

All you need to know about exporting cosmetic to China



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Introduction

1. General introduction
2. Compliance procedures
3. Compliance aspects
4. Assessment and tests
5. Children cosmetics

Legislation History

Governing Regulation: Cosmetic Supervision and Administration Rules (CSAR)

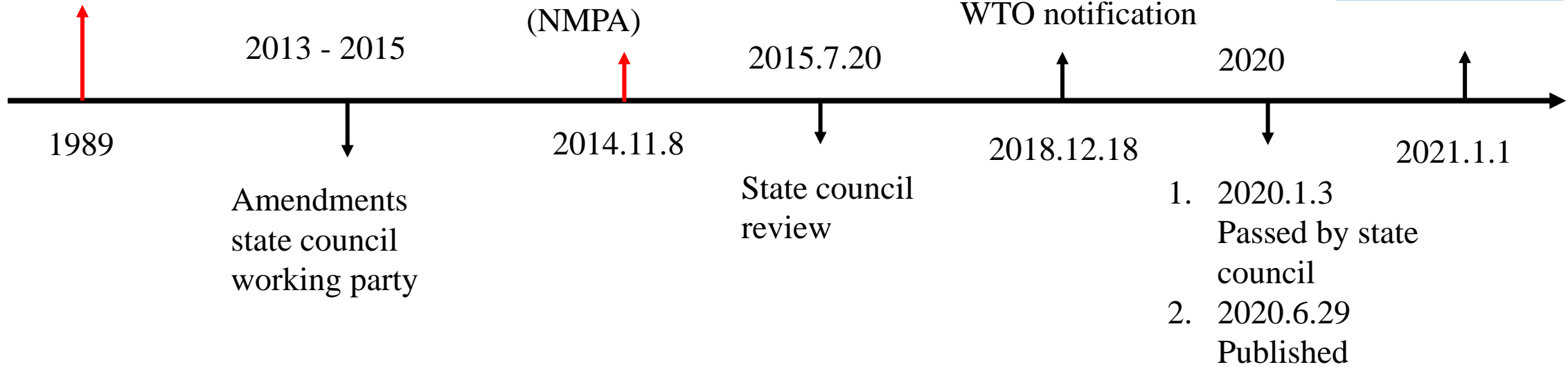
Managing Department: National Medical Products Administration (NMPA)

Cosmetics Hygiene
Supervision
Regulations

(Ministry of health)

Cosmetic Supervision
and Administration
Rules – 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

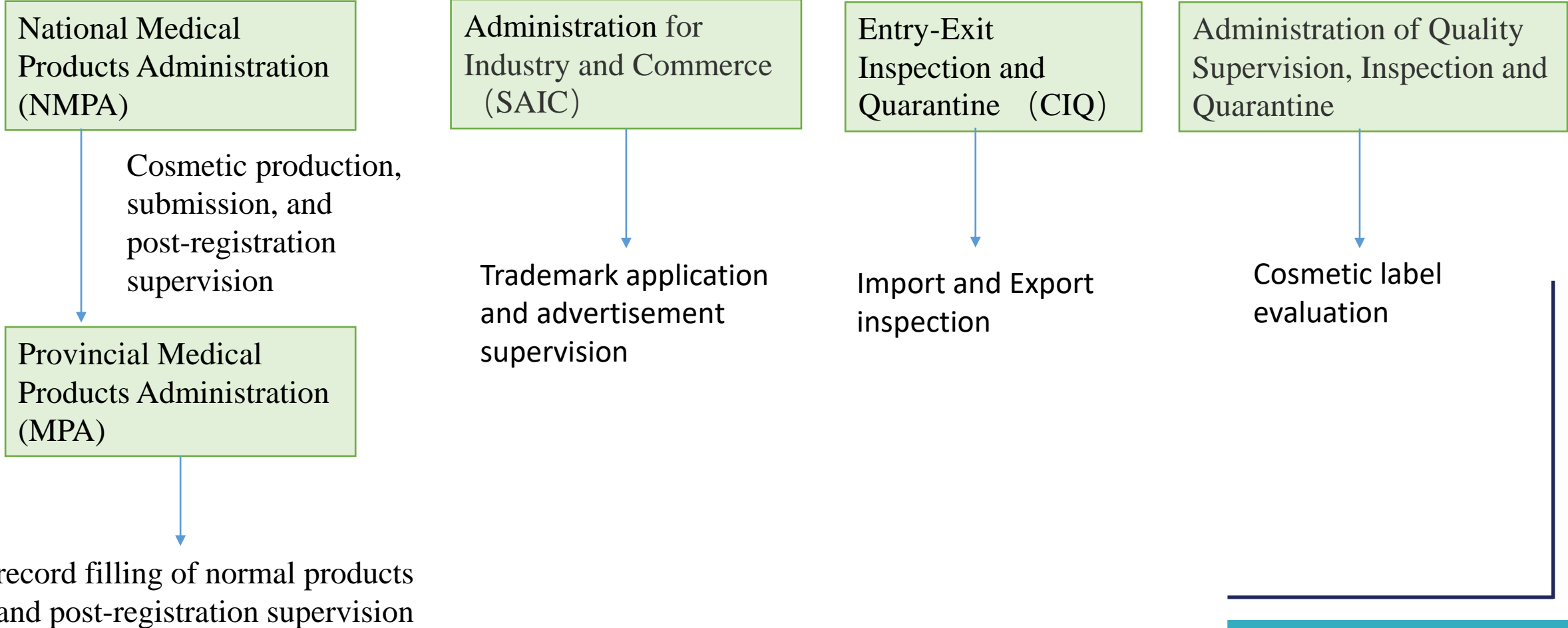
Chapter 3 – production and operation

Chapter 4 – supervision and administration

Chapter 5 – legal responsibilities

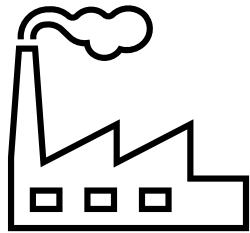
Chapter 6 – supplementary provisions (toothpaste and transition period)

Regulatory bodies

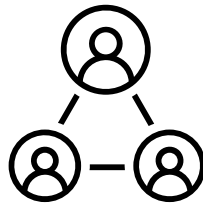


Who should register

- **Offline modes:** Companies who produce cosmetic products in China or Companies who intend to export cosmetic products to China.
- **Online modes:** Companies who intend to sell cosmetic products via online cross-border e-commerce such as TMALL, JD, etc.,



Manufacturer



Agent

Acting as a domestic responsible person:

- Submission
- Adverse reaction monitoring
- Recall whenever required
- Quality and safety responsibility
- ...

Important Lists

Lists	Definition
1. Safety and Technical Standards	Limit / forbidden components, test requirements, human safety test
2. IECIC	Cosmetic ingredient inventory (8972)
3. Banned ingredients in cosmetics	Ingredients under this list are banned for cosmetic use (1284)
4. Banned plant (animal) ingredients in cosmetics	Plant (animal) ingredients under this list are banned (109)
5. Restricted substances in cosmetics	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)
6. Preservatives allowed in cosmetics	Ingredients in this list are allowed for cosmetic use, but certain restrictions are applied (51)
7. Sunscreen agents allowed in cosmetics	See above (27)
8. Colorants allowed in cosmetics	See above (157)
9. Hair dyes allowed in cosmetics	See above (75)

Compliance Procedures

1. Cosmetic product classification
2. Record filling
3. Registration

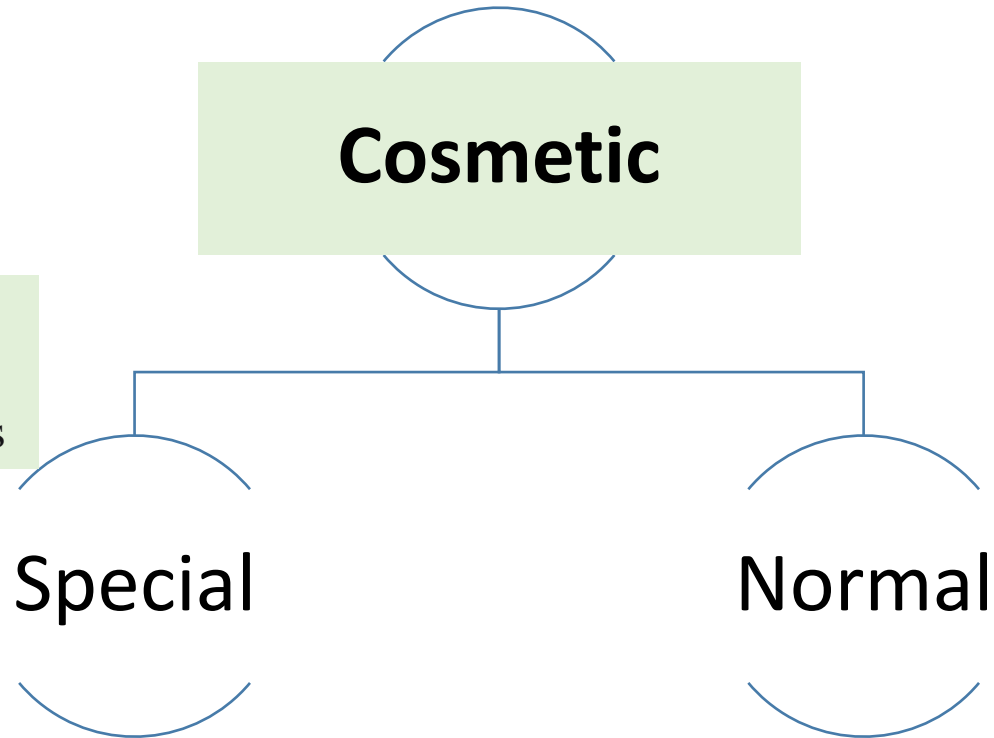
Classification

Definition of cosmetic:

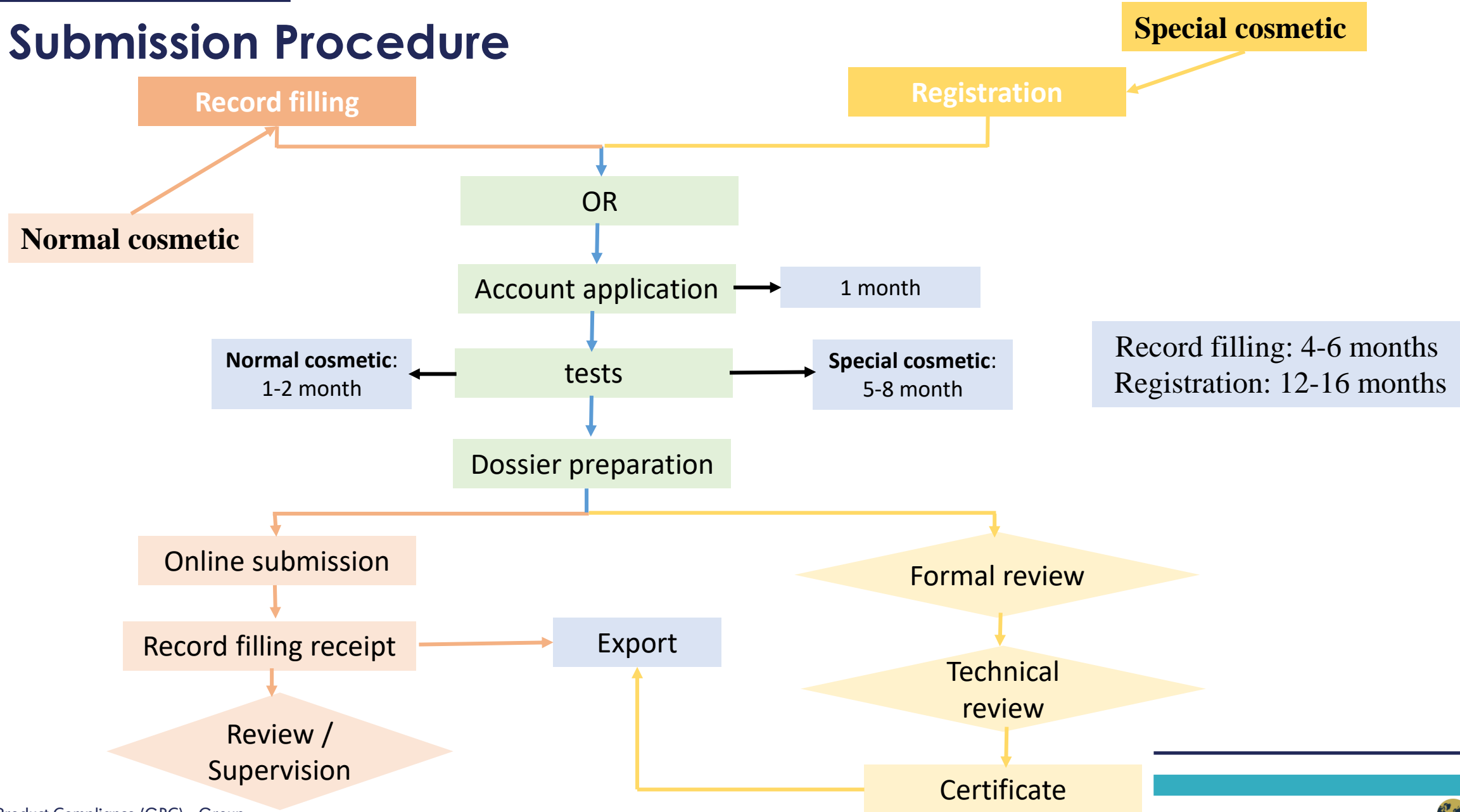
Daily chemical industrial products, for the purpose of cleaning, protecting, beautifying and modifying, applied to human body surfaces such as skin, hair, nails, lips, etc. by rubbing, spraying or other similar methods.

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

anti-freckle/whitening, sunscreen, hair dye, hair perm, anti-hair loss and new efficacies



Submission Procedure



Submission Dossier

The following documents need to be provided for doing cosmetic product record filling or registration:

1. Cosmetic registration / record filling information sheet and related documents
2. Product name
3. Product formula (Ingredient submission code)
4. Product executive standards
5. Product label sample manuscript
6. Product testing report
7. Product safety assessment documents

☆ *Imported cosmetics are required to submit certifications relating to manufacturing quality control of the overseas manufacturers.*

☆ *For products specially produced for the China market without the supporting documents, the applicant shall submit relevant research and test data for Chinese consumers.*

Summary for Registration and Record Filing

	Special Cosmetic	Normal Cosmetic
Pre-market	Registration	Record filing
Submission Body	Register (domestic) OR (abroad)	Record Filler (domestic) OR (abroad)
Assessment Agency	NMPA (domestic or abroad)	NMPA / MPA (abroad) Municipal MPA (domestic)
After Market	Certificate valid for 5 years	Annual report

Main Contents in Annual Report

- 1) Basic info and production of new cosmetic ingredient;
- 2) Information on cosmetic registrants, filers or entrusted manufacturers who use new raw materials to produce cosmetics
- 3) Information on cosmetics using new raw materials, including product name, product registration or filing number, number of products produced or imported, sold, etc.
- 4) Sampling inspection, investigation and recall of cosmetics produced with new raw materials.
- 5) The adverse reaction monitoring system, statistical analysis of adverse reactions and measures of cosmetics produced with new cosmetic ingredients for cosmetics manufacturers.
- 6) Risk monitoring and evaluation management system and measures of cosmetics produced with new cosmetic ingredients for cosmetics manufacturers

Compliance Aspects

1. Formula
2. Labelling
3. Packaging
4. Product certificate

Formula

Content of Formula

- Ingredient Name → Chinese / English / INCI
- Content range (%) → descending order
- Purpose of use → each ingredient. If special ingredients (anti-freckle and whitening, sunscreen, hair dye, perm, anti-hair loss), functional components must be marked
- Existed ingredients → Information sheet or ingredient code must be filled in
- New ingredients → permission from registrants or record filler
- Others → If denatured ethanol is used, the name and dosage of the denaturant should be stated; if the raw material of the category is used, the specific name of the raw material should be stated; if it is directly derived from a plant, the specific part of the original plant should be stated.

Standard Chinese name

Ingredients content range

Purpose of use

序号	标准中文名称	INCI 名称/英文名称	原料含量 (%)	复配百分比 (%)	实际成分含量 (%)	使用目的

二、配方表附件式样

序号	标准中文名称	生产商	原料报送码

填报说明：配方表中成分含量、实际成分含量的有效数字位数原则上不得超过

五位有效数字，应当按“四舍六入五成双”的原则进行修约。

Labelling

Print or stick is fine



不管是哪个版本，都有进口中文标贴
 标贴上的日期会随着不同的进批次而不断更新哦



除了中文标贴上的日期，瓶底下方也会有钢印的日期。
 如：LOT 34012 12/14，
 LOT表示截止日期，34012是厂家代码，12/14是月、年，
 那这个代码的意思就是保质到2014年12月

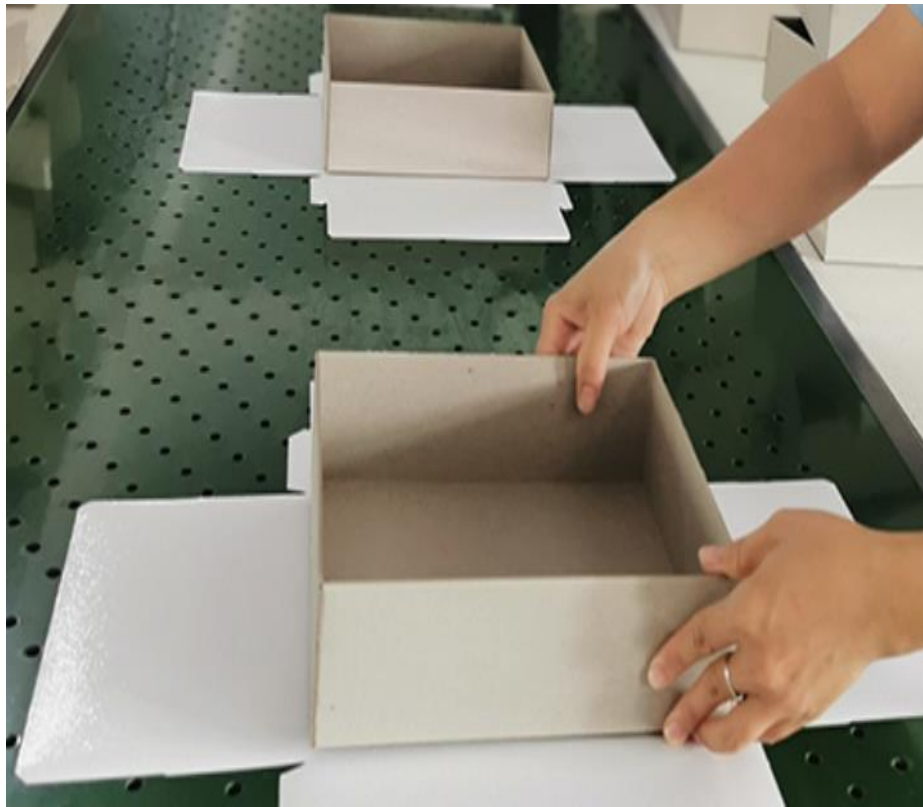
Content:

- Product name and registration number
- Names and addresses of registrant, record filler, authorized producer
- Production license number
- Standard number performs by the cosmetic
- Net weight
- Period of use, method of use and necessary safety warnings
- Composition sheet

But there shouldn't be:

- (1) content that expresses or implies that it has a medical effect;
- (2) false or misleading content;

Packaging



《Restriction of Excessive Packaging Requirements - Food and Cosmetics》 (GB 23350-2009)

- Porosity \leq 50%
- Cost \leq 20%
- Layers \leq 3 layers

Product certificate

Product Name

Registrants

Registration number:

J+4 year number + 4 serial number

Registration number

中华人民共和国

The People's Republic of China

进口特殊化妆品产品注册证

产品名称	中文	
	英文	
产品类别		
注册人	中文	
	英文	
地址	Country of origin	
生产国(地区)		地址
境内责任人	名称	
	地址	
审批结论	经审核, 该产品符合《化妆品监督管理条例》的有关规定, 现予批准。	
批准文号	Registration number	
批准日期	年月日	Valid period
批件有效期	截至 年 月 日	
备注		

国家药品监督管理局

(签章) (编号)

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.

Assessments and Tests

1. Safety assessment
2. Efficacy assessment
3. Tests

Safety Assessment

Legal basis: Cosmetic Safety and Technical Guidelines (2021 edition, enforced since May 2021)

Definition: Using toxicology tests results to evaluate the safeness of cosmetic product. It can be used as an alternative method to animal tests.

Scope of application:

- Only applies to normal cosmetic products
- Product safety risk assessment can fully confirm the product safety
- Must obtain relevant qualification certification of the production quality management system issued by government (GMP document)

Forbidden scope:

- The product is claimed to be used by infants and children;
- The product uses new cosmetic raw material that are still under safety monitoring ;
- The filing person, domestic responsible person, and production enterprise are listed as key supervision objects.

Efficacy Assessment

Legal basis: Specification for the Evaluation of Cosmetics Efficacy Claims (enforced since May 2021)

Efficacy assessment methods:

- Literature research, research data
- Cosmetic efficacy claim evaluation test (human efficacy evaluation test, consumer use test, laboratory test)

	Literature Research	Efficacy Claim test
Moisturizing, hair care, specific claims (raw material efficacy)	√	√ (Cosmetic)
Anti-wrinkle, firming, soothing, oil control, exfoliating, anti-hair breakage, anti-dandruff, claiming mildness (such as non-irritating), claiming quantitative indicators (time, statistical data, etc.):	×	√ (Cosmetic) (sometimes can be combined with literature research)
Anti-freckle and whitening, sun protection, hair loss prevention, acne removal, nourishment and repair	×	√ (Human)
Specific claims (claims suitable for sensitive skin, claims tear-free formula)	×	√ (Human / Consumer)
Claiming new efficacy	Select the appropriate evaluation basis according to the specific efficacy claim	

Efficacy Assessment

Exemption from publication of abstracts

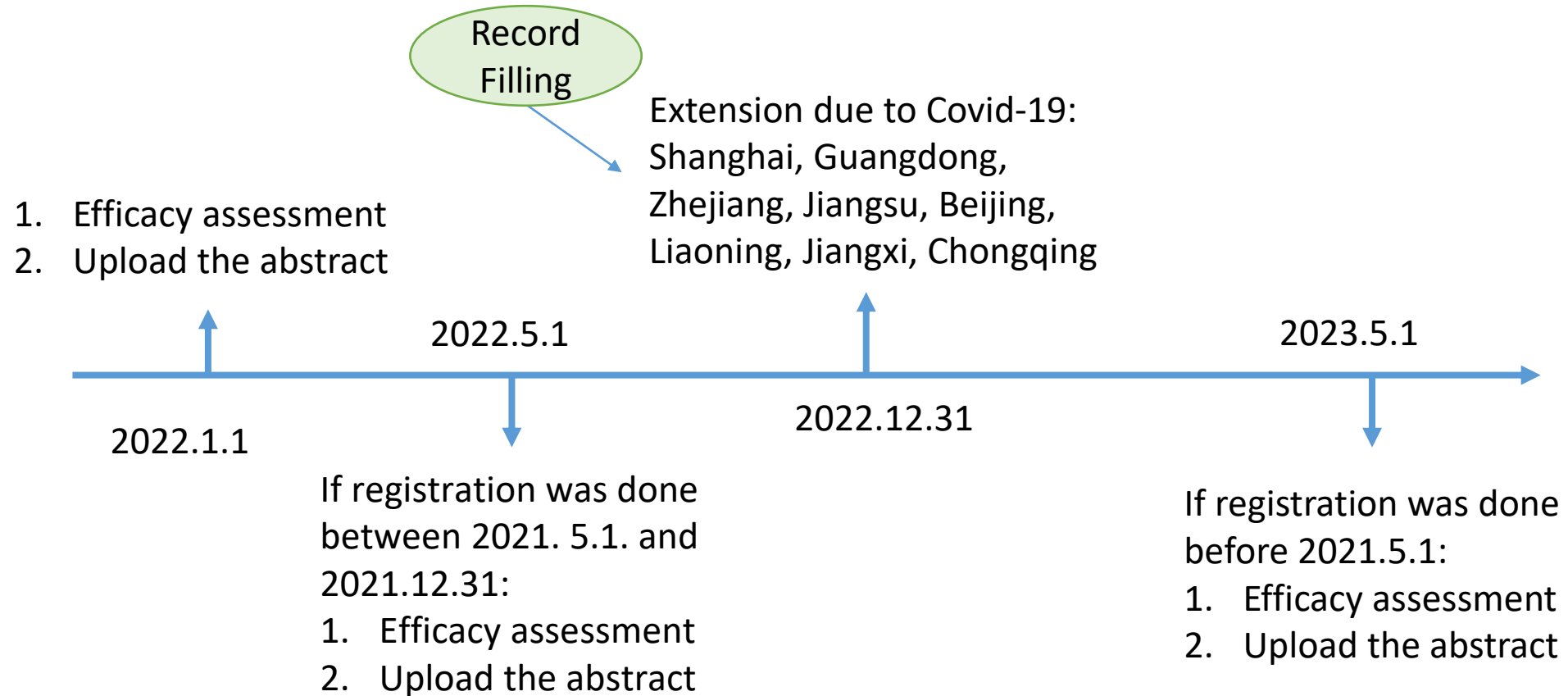
- Those that can be directly identified by sight, smell and other senses (such as cleaning, makeup removal, beauty modification, aroma, body refreshment, hair coloring, perm, hair color care, hair removal, deodorization and assisted shaving, etc.)
- The effect is achieved through simple physical covering, adhesion, friction, etc. (such as physical covering, freckle whitening, physical exfoliation, and physical removal of blackheads, etc.), and the effect claims that only have physical effects are clearly marked on the label.

Obligations after publication of abstracts:

data archiving and preservation for future reference

- Cosmetic efficacy claim basis data (to be translated into Chinese) and abstract
- Consistency certification materials (the product formula for the efficacy evaluation test is consistent with the registration record)

Important Deadlines for Efficacy Assessment



Tests to be taken for product inspect report

Legal basis: 《Technical guidelines》 (2021), 《Cosmetics registration and filing inspection work specification》

Content:

- Microbial experiment
- Physical and chemical experiments
- Toxicology test →
- Human safety test (for special cosmetics)
- Human efficacy test report, etc.

Exemption:

1. Normal cosmetics with relevant qualification certification of the production quality management system
2. The product safety risk assessment results can fully confirm the product safety.

Mandatory toxicological test → the same as the forbidden scope of safety assessment

1. The product is claimed to be used by infants and children
2. The product uses new cosmetic raw materials that are still under safety monitoring
3. According to the quantitative grading and scoring results, the filing person, domestic responsible person, and production enterprise are listed as key supervision objects

Regulations on the Supervision and Administration of Children's Cosmetics

Time: passed 2021.9.30, enforced 2022.1.1

Definition: Refers to cosmetics that are suitable for children under the age of 12 and have the functions of cleaning, moisturizing, cooling and sun protection.

Label requirement:

The label must be at least 1cm wide if the outer surface area of the product is smaller than 100cm², while if it is larger, then the label must be at least 2cm wide.

Formula requirements:

1. Long-term safety usage history ingredients. Not allowed to use **New Ingredient and ingredients generated by new technologies such as Genetic Technology and Nanotechnology**
(If there is no alternative ingredients, safety report must be provided)
2. Not allowed to use Ingredients for the purpose of freckle whitening, acne removal, hair removal, deodorization, dandruff removal, hair loss prevention, hair coloring, perming, etc.
3. Limit to use ingredients such as flavors, colorants, preservatives and surfactants



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