Latest Update of Cosmetics Regulations in China

Chemical Inspection & Regulation Service Ltd.

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Global Service Network

CIRS Group has established and will continue to improve its global service network.
Capable of providing regulatory consulting services in major global economies.

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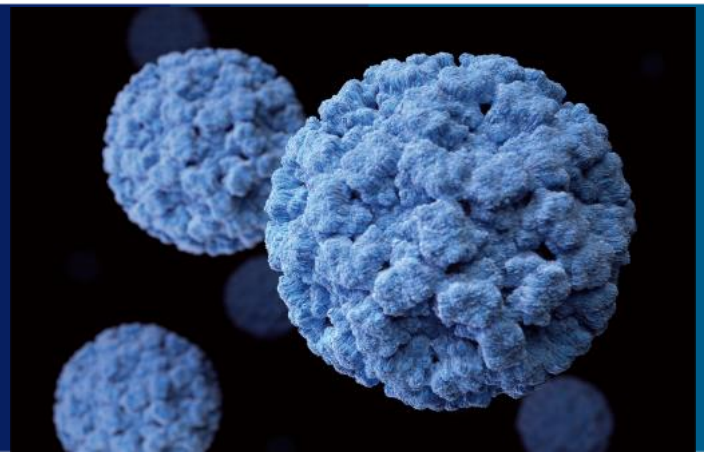
Statistics of Cosmetic Ingredients Filed/Registered under CSAR



01

New Cosmetic Ingredients Filed/Registered under CSAR

Total number: 344

6/2021-10/2025

Filing of new cosmetic ingredients without high safety risk

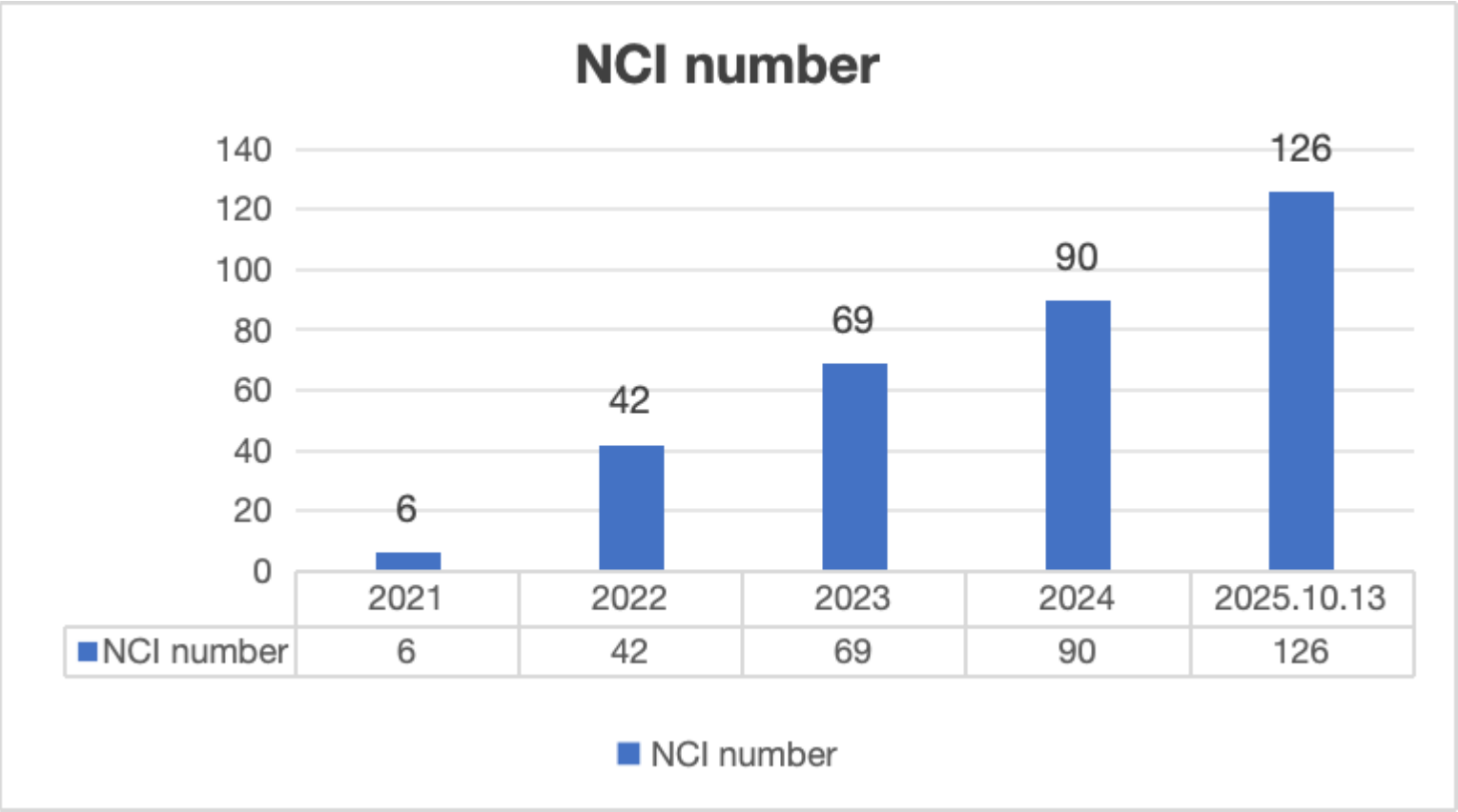
341

Registration of new cosmetic ingredients with high safety risk

3

Data source: NMPA website

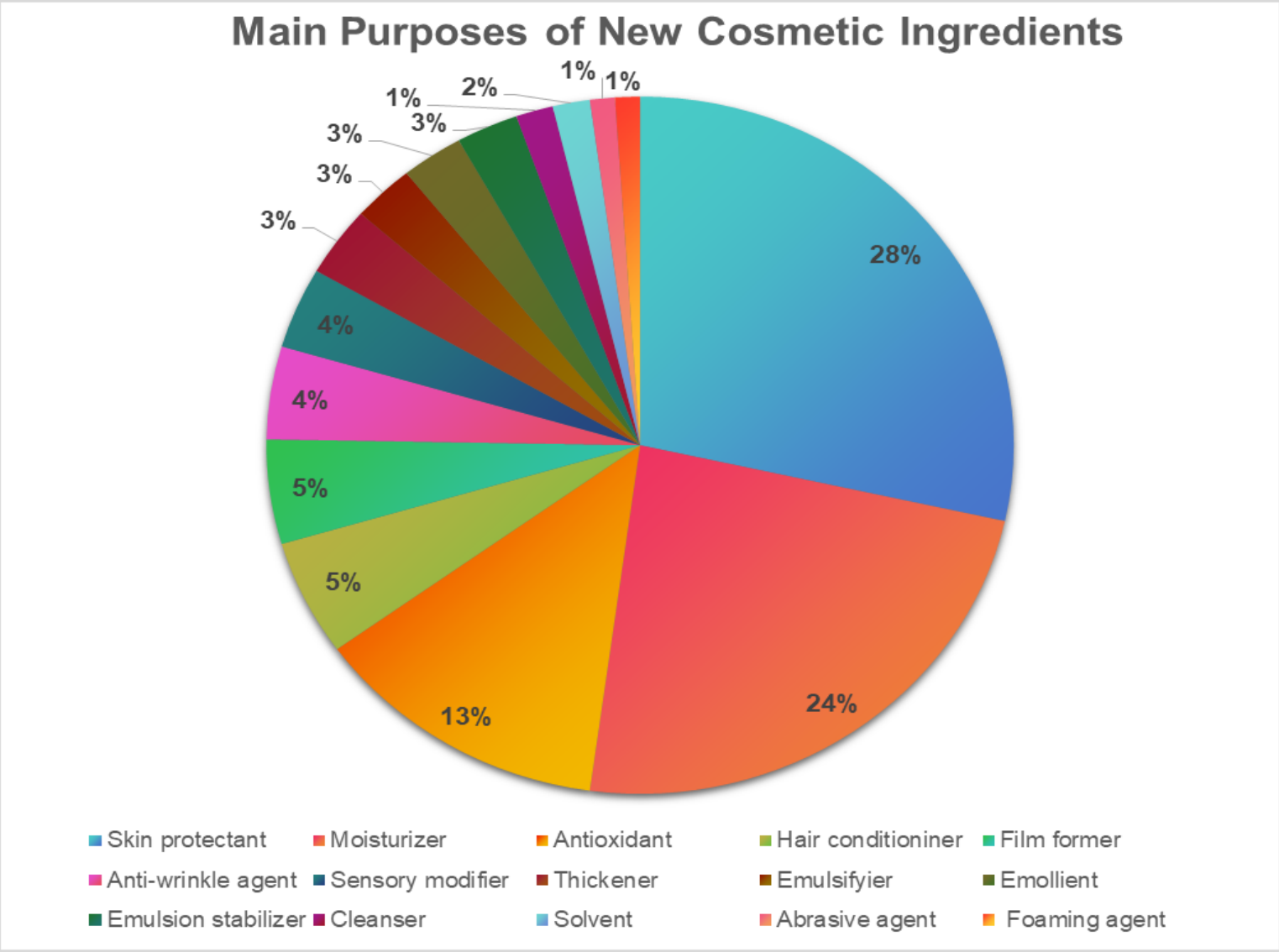
A Recent Look at New Cosmetic Ingredients in China



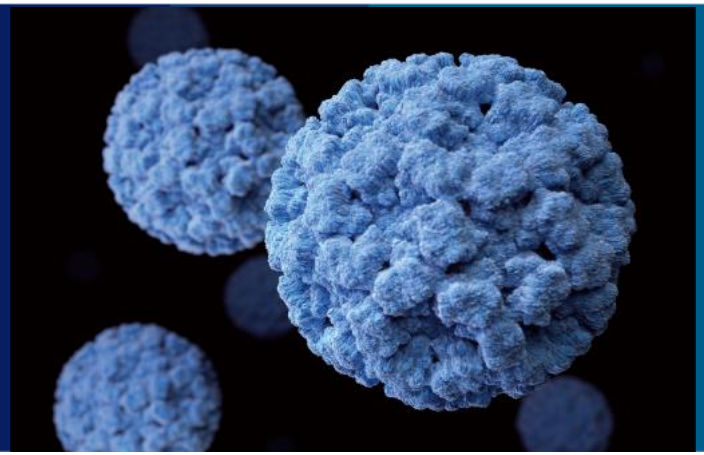
Among the 126 raw materials in 2025, only 14 are registered successfully non-domestically

Japan: 1
Italy: 5
Korea: 3
UK: 1
France: 2
USA: 1
Hong Kong: 1

Trends in New Cosmetic Ingredients in China



Latest Requirements for New Cosmetic Ingredients in China

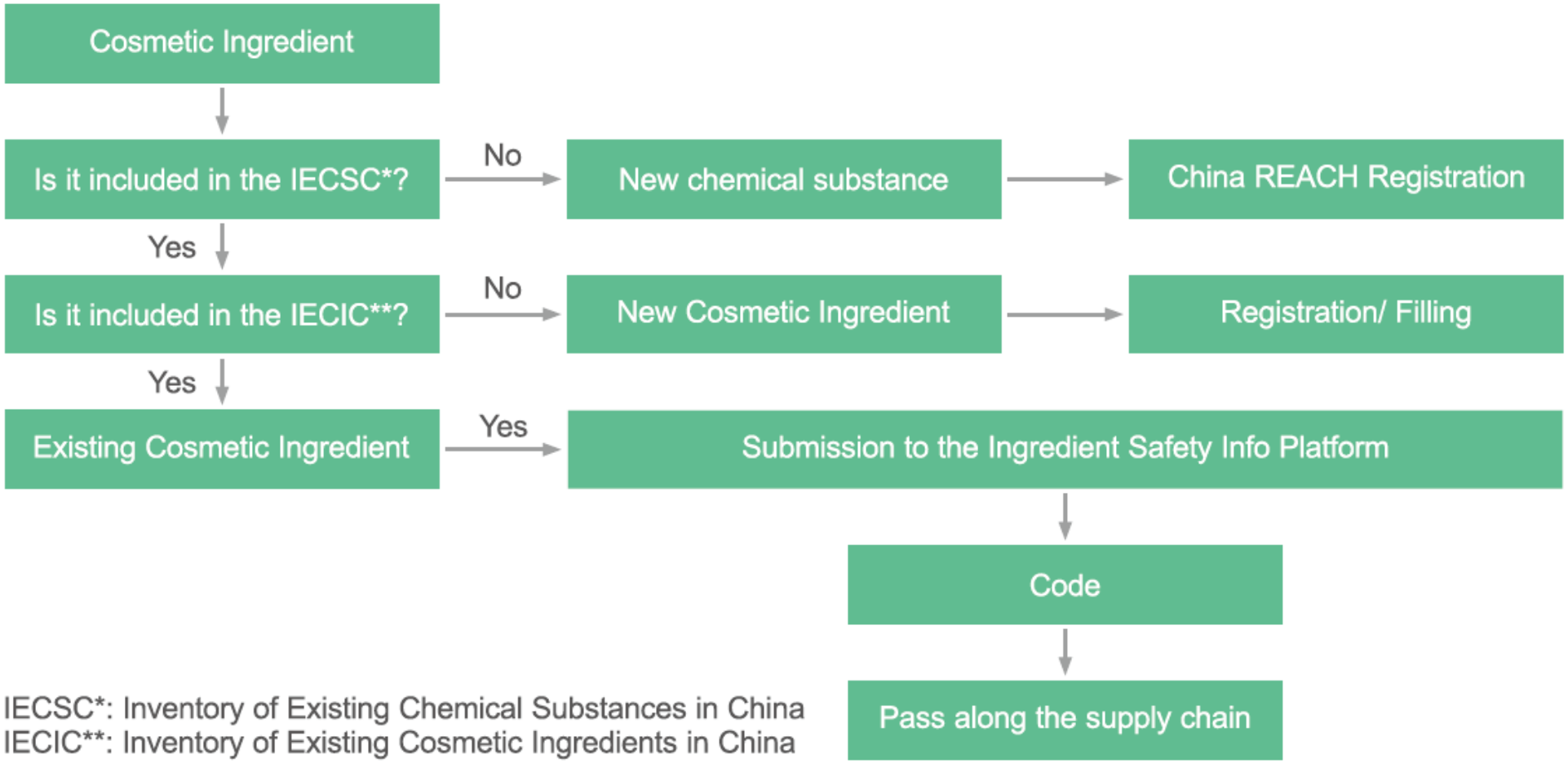


02

Defining New Cosmetic Ingredients in China under CSAR

A new cosmetic ingredient in China is defined as a natural or artificial ingredient used in cosmetics for the first time in China i.e. not included in the Inventory of Existing Cosmetic Ingredients in China (IECIC 2021)

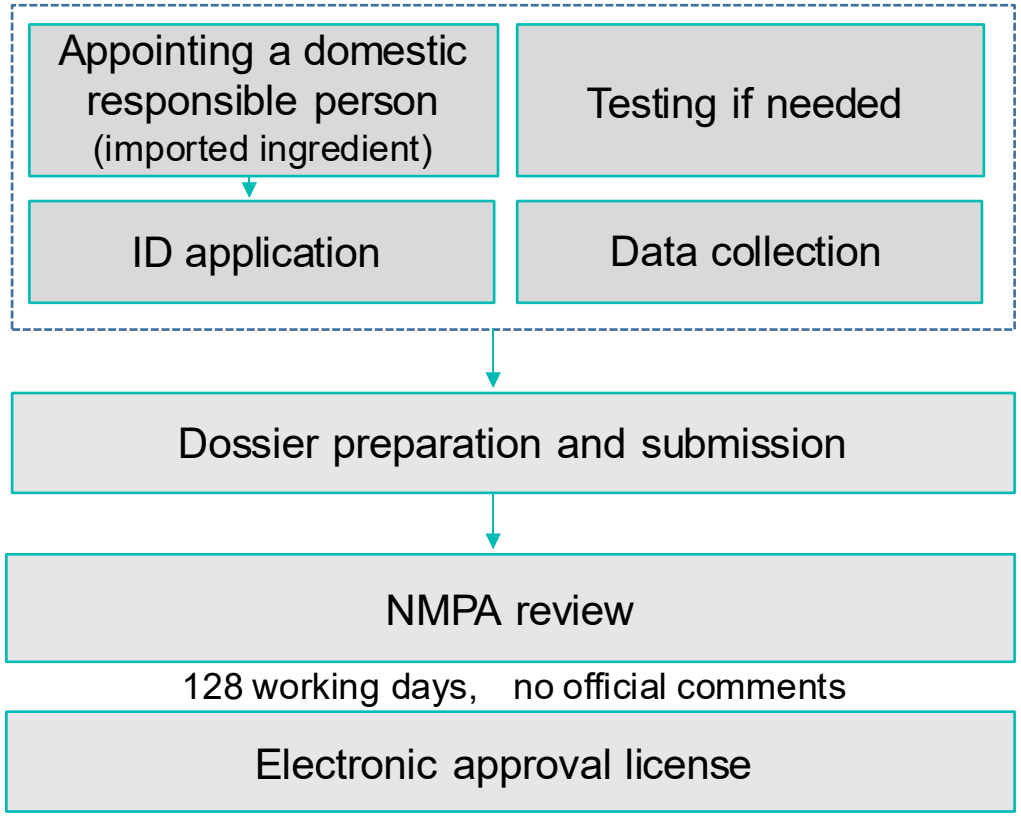
How to Ensure Your Cosmetic Ingredient is Compliant in China



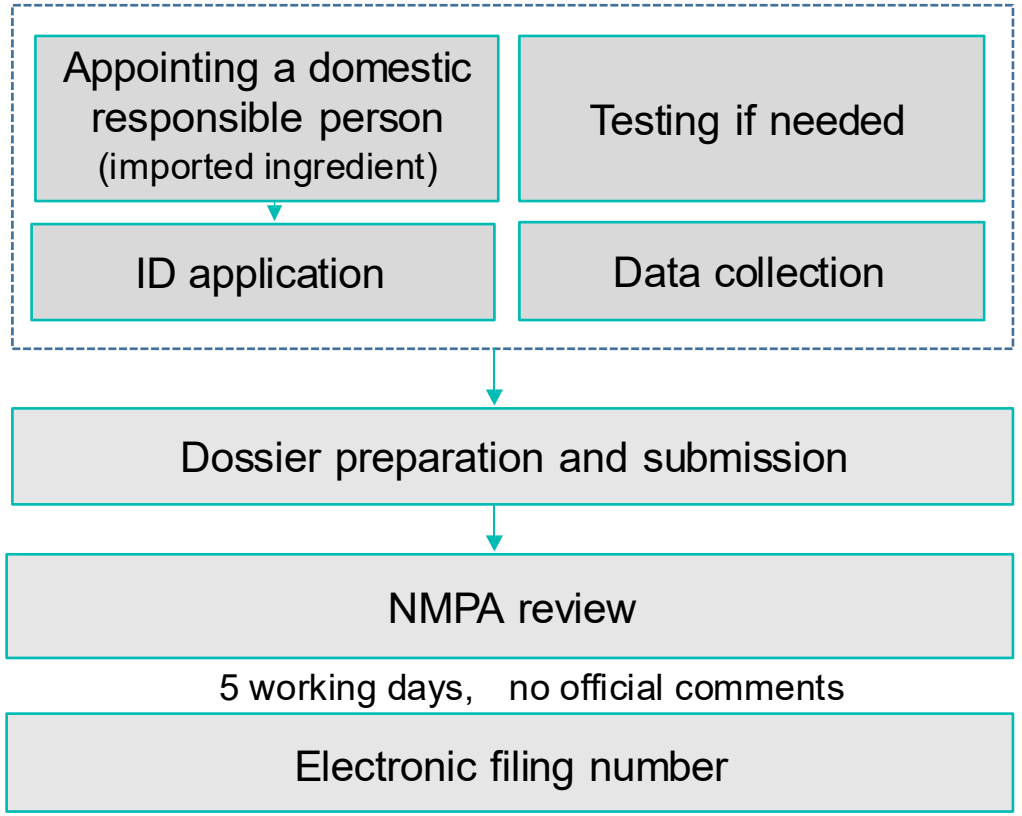
IECSC*: Inventory of Existing Chemical Substances in China
IECIC**: Inventory of Existing Cosmetic Ingredients in China

Key Steps for Compliance

New cosmetic ingredients with high safety risk

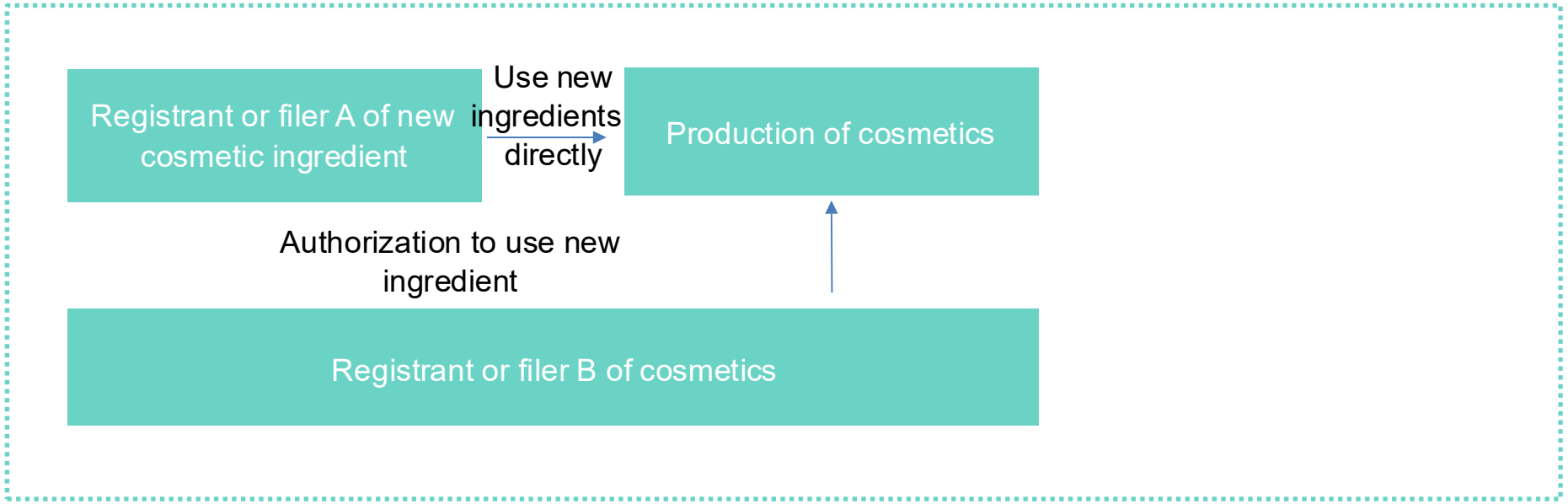


New cosmetic ingredients without high safety risk



Post-market obligations (3-year monitoring period)

Within the 3 years of safety monitoring period



Classification of New Cosmetic Ingredients by Risk Level

1	2	3 and 4	5	6
Scenario 1 – High regulatory concern Ingredients with special cosmetic claims (e.g. sunscreen, hair dye, whitening)	**Scenario 2 – General ingredients** Ingredients without special functions	**Scenario 3-4 – Overseas safe-use** ≥3 years of safe use in overseas cosmetics	**Scenario 5 – Consumer exposure history** Sufficient evidence of safe consumption history	**Scenario 6 – low-risk polymers**

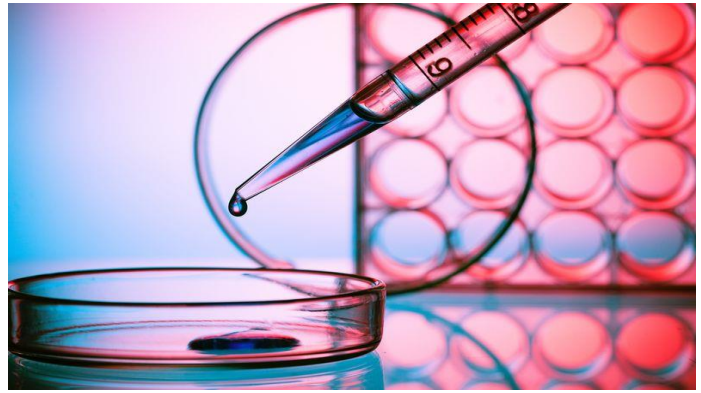
Testing Requirements

Testing item	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5	Scenario 6
Acute oral or dermal toxicity	★	★	★	★		
Skin and eye irritation/corrosiveness	√	√	√	√	√	√
Skin sensitization	√	√	√	√	√	
Skin phototoxicity	★	★	★	★	★	★
Skin photoallergy	★	★	★	★	★	
Genotoxicity	√	√	√	√		
Subchronic oral or transdermal toxicity	√	√	√			
reproductive and developmental toxicity	★					
Chronic toxicity/carcinogenicity combination	★					
Inhalation toxicity						
Long-term human trial safety	★					
Transdermal absorption						
Toxicokinetics						
Others						

Note： √ - Mandatory; ★ - Required depending on conditions

Animal Testing for Cosmetic Ingredients in China

Testing item	In vitro method	In vivo method
1. Acute oral toxicity		√
2. Acute Dermal Toxicity		√
3. Acute Inhalation Toxicity		√
4. Acute dermal irritation		√
5. Acute dermal corrosion	√	√
6. Acute Eye irritation	√	√
7. Skin sensitization	√	√
8. Skin phototoxicity	√	√
9. Skin Photoallergy		√
10. Subacute Oral Toxicity Study		√
11. Subacute Inhalation Toxicity Study		√
12. Teratogenicity	√	√
13. Reproductive toxicity		√
14. Subchronic oral/dermal/inhalation toxicity		√
15. Chronic Toxicity/Carcinogenicity		√
16. Immunotoxicity		√
17. Toxicokinetics		√ (draft)
18. Skin Absorption	√	√



Dossier Requirements

Mandatory info

- Administration information
- Ingredient identity and composition
- Manufacturing/preparation process
- Physicochemical properties
- Impurities and hazardous substances
- Quality standard and inspection results
- Safety assessment

Additional information (case-by-case)

- Source and safety background
- Structural identification
- Efficacy basis (if applicable)
- Analytical methods and verification data
- Stability data (accelerated/long-term)

Special Case: Dealing with Cosmetic Ingredients with High Biological Activity

General principles:

- Cosmetic ingredients should have mild, reversible effects
- They must not significantly interfere with human physiological functions

How to identify an ingredient with high biological activity?

- Has a clear biological target or mechanism of action
- Produces measurable biological effects at low concentrations
- Is designed based on substances known to have strong biological effects

High Risk → Scenario 1 Toxicity Tests Required

Scenario 5: Use of Safe Consumption Data (Historical Evidence Route)

- Allows safety assessment of a new cosmetic ingredient based on established safe consumption history
- Reduces the need for new toxicity testing when robust food-evidence exists

Key supporting docs required:

1. Evidence of safe consumption

- ❖ Food safety authorities
- ❖ Official public documents

2. Consistency with food-grade raw material

- ❖ Cosmetic ingredients should be comparable to the food-use material in terms of source and botanical/chemical identity, main components and safety indicators, manufacturing process
- ❖ Acceptable processes include food-like methods and if processing differs, the components profile, enrichment, and residual solvents must be evaluated

3. Consumption conditions and restriction

- ❖ Documented information on consumption method and use limits, applicable population groups and precautions or exclusions (if any)

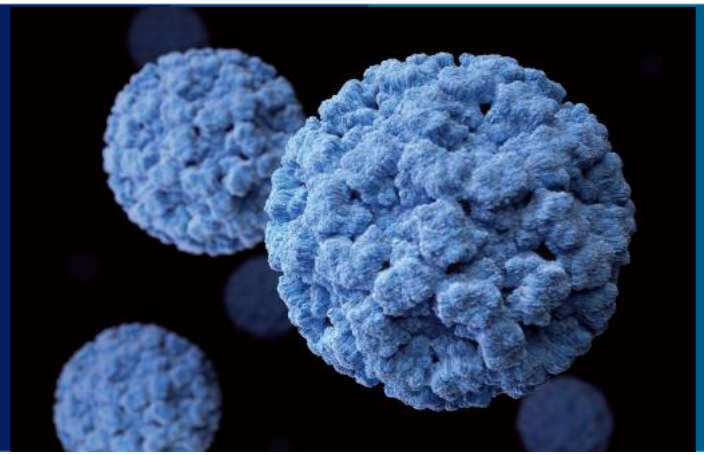
What Information Can Be Updated?

- **Administrative / contact information**
  - Filer contact details
  - Domestic responsible person contact details
  - Production contact details

- **Enterprise information**
  - Update filer or domestic responsible person information *(entity unchanged)*
  - Update production enterprise information *(production site unchanged)*
  - Change of filer or domestic responsible person

- **Ingredient-related information**
  - Change or add production site
  - Manufacturing process optimisation
  - Quality standard improvement
  - Shelf-life extension
  - Expansion of purpose of use
  - Update warnings and precautions

Latest Updates of New Cosmetic Ingredient Regulations



03

Regulations on Supporting Cosmetic Ingredient Innovation

- **Clearer rules for “new ingredient” classification**
  (More detailed technical guidance on how ingredients are categorized.)

- **Risk-based safety requirements**
  (Data requirements can be adjusted based on the ingredient’s risk level.)

- **Stronger link between ingredient R&D and finished products**

- **More efficient approval process (parallel filing)**
  (You may file a new ingredient and apply for a *special cosmetic* using it at the same time.)

Regulations on Supporting Cosmetic Ingredient Innovation

- **Priority support for ingredients first marketed in China**
  Encourages domestic-first innovation and speeds attention to those materials.)
- **Earlier regulator involvement**
  (More pre-submission guidance to improve dossier quality and avoid rework.)
- **Better coordination: NMPA + local MPAs**
  (Selected provincial MPAs can provide pre-consultation, regulatory Q&A, follow-up guidance
- **Standards development for key raw materials**
  (Focus on ingredients with high use, higher risk, or strong Chinese relevance.)
- **More acceptance of non-animal methods**
  (Promotes research/validation and regulatory use of alternative approaches.)
- **Ingredient information archives**
  (More structured record-keeping and data management for new ingredients.)

Technical General Rules for Registration and Filing of New Cosmetic Ingredients (Draft)

- Public comments: 24/09/2025 – 19/10/2025. Final version not completed yet.

- The dossier should be audit ready, rather than prepared for one-time submission. It should demonstrate compliance, authenticity, accuracy, completeness and traceability at all time.

- Original test reports should be available for inspection, not just summaries

- The filer/registrant/domestic responsible person should **retain samples** for future inspection

New Testing Methods

Issue date: 22nd Jan, 2025

Testing item	Reference method
Collagen Hydrogel-Eye Irritation Test (draft)	OECD 494

Issue date: 7th May, 2025
Implementation date: 1st Mar, 2026

Testing item	Reference method
In Chemico Skin Sensitisation The ARE-Nrf2 Luciferase LuSens Test	OECD 442D

Issue date: 29th Aug, 2025
Implementation date: 1st Mar, 2026

Testing item	Reference method
Skin Absorption：In vitro Method	OECD 428
Bovine Corneal Opacity and Permeability (BCOP) Assay	OECD 437
In Chemico Skin Sensitisation: Kinetic Direct Peptide Reactivity Assay（kDPRA）	OECD 442C
Immunotoxicity test	ICH S8 "Research on Immunotoxicity of Human Drugs“ , etc.

24 Reform Measures to CSAR

- *Opinions on Deepening Cosmetics Regulatory Reform and Promoting High-Quality Development of the Industry* (Nov 17, 2025)
- 24 major reforms across **5 areas** of CSAR which apply to cosmetic ingredients and finished products:

❑ Encourages innovation

❑ Optimising filing and registration

❑ Strengthening risk prevention and control

❑ Enhancing supervision

❑ Promoting alignment with global cosmetic regulations

Key Practical Regulatory Changes

- **Moving towards a more flexible and efficient process:** similar formulations under the same brand may share safety technical data. It is recommended to self-archive all safety data.
- **Dossier update review timelines shortened:** High-risk changes – 60 wkds and low-risk changes: 45 wkds
- **Progressive exemptions in animal testing:** for low-risk ingredients
- **Expansion of test method acceptable from foreign institutions**

CIRS Services

- ✓ Finished cosmetic compliance for China, South Korea, EU & UK
- ✓ New cosmetic ingredient registration in China
- ✓Chemical substance registration in China (China REACH), South Korea (K-REACH), EU REACH & UK REACH
- ✓ Domestic responsible person service in China, Korea, EU & UK
- ✓ Review & Preparation of a Chinese sticker
- ✓ Testing coordination in an NMPA accredited lab
- ✓ Efficacy evaluation testing in NMPA accredited lab
- ✓ Regulatory Consultancy & Training
- ✓ Global Cosmetic Services for other regions including Japan, Turkey, Vietnam etc.

KEY FIGURES

CIRS Testing

6 Evaluation Labs

Located in Hangzhou, CHINA

5000+ Clients

35+ Employees

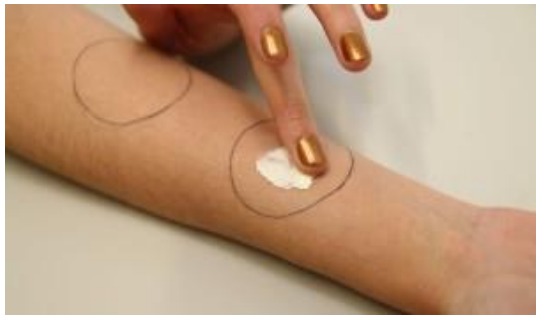
FOCUS

CIRS *in vivo* Efficacy Testing

SKINCARE
- Hydration
- Skin barrier repairing
- Nourishing
- Anti-wrinkle
- Firmness & Elasticity
- Soothing
- Brightening
- Skin whitening
- Exfoliating
- Oil Control
- Acne removal

SUN PROTECTION EFFICACY
- SPF testing *(in vivo)*
- UVA testing *(in vivo)*
- Water Resistance Test
- Very Water Resistance Test

HAIR CARE & SCALP CARE
- Professional analysis (dandruff)
- Scalp repairing
- Scalp hydration
- Anti hair loss efficacy



Other studies

CONSUMER USAGE TEST

SENSORY EVALUATION

SAFETY TEST (HRIPT)

THANKS !

微信公众号

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