and cosmetic fields today, Dr. Wolff Group has always taken R&D as its core competitiveness. In 1928, the company launched its first product, Alpecin, marking the official establishment of the brand. Since then, Dr. Wolff Group has continuously expanded its business areas, successively launching many well-known brands such as Linola (1938) and Alcina (1946). In 1987, the company established a new production base to further expand its production scale.

Over the past few decades, Dr. Wolff Group has continued to innovate and launched many products of epoch-making significance. From 2004 to 2005, it introduced the world's first caffeine anti-hair loss product, redefining the anti-hair loss hair care field. In 2008, the launch of Vagisan female intimate care cream broke the taboo in the female health field. In 2009, it launched a fluoride-free artificial enamel oral care product, leading a new trend in oral care. In 2020, it completed the R&D and production of a hand sanitizing gel in just one day, demonstrating its strong R&D strength. In 2021, the launch of the first medical-grade antiviral mouthwash further expanded its product line. In 2023, the introduction of DHI white-to-black shampoo consolidated its leading position in the anti-hair loss hair care field.

### **Global Layout and Family Heritage**

The global layout of Dr. Wolff Group began in the early 20th century, and it is now active in 68 markets worldwide. In 2024, its revenue approached hundreds of millions of euros, and all equity is held by the Wolff family. The Group's headquarters and production base are located in Bielefeld, Germany, with 15 offices worldwide in important cities such as Chicago, Shanghai, and Singapore, employing approximately 930 people.

The management of Dr. Wolff Group consists of fourth-generation family members Eduard R. Dörrenberg (CEO and Managing Partner), Christoph Harras-Wolff (Managing Partner), and Managing Directors Dr. Andreas Brinkhoff and Sybille Wasmuth. They have rich experience in marketing, sales, R&D, legal affairs, compliance, sustainable development, and finance, providing a solid guarantee for the company's sustainable development.

### **Two Business Divisions, Five Market Segments**

The business of Dr. Wolff Group covers two business divisions and a total of five market segments. The Cosmetics Division includes effective skincare, female intimate care, oral care, effective hair care, and beauty & makeup. Among them, effective skincare provides professional solutions for different skin problems; female intimate care focuses on female intimate care with the Vagisan brand as the core; oral care product includes brands such as Karex and Bioniq, using innovative technologies such as Bio-HAP (biological hydroxyapatite) to provide fluoride-free anti-cavity and tooth sensitivity care products; effective hair care mainly uses Alpecin and Plantur brands to provide anti-hair loss and hair care products; beauty & makeup covers makeup and skincare products to meet the diverse needs of consumers.

The Pharmaceutical Division, represented by the Linola brand, focuses on solutions for dry and itchy skin, dermatitis, and other problems. Since its launch in 1938, Linola has been one of the leading medical skincare brands in the German pharmacy channel, providing consumers with safe and effective skincare products based on the company's proprietary technologies from independent research results.

### **Core Brands: Market Leaders and Innovation Pioneers**

The core brands of Dr. Wolff Group hold important positions in the global market. Alpecin is the No. 1 shampoo brand in Germany, with a market share of 45%, and its Bio-Black shampoo was named the Best New Product Launch of 2023. Plantur is a female anti-hair loss hair care brand, ranking among the top ten hair care brands in Germany with a market share of 20%. Vagisan is the No. 1 female health brand in German pharmacies, focusing on vaginal dryness care and lactic acid products. Karex uses Bio-HAP technology to provide fluoride-free anti-cavity products. Bioniq's biomimetic enamel technology can repair microscopic damage to the enamel surface and relieve tooth sensitivity. Since 1946, Alcina has been a professional salon brand focusing on hair and skin care, with a rich product line covering hair care, skin care, and makeup, with more than 600 SKUs, serving more than 10,000 professional hair salons.

### **Scientific Research Strength: Innovation as the Core Driving Force for Development**

Dr. Wolff Group takes its independent research results and patented technologies as its core competitiveness, continuously promoting product innovation. For example, the Bio-Black shampoo uses patented technology to effectively prevent hair loss and promote hair growth. Bio-HAP technology replaces traditional fluoride, reducing the risk of fluorosis while providing efficient anti-cavity protection. Biomimetic enamel technology can repair microscopic damage to the enamel surface, caring for healthy and white teeth. These innovative technologies not only enhance product efficacy but also bring safer and more effective health and beauty solutions to consumers.

### **Sustainable Development and Social Responsibility: Green Production and Environmental Protection Packaging**

Dr. Wolff Group not only focuses on product R&D and innovation but also actively fulfills its social responsibilities. Since winning the "German Environmental Award" in 1993, it has been committed to sustainable development, promoting measures such as environmental protection packaging and green production, and striving to reduce its impact on the environment. The company reduces carbon emissions and protects

natural resources by using recyclable materials and optimizing production processes. In addition, Dr. Wolff Group actively participates in social welfare activities, supporting education, environmental protection and health undertakings, and contributing to social sustainable development.

### **Globalization and Digital Transformation: Expanding Markets and Enhancing Influence**

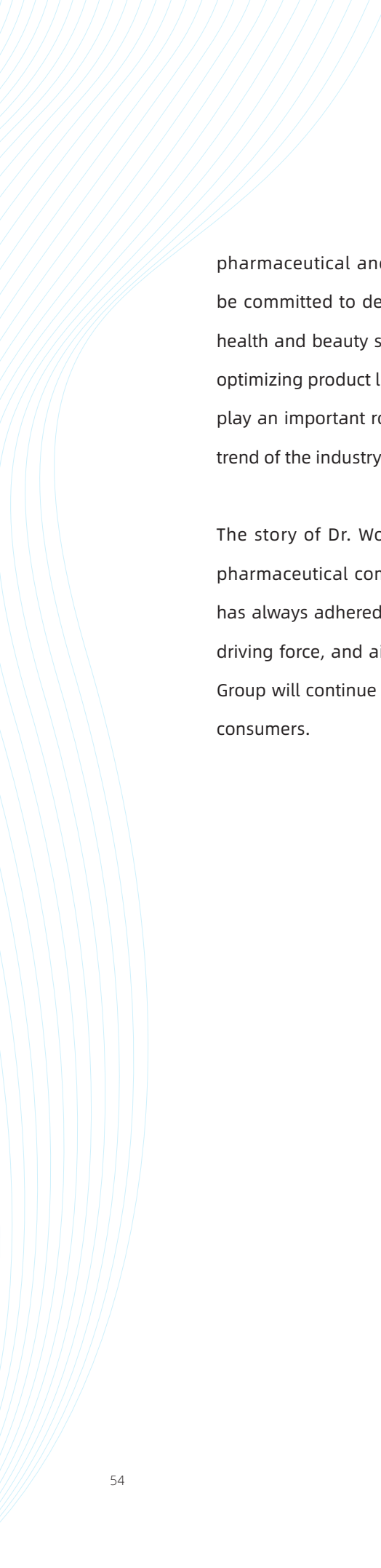
In the process of globalization, Dr. Wolff Group continues to expand its market share by setting up offices in different countries and regions. At the same time, it actively embraces digital transformation, establishes the eWolff digital business division, accelerates the expansion of online channels, and enhances the brand's global influence. Through digital platforms, Dr. Wolff Group can better understand consumer needs, provide personalized products and services, and further consolidate its position in the global market.

### **Deepening the Asian Market: China's Strategic Layout and Omni-channel Expansion**

Since entering the Chinese market in 2015, Dr. Wolff Group has always adhered to the strategy of "global scientific research + local adaptation", deeply insighting into the needs of local consumers - from the strong efficacy demands of anti-hair loss and hair care products to the refined trends of intimate care. With the Shanghai regional headquarters as the core, the Group has targeted the layout of star brands Alpecin caffeine hair care and Vagisan female intimate care, fully covering mainstream e-commerce platforms such as Tmall, JD.com, and TikTok, and at the same time, joining hands with high-quality offline channels such as Sam's Club, Costco, Watsons, and Pang Donglai to build a full-link consumption scenario. In the future, it will continue to introduce more brands and products based on local insights, and continue to provide Chinese consumers with more convenient and high-quality German personal care solutions.

### **Future Outlook: Sustained Innovation, Serving the World**

With its century-old German rigorous spirit, strong scientific research strength and innovative product line, Dr. Wolff Group has become an important force in the global



pharmaceutical and cosmetics fields. In the future, Dr. Wolff Group will continue to be committed to developing more efficient and safe products, providing high-quality health and beauty solutions for global consumers. By continuously expanding markets, optimizing product lines, and enhancing brand influence, Dr. Wolff Group will continue to play an important role in the global health and beauty field and lead the development trend of the industry.

The story of Dr. Wolff Group is a legend of heritage and innovation. From a small pharmaceutical company in 1905 to a world-renowned brand today, Dr. Wolff Group has always adhered to the concept of putting consumers first, taking innovation as the driving force, and aiming at sustainable development. In future development, Dr. Wolff Group will continue to uphold this concept and bring more health and beauty to global consumers.



## Youthretain Bio-Tech: Innovative Technology, Exceptional Service

Youthretain Bio-Tech has deeply engaged in the field of cosmetic efficacy ingredients for fifteen years. With the core development philosophy of "Innovative Technology, Exceptional Service", it has grown into an industry benchmark integrating "forward-looking ingredients R&D + customized technical solutions + full-lifecycle service support from ingredients to terminal product market".



Driven by "biological technology", Youthretain has established a three-dimensional collaborative R&D system of "innovation R&D - quality & safety assurance - green sustainability", forming a full-link innovation closed loop from basic research to industrial transformation.

The "Youthretain Beijing Innovation R&D Center", officially launched at the end of 2023, boasts a specialized R&D team for cosmetic ingredients led by 2 consultant professors

and 2 full-time post-doctorates, integrating multidisciplinary expertise. Composed of master's and doctoral talents from top universities like Tsinghua University, Beijing University of Chemical Technology, Shanghai Jiao Tong University, and Southeast University, including senior industry experts with over 20 years of experience, they have rich scientific research experience in their respective fields, having led or participated in multiple national projects. They jointly integrate technologies from dermatology, biochemistry, materials science, etc., to achieve the industrialization of bioactive materials from laboratory research to functional ingredients in the cosmetics industry, with plans to extend some research achievements to the healthcare sector.



Currently, Youthretain has successfully built five core technology platforms: Synthetic Biology, Green Synthesis - Aspartic Acid Derivative Development, Molecular Delivery Technology, Chinese Authentic Herbal Extract Active Substances (water-soluble/oil-soluble active molecule extraction, supramolecular extraction), and Medicinal Edible Fungus Fermentation Technology.

Based on innovation and relying on the above five core technology platforms, Youthretain has achieved multiple industry-first breakthroughs in a short period.

Focusing on innovative output in various technical fields, the R&D team currently has systematic R&D achievements including: 1 record of new cosmetic ingredient with the National Medical Products Administration, more than 10 authorized invention patents and utility model patents, and leading the formulation of the "Application Specifications for Anti-aging Active Ingredients in Cosmetics" group standard.

**We are the world's first enterprise to produce M6P (Mannose Phosphate Sodium) through synthetic biology green manufacturing.**

Through the synthetic biology laboratory jointly established with Beijing University of Chemical Technology, we hold multiple exclusive high-quality genetically engineered bacterial strain resources, and simultaneously integrate an AI-directed enzyme screening platform to subvert traditional processes, build a green R&D production line, achieve high yield of hexokinase, use phosphate instead of expensive ATP as a substrate, reduce mass production costs while significantly improving enzyme catalytic efficiency, and ultimately obtain high-purity Mannose Phosphate Sodium. The product's efficacy mechanism targets dual pathways of cellular energy supply and autophagy. Verified by third-party complete experiments, it becomes a rare patented active ingredient in the market with both significant anti-aging and whitening effects.

**The first enterprise to independently develop Aspartic Acid Chelated Zinc (Aspartate Zinc).**

Based on the R&D team's 20+ years of polyaspartic acid research and technology transformation, aiming to provide innovative structural expansion for the cosmetics field, we successfully developed the world's first Aspartic Acid Chelated Zinc (Aspartate Zinc), achieving a breakthrough in zinc ion sustained-release technology, solving the limitations of traditional zinc salts in practical applications and skin irritation caused by concentration differences. Meanwhile, leveraging the structural characteristics of aspartic acid proteins, it achieves safe and long-acting oil control in efficacy. For this innovative achievement, we have successfully established an independent intellectual property system and completed the record of new cosmetic raw materials and patent layout.

**The first enterprise to synthesize a special wheat germ octapeptide using synthetic biology technology.**

In recent years, bioactive peptides extracted from wheat germ have attracted extensive research attention, with precise screening of wheat active peptides yielding rich medical research achievements. The latest wheat peptide developed by the Youthretain Innovation R&D Center is a brand-new octapeptide structure with an unprecedented peptide sequence (relative molecular weight about 900 Daltons). Through AI algorithm-based efficient screening of target bioactive peptides, we jointly developed a microbial high-efficiency expression system to replicate wheat germ-derived polypeptides and achieved mass production via synthetic biology technology, simultaneously completing patent layout for this structure and preparation method. In terms of efficacy, this ingredient is known as "plant EGF", with repair effects comparable to EGF. Verified by extensive in vitro efficacy tests and clinical trials for post-medical cosmetology classification management, it has become an innovative ingredient that meets the needs of post-medical aesthetic repair, combining applicability for sensitive skin with high-efficiency skincare characteristics.

To ensure product quality stability, safety, and verify the effectiveness of active ingredients in application, we have established a "Quality Analysis and Efficacy Evaluation Center", establishing a full-link quality assurance system from ingredient traceability to product launch. Equipped with high-precision detection equipment such as HPLC, LC-MS/MS, and Varioskan ALF multi-function microplate readers, the center has established hundreds of internal control standards to monitor and evaluate the physical and chemical indicators of active substances. In the efficacy verification process, in vitro and cellular efficacy testing platforms have been established, along with



a self-owned cell line library. The efficacy evaluation system covers categories such as soothing, repairing, oil control, anti-wrinkle, whitening, anti-acne inflammation, and firming, while a complete ingredient toxicology safety file has been established to provide scientific and safe support for product efficacy claims.

As a national high-tech enterprise and a science and technology innovation demonstration enterprise in the cosmetics industry, we adhere to collaborative innovation among industry, academia, research, and medicine, promote industry technology upgrading through evidence-based R&D models, empower the health industry with original Chinese biotechnology, and are committed to building a sustainable development paradigm for the harmonious coexistence of the Beauty Economy and ecological civilization.



中国化妆品法规与发展  
China Cosmetics  
Regulations and Development

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REFERENCE FOR THE INDUSTRY  
WORK EXCHANGE