

# China Cosmetic Ingredient Compliance under CSAR

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**REACH24H**



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China new cosmetic ingredient  
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# NCI VS Submission code

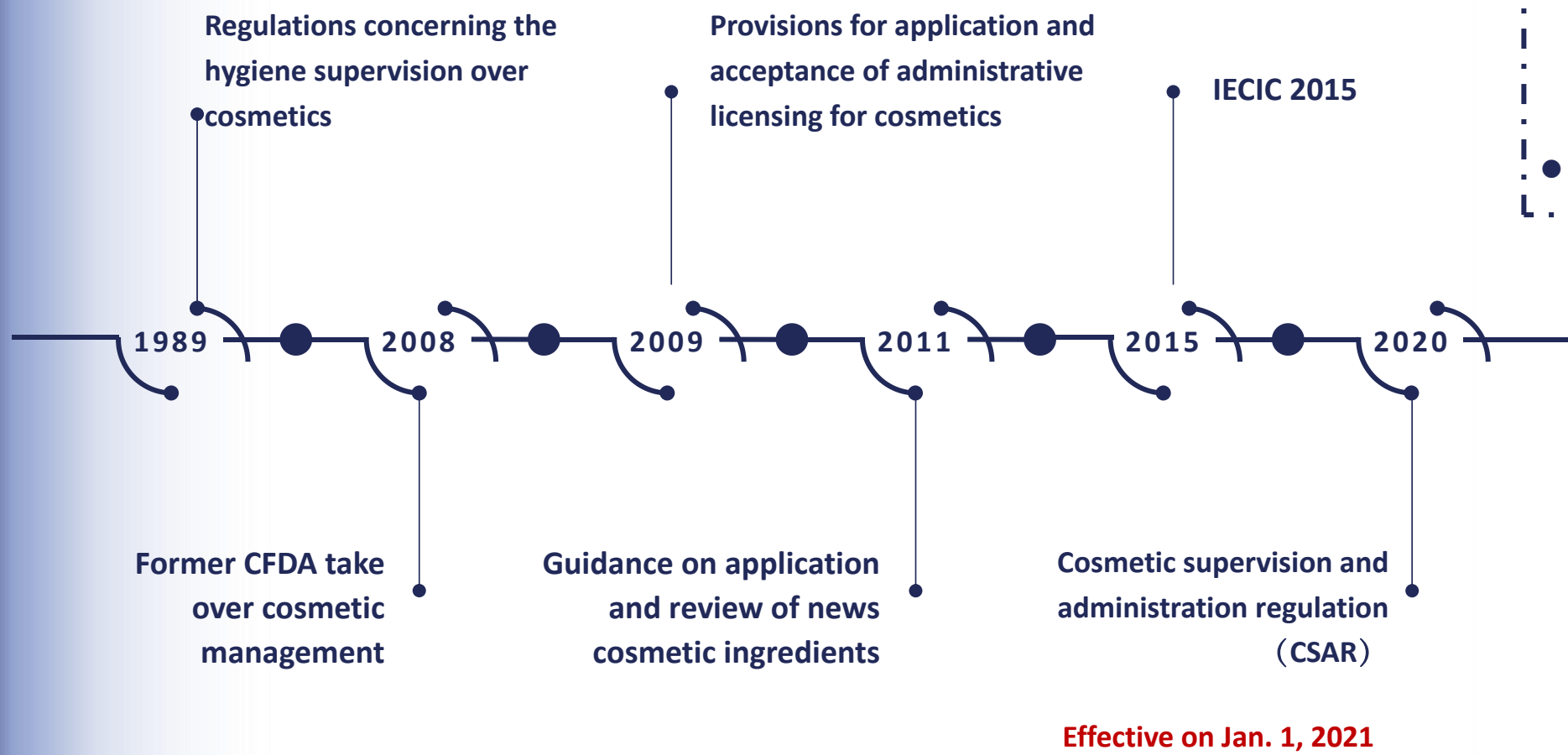
Difference	China New Cosmetic Ingredient (NCI)	China Cosmetic Ingredient Submission Code
Applicable scope	Only for ingredients which are <b>NOT listed in IECIC *</b>	For ingredients which are <b>listed in IECIC *</b>
Applicant	Who want to use NCI Who can take the main responsibility of ingredient safety	Ingredient manufacturer
Purpose	Get the approval to Chinese market	Get the code, deliver it to cosmetics companies instead of full information disclosure

\* IECIC: Inventory of Existing Cosmetic Ingredients in China

# Part A

**China new cosmetic ingredient  
registration and notification**

# Legislation progress



- Effective on May 1, 2021**
- Provisions for management of new cosmetic ingredient registration and notification dossiers
  - IECIC 2021



- Publicized NCIs:**
- **6 ingredients in 2021**
  - **11 ingredients in 2022, May**

# Legislation progress

## Regulations concerning the

## Provisions for application and

序号	标准中文名称	备案号
1	β-丙氨酸羟脯氨酸二氨基丁酸苯...	国妆原备字20210003
2	月桂酰甲基羟乙基磺酸钠	国妆原备字20210006
3	四氟丙烯	国妆原备字20210005
4	雪莲培养物	国妆原备字20210004
5	月桂酰丙氨酸	国妆原备字20210002
6	N-乙酰神经氨酸	国妆原备字20210001

management

cosmetic ingredients

序号	标准中文名称	备案号
1	水解透明质酸锌	国妆原备字20220008
2	双-鲸蜡硬脂基氨基端聚二甲基硅氧...	国妆原备字20220005
3	β-烟酰胺单核苷酸	国妆原备字20220007
4	聚甲基倍半硅氧烷/三甲基硅烷氧...	国妆原备字20220003
5	β-烟酰胺单核苷酸	国妆原备字20220002
6	鲸蜡基二甘油三(三甲基硅氧基)...	国妆原备字20220001
7	β-烟酰胺单核苷酸	国妆原备字20220009
8	红藜 (Chenopodium ...)	国妆原备字20220006
9	铁皮石斛原球茎	国妆原备字20220010
10	丙烯酰基二甲基牛磺酸钠/VP ...	国妆原备字20220004
11	N-乙酰神经氨酸	国妆原备字20220011

(CSAR)

Effective on Jan. 1, 2021

Effective on May 1, 2021

- Provisions for management of new cosmetic ingredient registration and notification dossiers
- IECIC 2021



Publicized NCIs:

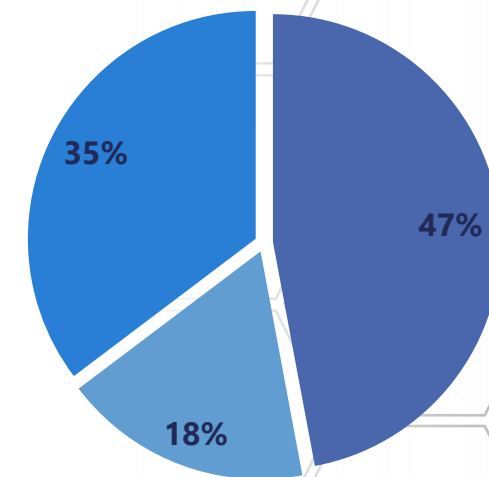
- 6 ingredients in 2021
- 17 ingredients in 2022

## Publicized NCIs (Till the end of May, 2022)

Name	Function
N-乙酰神经氨酸 Acetylneuraminic Acid	HUMECTANT
月桂酰丙氨酸	CLEANSING
β-丙氨酰羟脯氨酰二氨基丁酸苄胺 Beta-Alanyl Hydroxyprolyldiaminobutyroyl Benzylamide	SKIN PROTECTING
雪莲培养物	ANTIOXIDANT
四氟丙烯 Tetrafluoropropene	PROPELLANT
月桂酰甲基羟乙基磺酸钠 Sodium Lauroyl Methyl Isethionate	CLEANSING
鲸蜡基二甘油三(三甲基硅氧基)硅乙基聚二甲基硅氧烷 Cetyl Diglyceryl Tris(trimethylsiloxy)silylethyl Dimethicone	EMULSIFYING
β-烟酰胺单核苷酸 Nicotinamide Mononucleotide	SKIN PROTECTING, HUMECTANT, ANTIOXIDANT
聚甲基倍半硅氧烷/三甲基硅烷氧基硅酸酯 Polymethylsilsesquioxane/Trimethylsiloxysilicate	FILM FORMING
丙烯酸基二甲基牛磺酸钠/VP交联聚合物 Sodium Acryloyldimethyltaurate/VP Crosspolymer	THICKENERS
双-鲸蜡硬脂基氨基端聚二甲基硅氧烷 Bis-Cetearyl Amodimethicone	HAIR CONDITIONING
红藜 (Chenopodium formosanum) 提取物	SKIN PROTECTING
β-烟酰胺单核苷酸 Nicotinamide Mononucleotide	SKIN PROTECTING, HUMECTANT,
水解透明质酸锌 Zinc hydrolyzed hyaluronate	SKIN PROTECTING, HUMECTANT
β-烟酰胺单核苷酸 Nicotinamide Mononucleotide	ANTI-WRINKLE, SKIN PROTECTING, ANTIOXIDANT
铁皮石斛原球茎	ANTI-WRINKLE, HUMECTANT
N-乙酰神经氨酸 Acetylneuraminic Acid	HUMECTANT, ANTI-WRINKLE, SKIN PROTECTING, ANTIOXIDANT

**NUMBER**

■ Edible history ■ Polymer ■ Others

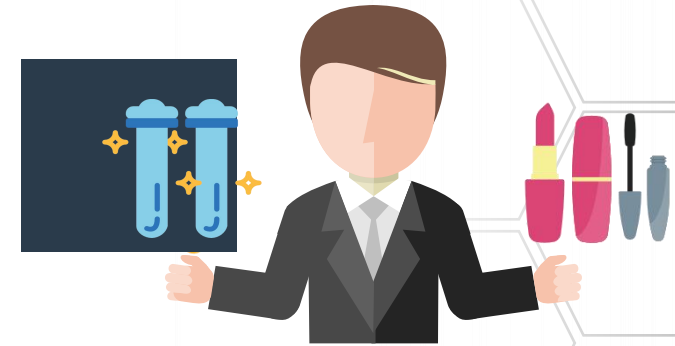


# What is NCI?

## Definition:

Natural or artificial ingredients used for cosmetics for the first time in the ***territory of the People's Republic of China***

- It should be **single source**
- **High risk:** preservative, sunscreen, colorant, hair-dyeing, freckle removing and whitening
- **Medium risk:** anti-hair loss, anti-acne, anti-wrinkle, anti-dandruff, deodorant
- **Low risk:** other efficacy, ingredient not considered as high/medium risk

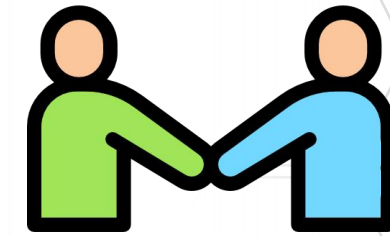




# Who can apply for NCI?

## Registrant/notifier:

- Fulfill the **obligations** in accordance with the law
- Be responsible for the **quality and safety** of NCIs
- Overseas enterprises --> **Domestic responsible (legal) person**

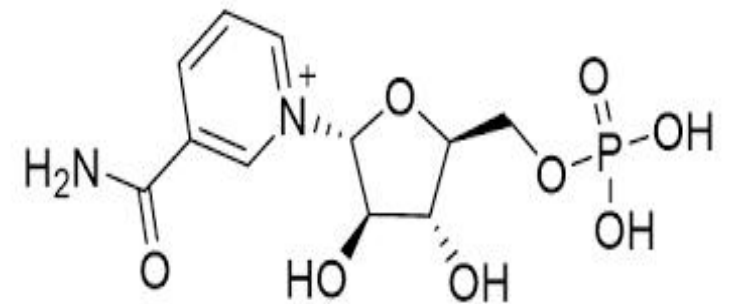


## Rights:

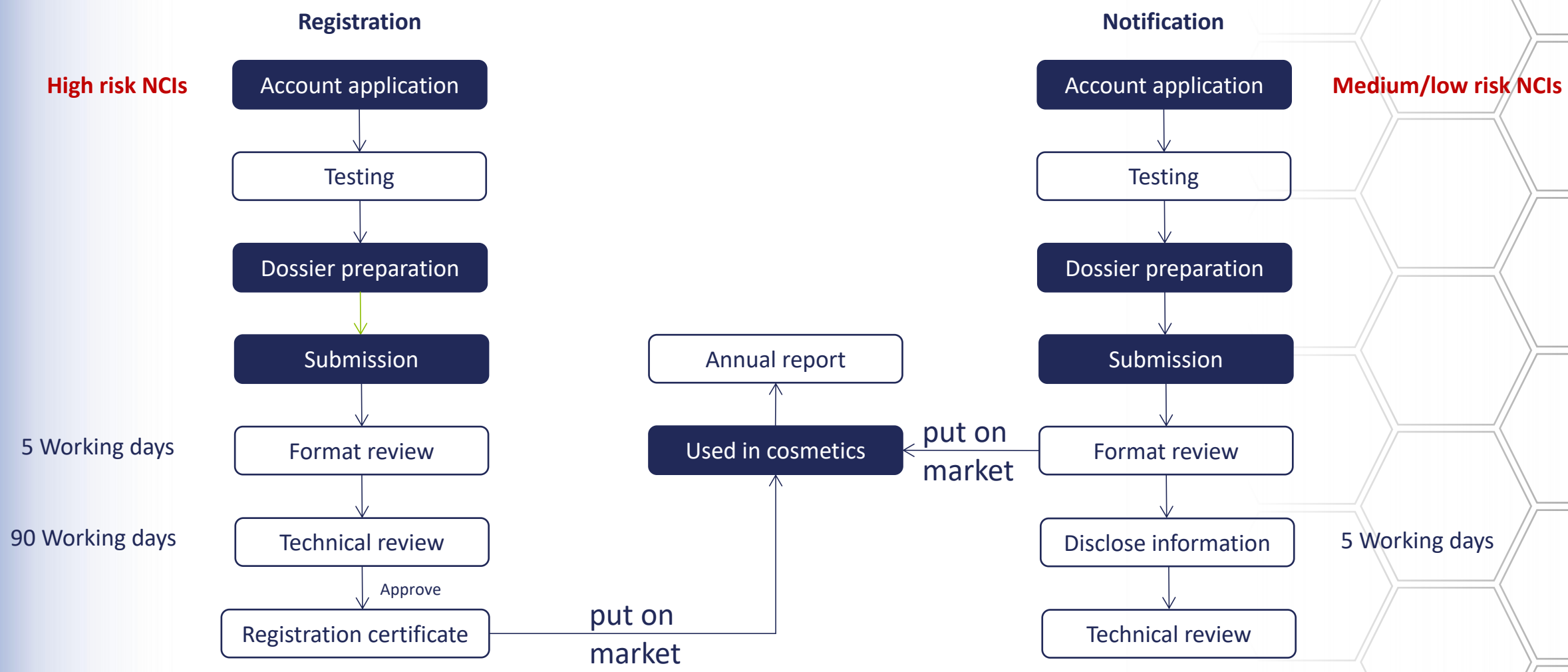
1. Self-use
2. **Authorize** other cosmetic company to produce cosmetics using NCI

## Obligations:

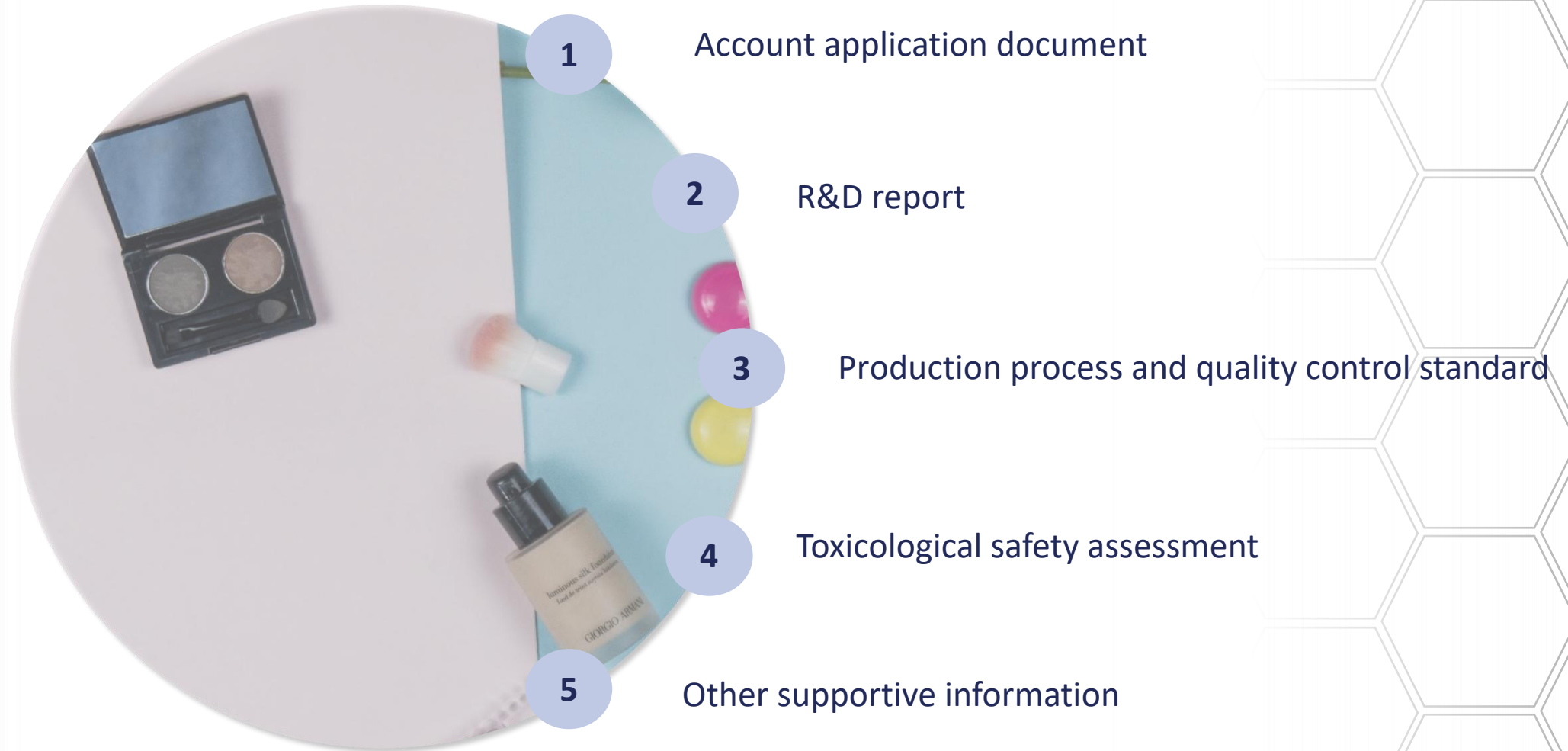
1. Provide data for safety assessment of NCI
2. Responsible for the quality and safety of NCIs
3. Establish a safety risk monitoring and evaluation system



# Application pathway



# Dossier requirement



Please note: after all information was filled in platform, **technical requirement document** will be generated, it will be **Publicized** in NMPA platform when the process is finished.

# Efficacy data

Data type		High/medium risk	Low risk	Remark
Test data	In vitro test	Mandatory	Optional	Priority of standard method*
	In vivo test			
	Human Trial			
Non-test data	Literature	Optional	Optional	Research data
	Regulation			Standard/catalogue/ancient code/book

\* **Safety and Technical Standards for Cosmetics (STSC) 2015** > Pharmacopoeia of the People’s Republic of China > National standards > Internationally accepted methods > Self-developed testing methods

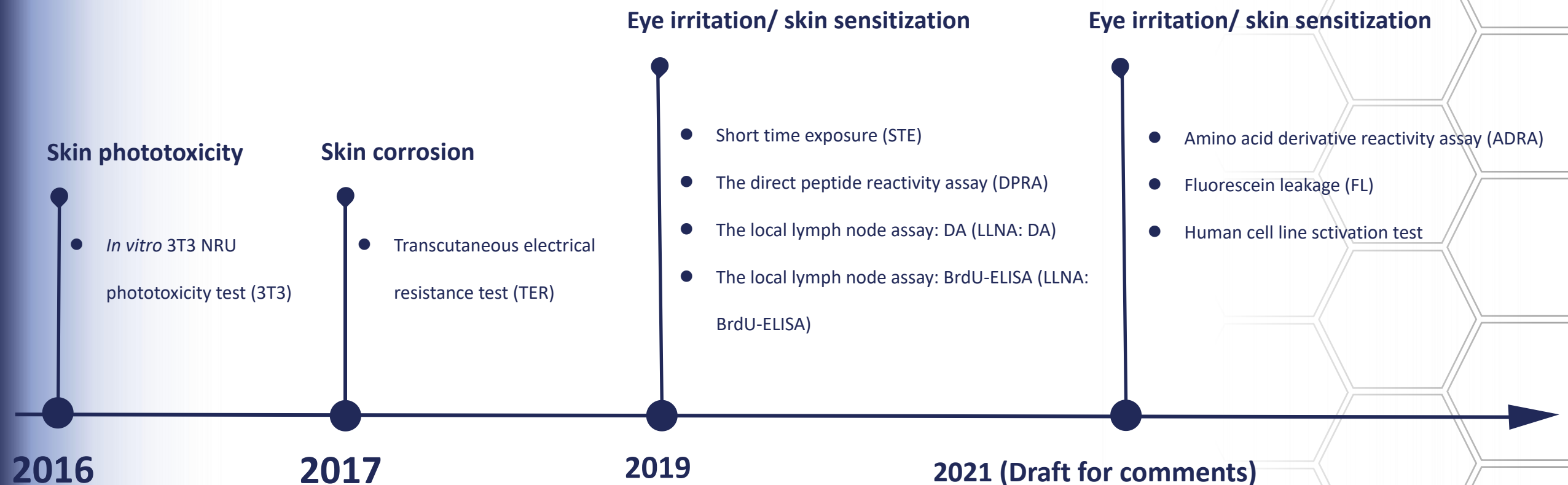
\* For **self-developed testing methods**, the relevant documents on the applicability and reliability of the method shall be submitted at the same time

# Toxicological endpoints

Endpoints	Non-low risk	Low risk	Non-low risk with a history	Low risk with a history	Edible history	Polymers
Acute Oral/Dermal Toxicity	√	√	√	√ (could be conditional exempted)	×	×
Skin and Acute Eye Irritation/Corrosion	√	√	√	√	√	√
Skin Sensitization	√	√	√	√	√	×
Skin Phototoxicity/Photoallergy (could be conditional exempted)	√	√	√	√	√	√ (Photoallergy Test is exempted)
Mutagenicity	√	√	√	√	×	×
Repeated-dose Oral or Dermal Toxicity	√	√	√	×	×	×
Teratogenicity	√	×	×	×	×	×
Chronic Toxicity/Carcinogenicity Combined	√	×	×	×	×	×
Long-term human trial safety	√	×	×	×	×	×
Inhalation Toxicity (When the NCI may be exposed by inhalation)	√	×	×	×	×	×

\* Nanomaterial, NCIs with health hazard effects and NCIs with high biological activity may need to provide more toxicological data

# Alternative method



Please note: the appropriate **Integrated Approaches to Testing and Assessment (IATA)** shall be selected.

# Alternative method NOT included in STSC

## Alternative method NOT included in STSC:

- ✓ International authoritative validation agencies of alternative method
- ✓ Proofs that the method can accurately predict the toxicological endpoint

## Document to prove the validity of method:

- ✓ Brief description of the research process
- ✓ Research data, result analysis, research conclusions, etc.
- ✓ No less than 10 tested substances of known toxicity



# Monitoring period

- **Start time of the 3-year monitoring period :**

From the date when the **cosmetics using this NCI are notified or registered for the first time**

- **Annual report, safety risk monitoring and evaluation :**

Summarize and analyze the use and safety of the approved NCI, and the possible safety issues and regulatory change of similar ingredients, formulate report and submit

- **For notified NCI, technical review will be conducted during 3-year monitoring period**



# Part B

**China cosmetic ingredient  
submission code application**

# Transition period

- **Starting from 2022, high risk ingredients** are required to submit ingredient safety information or submission code when the finished product is registered/notified
- **Starting from 2023, all ingredients** are required to submit ingredient safety information or submission code when the finished product is registered/notified
- Cosmetic products **already registered or notified** are required supplementation of ingredient safety information or submission code **before May 1, 2023**

**Ingredient safety information and submission code are both acceptable!**

# What is submission code?

## Definition:

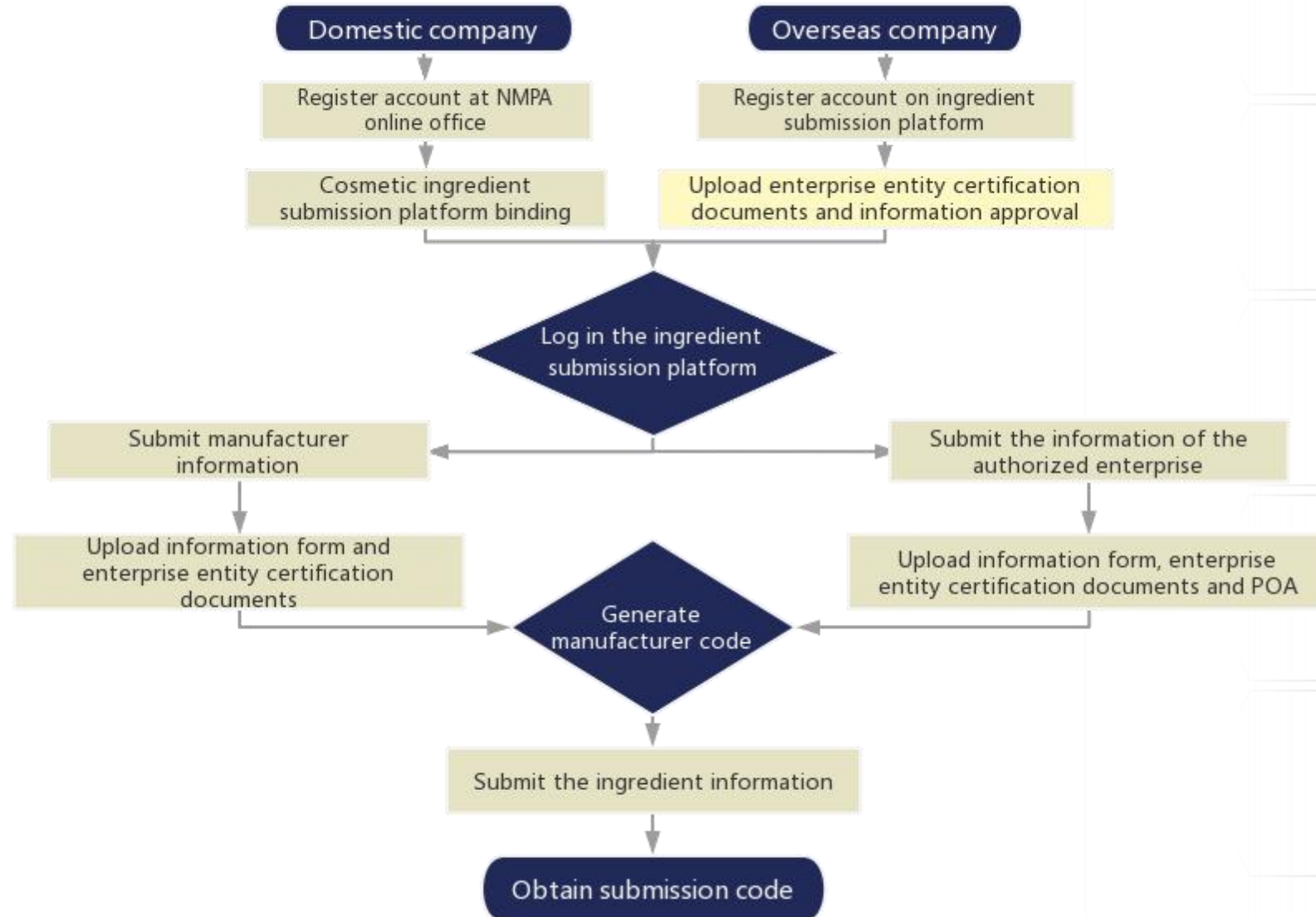
- Automatically generated after ingredient safety information is filed on official online platform
- Composed of three parts:

**Ingredient code-Manufacturer code-Specification code.**

# Who can be application entity?

- **Actual** production enterprise
- **Affiliated enterprise** that belongs to the same group as the actual production enterprise
- **Entrusting enterprise** in the activity of entrusted production (brand owner)

# How to apply for submission code?



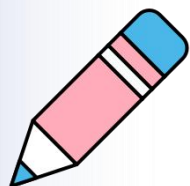
# Enterprise information management

No.	Submission forms	Documents required
1	Submitted by domestic ingredient manufacturers themselves	<ol style="list-style-type: none"> <li>1. Scanned copy of the stamped Enterprise Information Form (ANNEX 13)</li> <li>2. The business license</li> </ol>
2	Submitted by overseas ingredient manufacturers themselves	<ol style="list-style-type: none"> <li>1. Scanned copy of the stamped Enterprise Information Form (ANNEX 13)</li> <li>2. Enterprise entity certification documents of the ingredient manufacturer <b>(shall be notarized by the Chinese notary public office or certified by the Chinese embassy)</b></li> </ol>
3	Overseas ingredient manufacturer authorizes other domestic enterprise to submit	<ol style="list-style-type: none"> <li>1. Scanned copy of the stamped Authorized Enterprise Information Form (ANNEX 13)</li> <li>2. Enterprise entity certification documents of the ingredient manufacturer</li> <li>3. POA</li> </ol>
4	Overseas ingredient manufacturer authorizes other overseas enterprise to submit	<ol style="list-style-type: none"> <li>1. Scanned copy of the stamped Authorized Enterprise Information Form (ANNEX 13)</li> <li>2. Enterprise entity certification documents of the ingredient manufacturer <b>(both sides shall be notarized by the Chinese notary public office or certified by the Chinese embassy)</b></li> <li>3. POA</li> </ol>

Please note: after the enterprise information is submitted, an **unique manufacturer code** will be generated.

The enterprise information cannot be modified after the unique manufacturer code been generated, so it is necessary to **ensure its accuracy.**

# Safety information



Fill in  
step by step  
in the platform



- ◆ **Basic information and manufacturing process**
- ◆ **Quality control requirements and characteristic parameters**
- ◆ Limit requirements for risky substances
- ◆ Assessment conclusions of international authorities
- ◆ Brief description of the requirements for use in other industries
- ◆ Other issues to be explained

- Cosmetic ingredient submission code will be randomly generated without verifying
- NMPA will publish the submission code (<http://ciip.nifdc.org.cn/hzpYL/yIgsInfo>). **The trade name, whole composition and part of the code will be hidden**

**Mandatory**

**Optional**

Based on the actual condition

# Requirements for Safety Information

## Basic Information and Manufacturing Process

- ✓ **Composition** Consistent with the IECIC, typical value/target value is required for physical mixing of ingredients
- ✓ **Physical chemical:** Solubility and others
- ✓ **Remark:** Nano ingredients, Hydrocarbons derived from petroleum and coal tar, lake colorants
- ✓ **Function&Recomended concentration:** Based on the actual
- ✓ **Use restrictions:** STSC2015
- ✓ **Manufacturing process:** Brief description, information of directly nature srouce and engeneering strains

## Quality control and Limit requirements

- ✓ **Quality control:** Identification and quantitative information of indicators
- ✓ **Limit requirements:** Heavy Metal, Microbiological Indicators, Pesticide Residue and others risky substances

## Assessment Conclusions of International Authorities

- ✓ **Assessment institution:** SCCS/CIR/IFRA/WHO/FAO
- ✓ **Restrictions in other industries:** Such as food, food contact material, durg and others



# Saf 化妆品原料安全信息登记平台

序号	原料组成	原料报送码
1	铁皮石斛 (DENDROBIUM OFFICINALE) 提取物 丙二醇 .....	100003*****
2	二裂酵母发酵产物溶胞产物	002162*****
3	羟基频哪酮视黄酸酯 异山梨醇酐二甲醚	100006*****
4	金钗石斛 (DENDROBIUM NOBILE) 提取物 丁二醇 .....	100007*****
5	甜菜碱水杨酸盐	006666*****
6	抗坏血酸四异棕榈酸酯	004106*****
	昆诺阿藜 (CHENOPODIUM QUINOA) 籽提取物	

显示第 1 到第 20 条记录, 总共 92208 条记录 每页显示 20 条记录

< 1 2 3 4 5 ... 4611 >

Fill  
step by  
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- Cosmetic ingredient submission code will be randomly generated without verifying
- NMPA will publish the submission code (<http://ciip.nifdc.org.cn/hzpYL/yLgsInfo>). **The trade name, whole composition and part of the code will be hidden**

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# How to renew info

## For ingredient manufacturer:

It **CAN NOT** be modified or deleted for now. If you need to renew the corresponding information, it is necessary to **SUBMIT IT AGAIN**

## For cosmetic manufacturer:

Apply for changes or maintain on the NMPA platform, according to the **specific reason** of changing the submission code

# Pros and tips

	Ingredient manufacturer	Cosmetics enterprises
Pros	Peer competitive advantage	Streamline process
	Confidential information	Credible cosmetics formulation
	Credibility	Credible restriction and potentially risky substances
Tips	Provide the correct manufacturer name when authorized	Verify the associated manufacturer name and other information
	Provide the correct trade name and composition	Verify the associated ingredient composition with the corresponding information in formulation
	Quality specifications and risk substance control are correct with the actual condition	Verify the corresponding Codes are correctly associated

# Thank You.

Contact us for global regulatory services



<https://gpcgateway.com/>



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