

GPC cosmetic series webinars – session 1

# Overview of Chinese Cosmetic Regulation (CSAR)

State Council Order No.727

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Apr. 2023



# GPC China Cosmetic Compliance series

6 April

Overview of CSAR regulation

13 April

New cosmetic ingredients

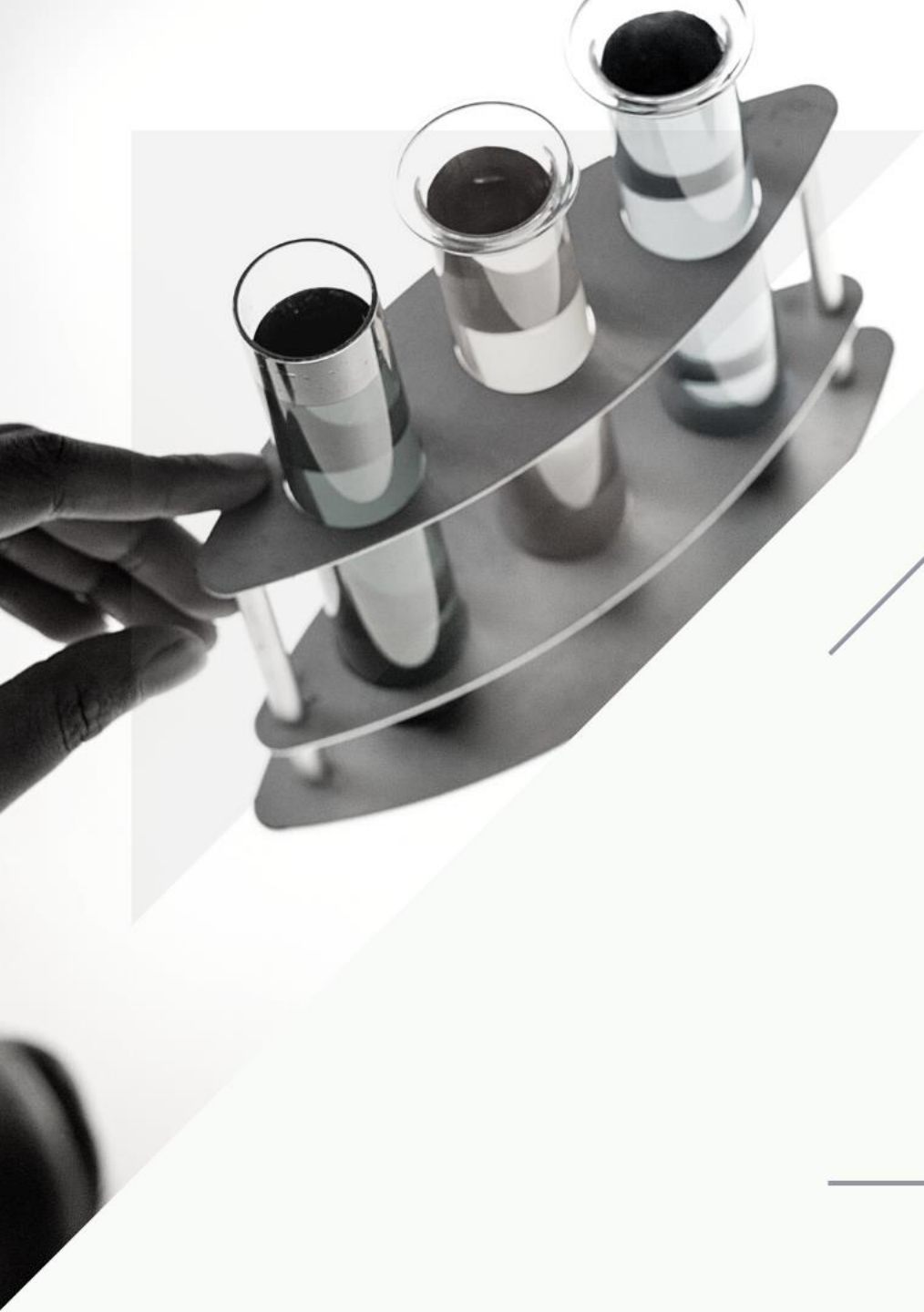
2 May

Existing cosmetic ingredients

11 May

Cosmetic products

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# outline

- Introduction
- Key components
- Post-registration management
- Updates on toothpaste regulation
- Updates on transition measures



# General Introduction

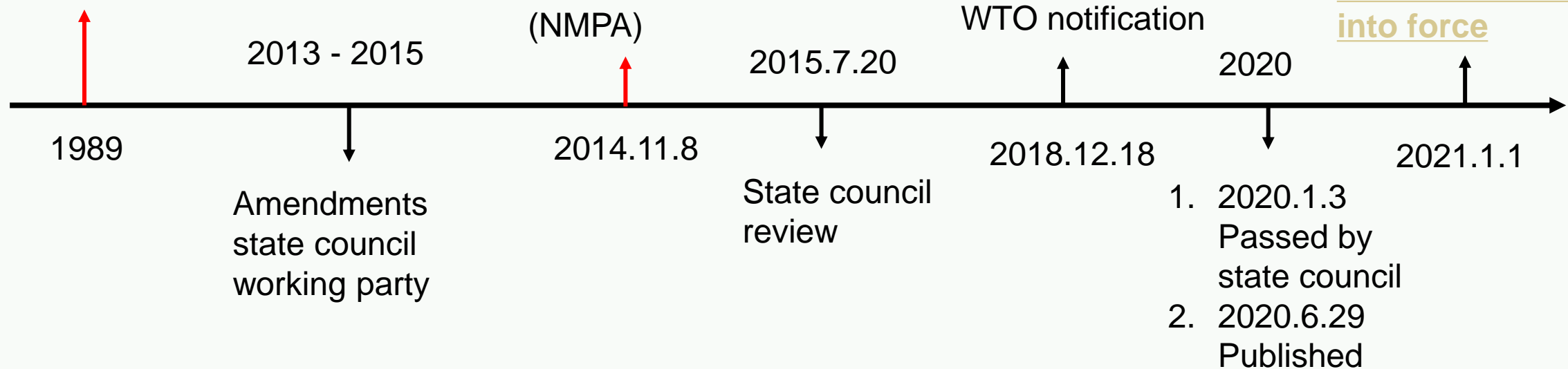
# Legislation History

Managing authority: NMPA -- National Medical Product Administration

Cosmetics Hygiene  
Supervision  
Regulations  
(Ministry of health)

Cosmetic Supervision  
and Administration  
Regulations – public  
consultation  
(NMPA)

State council  
order No.727  
(CSAR) Came  
into force



# Regulation Structure

## Cosmetics Supervision and Administration Regulations (CSAR, 2021)

- Chapter 1 – general provisions
- Chapter 2 – raw materials and products
- Chapter 3 – production and operation
- Chapter 4 – supervision and administration
- Chapter 5 – legal responsibilities
- Chapter 6 – supplementary provisions (toothpaste and transition period)



# Technical Guidelines

- Technical Guidelines on Cosmetic Safety Evaluation (2021)
  - Qualification on cosmetic safety evaluation people
  - Risk evaluation
  - Toxicology evaluation
  - Safety report (both ingredients and products)
- Cosmetic Safety Technical Specification (2019)
  - Prohibited and permitted ingredients
  - Providing information on all sorts of tests specification
  - 2022 version is under discussion

# Ingredients Related Rules

- Provisions for Management of New Cosmetic Ingredient Registration and Notification Dossiers (May 2021)
- Administrative Measures on Cosmetics Registration and Notification(May 2021)

Only target for cosmetic ingredients registration



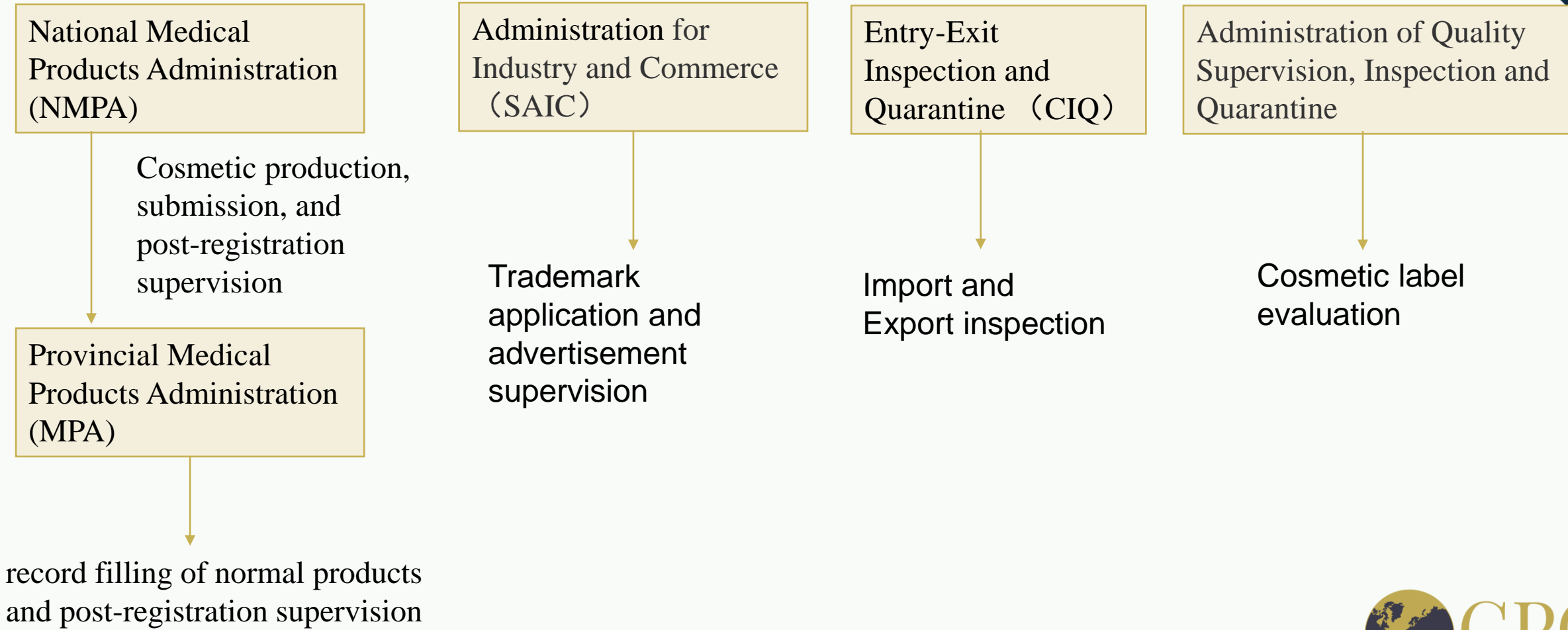
# Important lists

Lists	Definition
1. IECIC (2021)	Cosmetic ingredient inventory (8972)
2. Banned ingredients in cosmetics (2021)	Ingredients under this list are banned for cosmetic use (1284)
3. Banned plant (animal) ingredients in cosmetics (2021)	Plant (animal) ingredients under this list are banned (109)
4. Restricted substances in cosmetics (2021)	The use of the ingredients in this catalogue must meet the corresponding restriction requirements, such as the application scope, the maximum allowable concentration in cosmetics, impurities, the users, and the labeling requirements (47)
5. Preservatives allowed in cosmetics (2015)	Ingredients in this list are allowed for cosmetic use, but certain restrictions are applied (51)
6. Sunscreen agents allowed in cosmetics	See above (27)
7. Colorants allowed in cosmetics (2015)	See above (157)
8. Hair dyes allowed in cosmetics (2015)	See above (75)



# Key Components

# Managing Authorities



National Medical Products Administration (NMPA)

Cosmetic production, submission, and post-registration supervision

Provincial Medical Products Administration (MPA)

record filling of normal products and post-registration supervision

Administration for Industry and Commerce (SAIC)

Trademark application and advertisement supervision

Entry-Exit Inspection and Quarantine (CIQ)

Import and Export inspection

Administration of Quality Supervision, Inspection and Quarantine

Cosmetic label evaluation

# Key Definitions

Products with hair growth, breast enhancement or bodybuilding categories are not cosmetic

- **Cosmetic:**

Daily chemical industrial products, for the purpose of cleaning, protecting, beautifying and modifying, applied to human body surfaces such as skin, hair, nails, lips, etc. by rubbing, spraying or other similar methods.

- **cosmetic ingredients :**

Ingredients used in cosmetic formulation. According to the using history in China, it can be classified into

- Existing Ingredients: Included in IECIC (2021 edition), or
- New Ingredients: Ingredients, natural or artificial, for the first time, used in cosmetic products in China

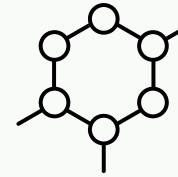
# Key Terms

Ingredients	Existing Ingredients		Included in IECIC	Ingredient submission
	New Ingredient	High risk Ingredients	Antiseptic, sunscreen, coloring, hair dyeing, freckle removal and whitening	Registration
		Low risk Ingredients	Those left	Record filling
End products	Special Cosmetics		hair coloring, perming, freckle whitening, sun protection, anti-hair loss, etc.	Registration
	Normal Cosmetics		Those left	Record filing

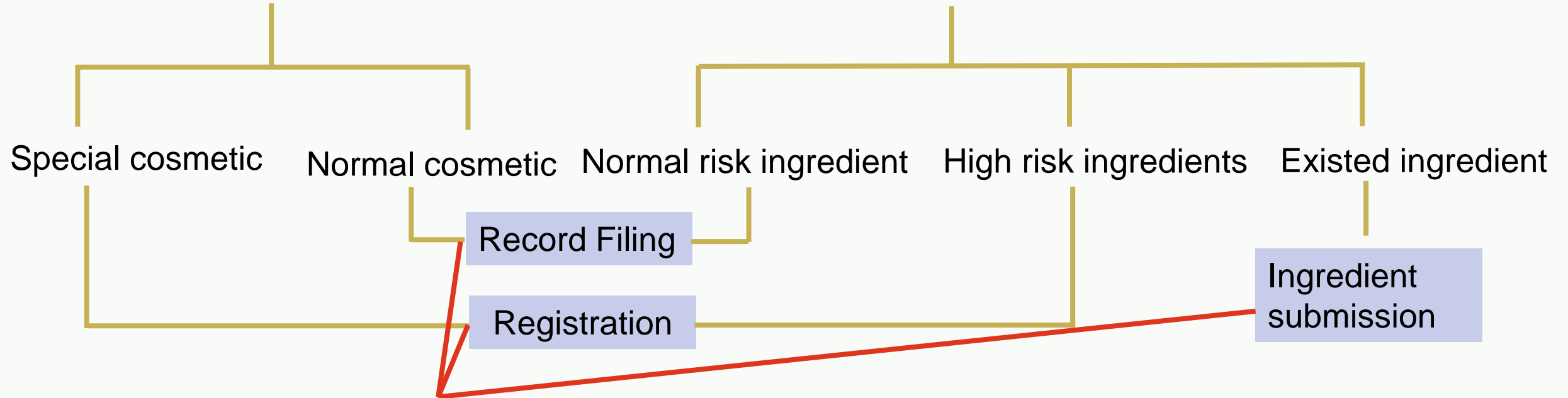
# Categories & Submission Types



## Cosmetic



## Raw Ingredients



Three Registration Types  
under NMPA Order No.792

# Submission body



Chinese producers  
Importers



Foreign cosmetic product  
manufactures

Offline:  
Chinese agent

Online via T-  
MALL, JD,  
Amazon etc.:  
Platform rules



Foreign raw ingredients  
manufactures

Limited to ingredient  
submission codes only

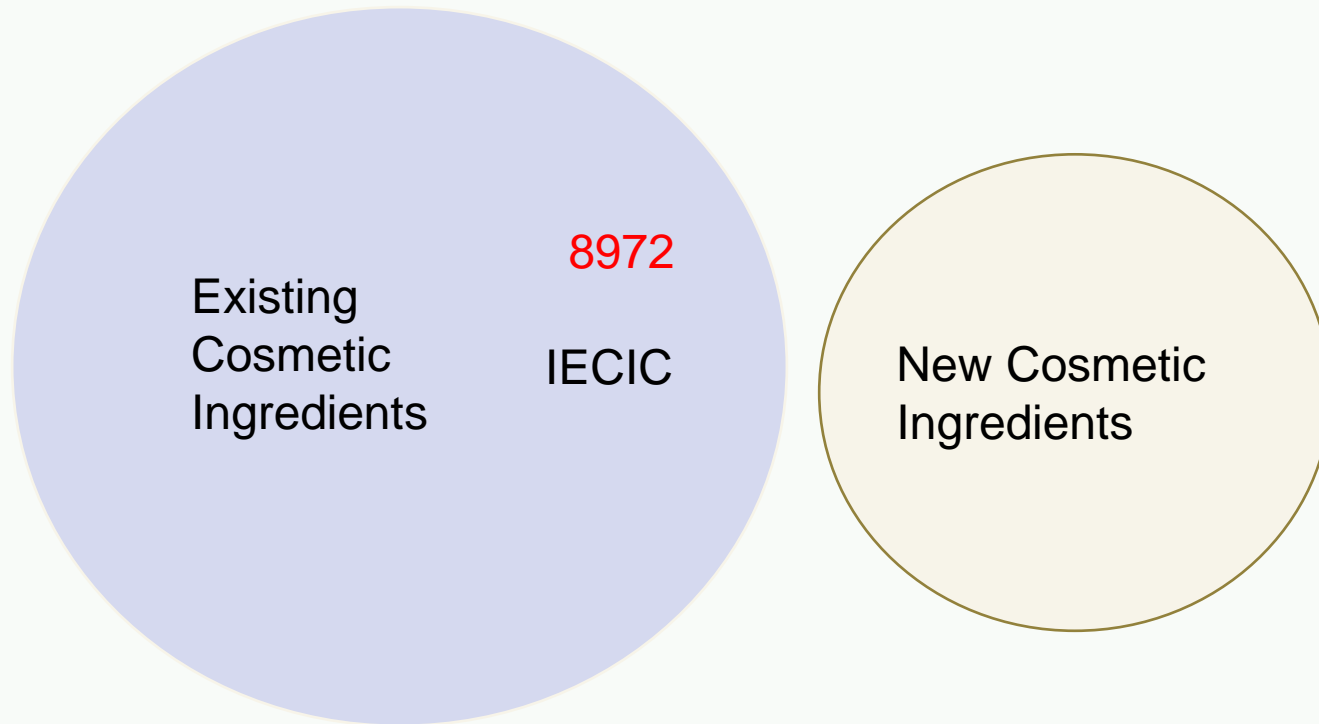
## Qualification for being an Agent:

- Registered in China
- Compatible quality management system
- Able to monitor cosmetic risk and evaluate it



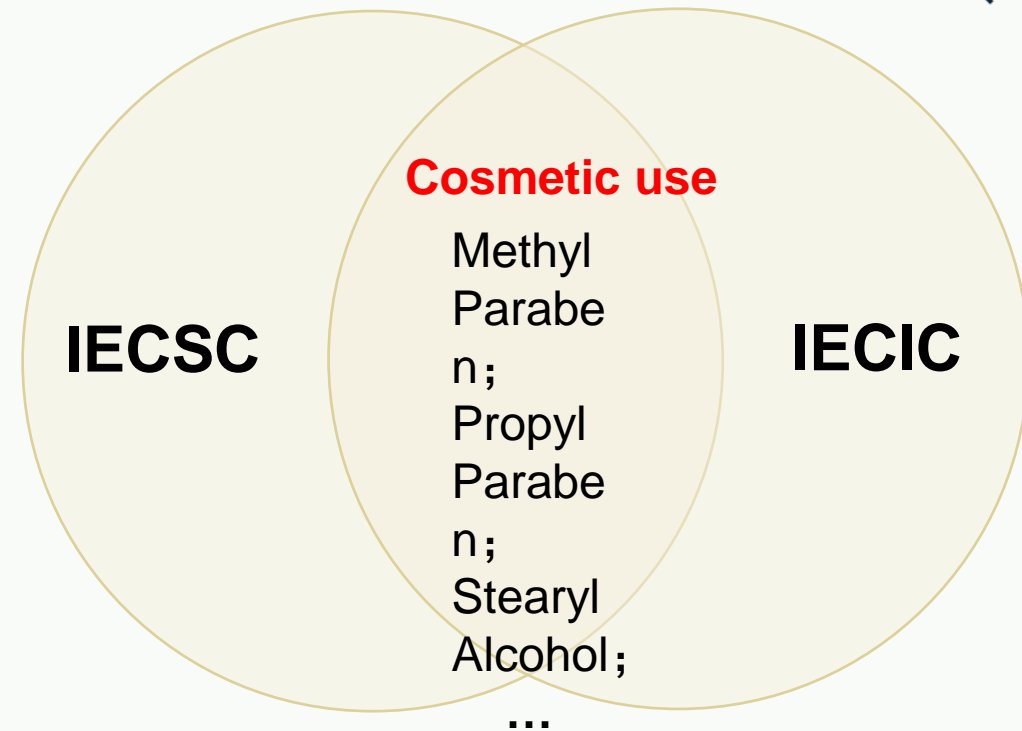
# IECIC

## IECIC: Inventory of Existing Cosmetic Ingredients in China (2021)

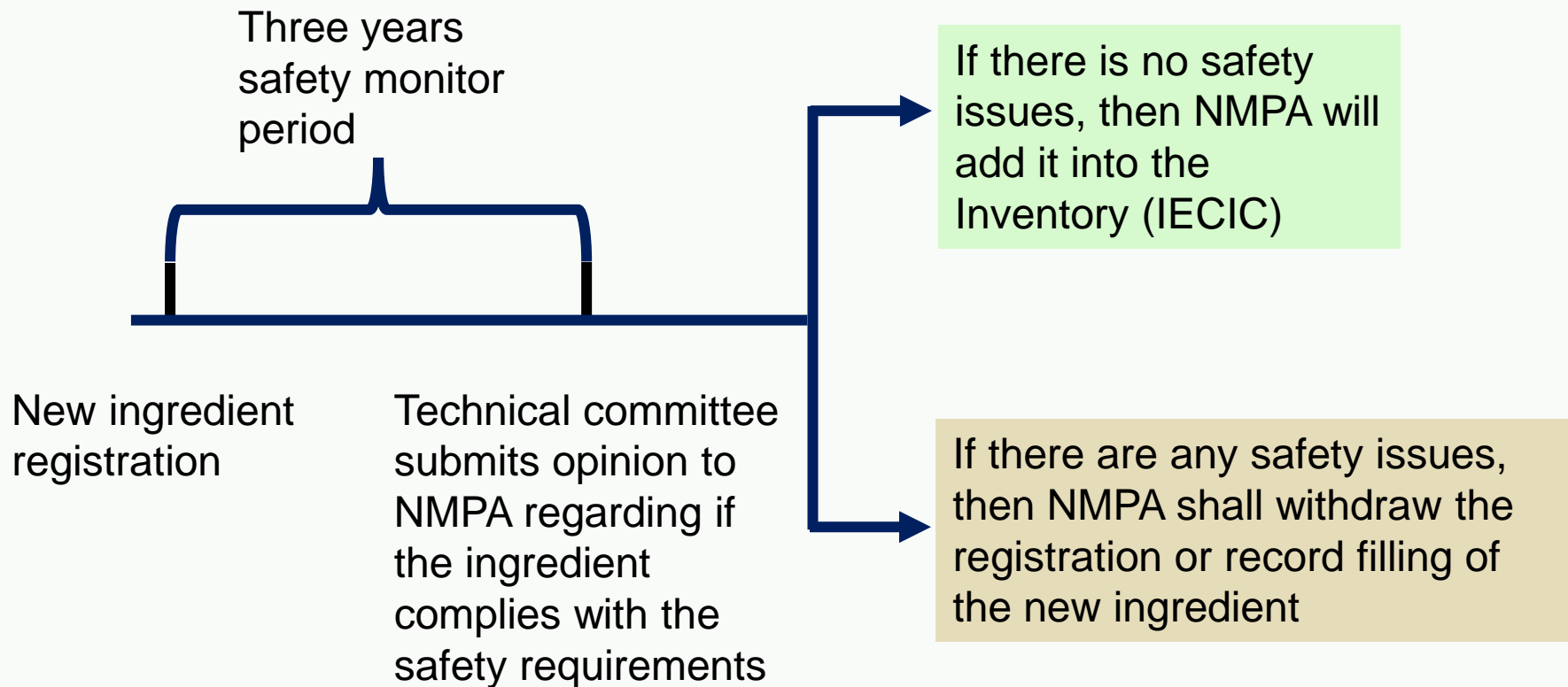


# Link with REACH Compliance

- **IECSC** (Chemical) – Inventory of **Existing Chemical Substances** Produced or Imported in China
- **IECIC** (Cosmetic Ingredients) – Inventory of Existing **Cosmetic Ingredients** Produced or Imported in China



# IECIC Inclusion (cosmetic Ingredients inventory)



# Certificate Management

For cosmetic certificate, valid for 5 years, possible to extend, except:

- Not apply for extension within certain period – 30 days
- Relevant national mandatory standards and technical requirements are modified, while the cosmetic can't meet the requirement

# Online Digital Certificate

## From October 1, 2022:

- Special cosmetic products which are registered after Oct.1, digital certificates will be granted. Paper-based certificates which were granted before, it will be valid within the validation period. But it won't be renewed.
- Special cosmetic products certificate which are allowed to change under Measures for Cosmetic Registration and Notification, the registrants shall return the paper-based certificates to NMPA according to CSAR requirements.

Additionally, this notification specifies the way and place for picking up the digital certificates. Once the digital certificates are prepared, it will be uploaded to the registrants' NMPA accounts. Registrants can pick up it by log into NMPA online service center. The digital certificates can be used in many forms, including certificate authorization, scan to check, online verification, online sharing etc.



# Post-registration Management

# Legal obligations



## COMPANY

- Make sure the reality of their documents and tests
- Recall
- Update information in a timely manner
- Annual report



## Agent

- Register and file submission
- Assist registrants to do post-registration work (ie. safety monitoring plan, annual report)
- Recall products
- undertake corresponding safety and quality responsibilities of new cosmetic ingredients placed in the Chinese market;
- Cooperate with the supervision and inspection work of the supervision departments.



# Legal Liabilities

## Civil liability

Compensate for infringement on consumers  
up to 3 times

## Administrative liability

- Confiscation
- Fines
  - Individual -- 3-5 times / 5 years
  - Company -- 50-100 thousand RMB or 15-30 times
- Recall → up to 500 thousand / 5 years

## Criminal liability

Very serious situation, directly apply the part of market economy management part of criminal law

For foreign registers who didn't respect the punishments, the restriction time can be **up to 10 years**



# Toothpaste Regulation

# Toothpaste Regulation

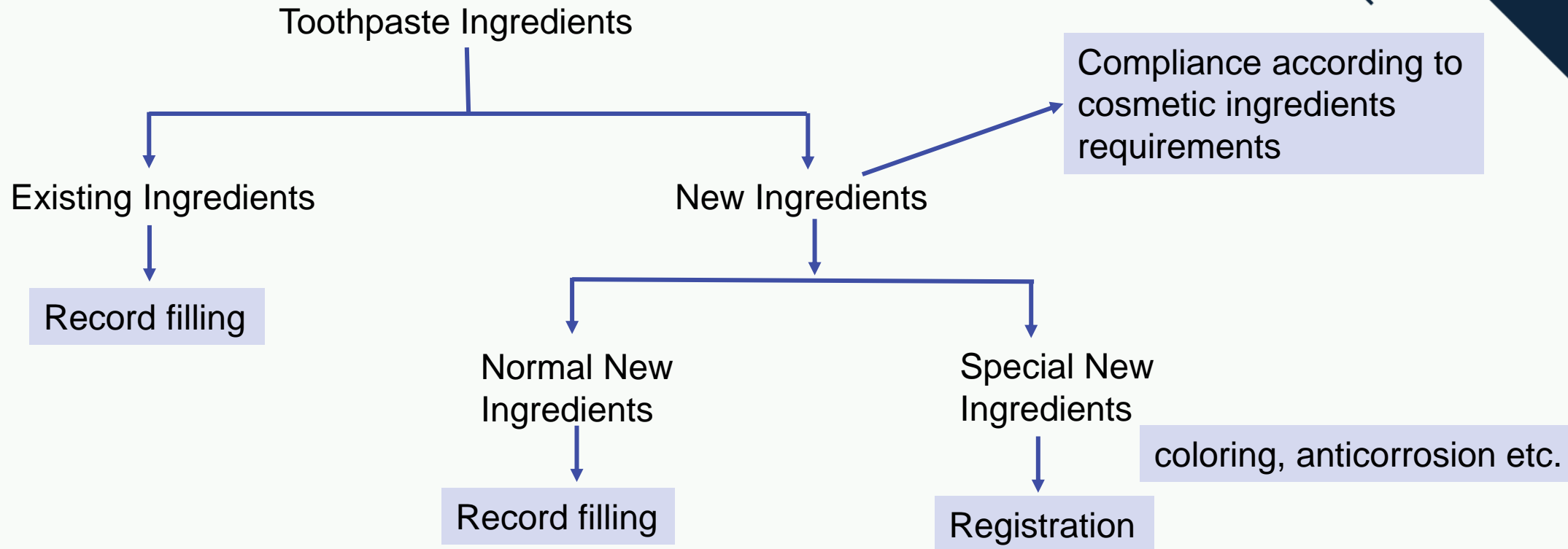
Under CSAR, toothpaste was managed according to normal cosmetic products. 16<sup>th</sup> March 2023, State Administration for Market Regulation announced “**Toothpaste Supervision and Management Measures**” which will be enforced from 1 Dec. 2023.

- **Definition:** A paste-like product which is applied to the surface of human teeth by friction for the main purpose of cleaning.
- **Authority:** National Medical Product Administration (NMPA)
- **Scope of application:** Toothpaste manufacturing and sales activities in China
- **Toothpaste inventory:** All ingredients which are used in toothpaste products sold in China before 31 July 2020

**Not according to cosmetic ingredients inventory IECIC**

- **Children toothpaste:** According to children cosmetic regulation

# Toothpaste Ingredients



# Required documents for record filling

- Record filler's name, address and contact
- manufacturer's name, address and contact
- Product name
- Product formula
- Standard
- Sample draft of label
- Test reports
- Safety evaluation report

For **imported toothpaste**, proof of sales in the production country should be provided. If it is design for Chinese market only, then research and experimental for Chinese consumers shall be provided

# Efficacy Claim

- Reference materials, research data or abstract of efficacy claim shall be published on record filling platform.
- According to the consideration of efficacy claim and target users of toothpaste, NMPA will make toothpaste categories.

# Label requirements

- Product name
- Applicants (agents) name and address
- Manufactures name and address, certificate number (Chinese manufactures)
- Standard
- All ingredients
- Net weight
- Usage period
- Warning sentences



# Naming rules and registration no.

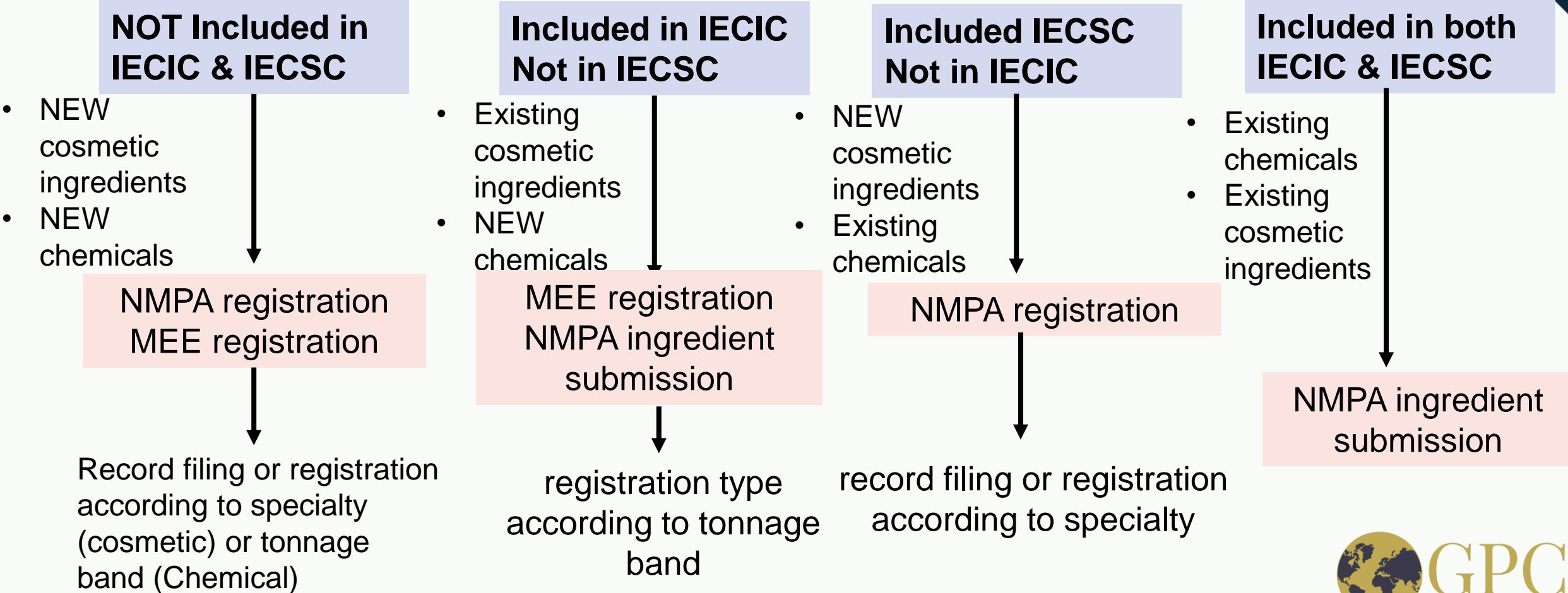
- Naming rules: Trade names + generic name + toothpaste
- Registration number:
  - New ingredients: previous record number + year + this year's ingredient's serial number
  - Chinese toothpaste: simplified name of registration place + net record number + year + ordinal number
  - overseas toothpaste: code of agent's place + year + ordinal number

# Transition period

In general, there are 5 years transition period for those which was registered before

New product registration and filing application	
Since 1st Apr 2021	ID application
Since 1st May 2021	<ul style="list-style-type: none"><li>• New application for the registration and filing of new cosmetics ingredients through the new online info service platform available</li><li>• Fill in the source and trade name of raw materials of product formula;</li></ul>
Since 1st Jan 2024	<ul style="list-style-type: none"><li>• Safety-related info need to be provided for special raw material registration</li></ul>
Since 1st Jan 2024	<ul style="list-style-type: none"><li>• The quality and safety info of <b>all raw materials</b> need to be provided</li></ul>
<u>Before 1st Jan 2024 • Supplement to provide the quality and safety info of all ingredients in the formula</u>	

# Summary: Registration Obligations





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The banner features a photograph of several people in business attire sitting around a table, focused on their work. The GPC logo is visible in the top right corner. A dark blue banner at the bottom contains the event title and dates in white and yellow text.

**Masterclass on BIS Certification: Preparation and Submission**

**April 12**  
12:30 – 13:30 CEST  
16:00 – 17:00 IST

Masterclass on BIS Certification: Preparation and Submission

APRIL 12 12:30 – 13:30 CEST / 16:00 – 17:00 IST



The banner has a blue background with the GPC logo in the top left. In the center, three wooden blocks spell out 'Q AND A', with a question mark on the 'A' block. A dark blue banner at the bottom contains the event title and dates in white and yellow text.

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APRIL 14 12:30 – 13:30 CEST / 16:00 – 17:00 IST



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