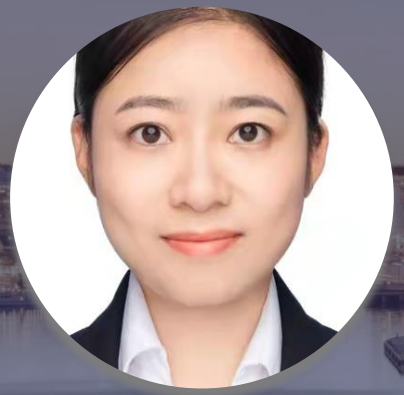
GPC
Global Product Compliance

Cosmetic Ingredients Compliance in China



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Europe | India | South Korea | Eurasia | Turkey | Taiwan | Australia | Ireland

1. General Introduction

2. Cosmetic
Existed Ingredients

3. Cosmetic
New Ingredients

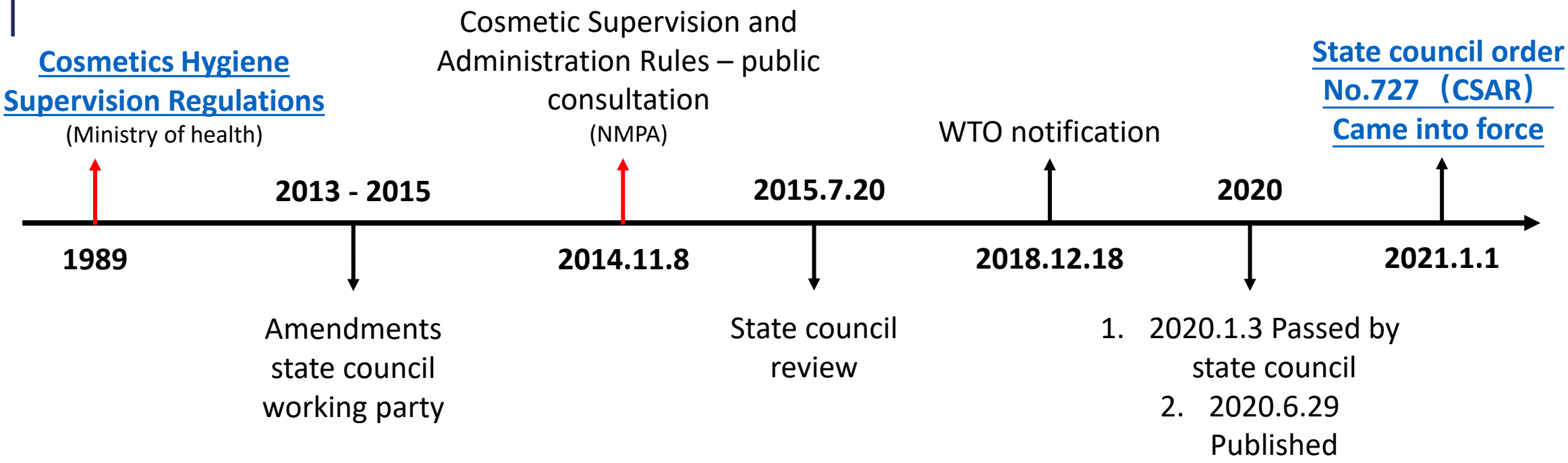
4. Q&A

General Introduction

1. Categories of ingredients
2. Submission body
3. Link with REACH registration

Legislation

- **Governing Regulation: Cosmetic Supervision and Administration Rules (CSAR)**
  - Provisions for Management of New Cosmetic Ingredient Registration and Notification Dossiers (May 2021)
  - Administrative Measures on Cosmetics Registration and Notification(May 2021)
- **Managing Department: National Medical Products Administration (NMPA)**



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)

Submission Body

Representatives

Importers

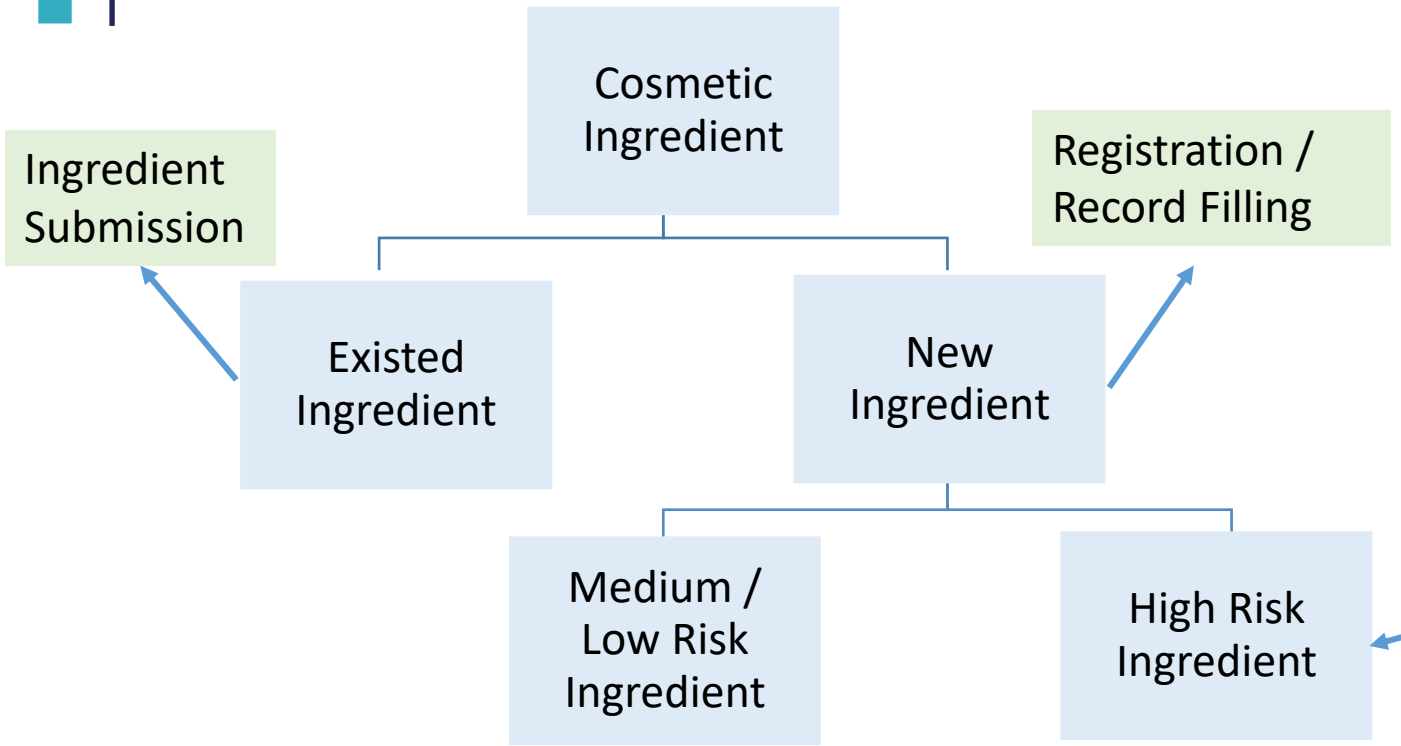
1. The ingredients will be registered under the Agent’s name
2. Authorization letter need to be provided, including full names in Chinese and English of both parties, addresses, authorization scope, authorization period, etc.

Classification

Definition of cosmetic ingredients :

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

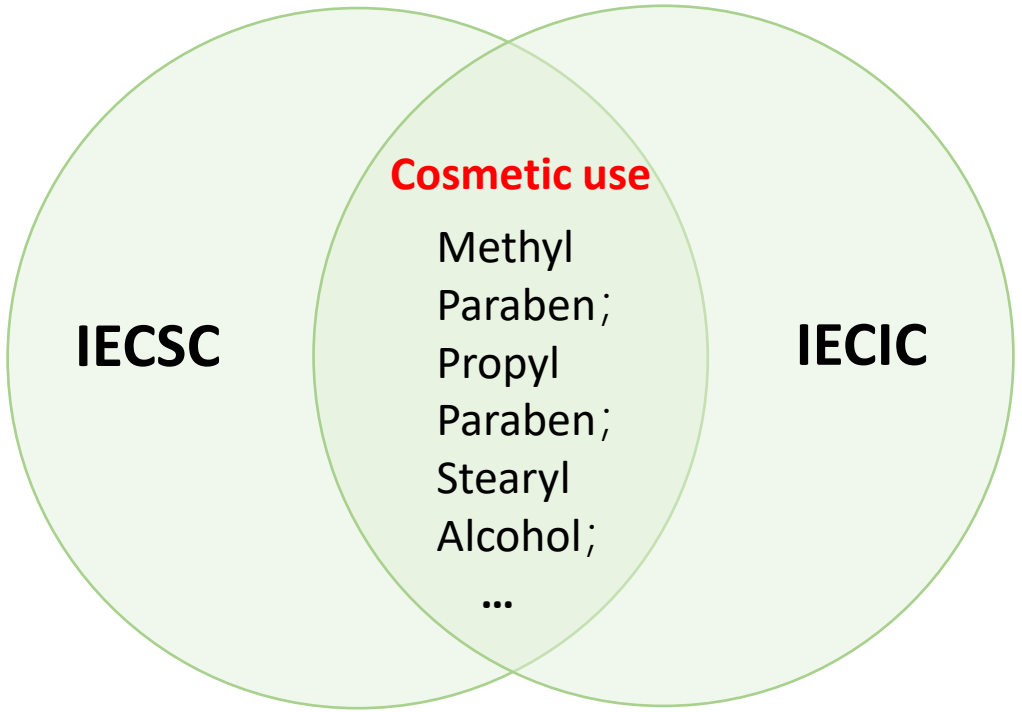
- **Existed Ingredients**: Included in IECIC (2021 edition), or
- **New Ingredients:** Ingredients, natural or artificial, for the first time, used in cosmetic products in China



1. Preservatives
2. UV filters
3. Colorants
4. Hair dyes
5. Freckle removing or whitening agents

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



Cosmetic Existed Ingredients

1. Submission platform
2. Submission requirements
3. Submission procedures

Submit by Foreign manufacturers

For manufactures, domestic or overseas, it is possible to submit information under your company's name.

Ingredient manufacture *refers to "an enterprise that is responsible for the safety of the ingredient(s)". It can be:*

- **Actual production company of the ingredients;**
- **An affiliated company that belongs to the same group of company as the actual production company of the ingredients;**
- **The entrusted enterprise in the act of entrusting the production of the ingredients.**

The "name of the ingredient manufacturer" needs to be **unique, correct, and consistent** with the content contained in the enterprise's main body certification document.

Submit by Yourself

- **Advantages**
  - Cost-saving, free of charge or one time payment
  - Time-saving, you will have the opportunity to manage your own account, to check the substance information, and to **add** ingredients at anytime.
  - The ingredient is registered under your own name
- **Enterprise verification**
  - Application form for legalization
  - Original version and copy of notarized documents
  - Copy of passport of the applicant
  - Authorization letter and ID of authorized person
- Apply for an account at '**Cosmetic Ingredients Safety Information Registration Platform**'

中华人民共和国驻外使领馆领事认证申请表

Application Form of Consular Legalization of the Embassy/Consulate of the People's Republic of China

★申请人须如实、完整、清楚地填写本表格，请逐项在空白处用中文或英文大写字母打印体填写，或在□内打✓选择。The applicant should fill in this form truthfully,completely and clearly. Please type the answer in capital English letters in the space provided or tick (√) the relevant box to select.

1、个人申请 Applicant (For Individual Use Only)

姓名 Name		性别 Gender		出生地点 Place of birth	
出生日期 Date of birth (yyyy-mm-dd)		国籍 Nationality		职业 Occupation	
身份证件种类 Type of ID		身份证件号码 Number of ID			
工作机构或学校名称 Name of employer/school		工作机构或学校地址 Address of employer/school			
家庭住址 Home address		电子邮箱 E-mail address			
住宅电话 Home phone number		手机 Mobile phone number			

2、企业及其他组织申请 Applicant (For Company/Organization Use Only)

企业或其他组织名称 Name of company/organization					
联系地址 Address		电话 Phone Number			
法定代表人信息 Legal Representative of company/organization	姓名 Name		出生日期 Date of birth(yyyy-mm-dd)		
	证件种类 Type of ID		证件号码 Number of ID		

3、公证书或其他证明文书证明的事项
Matters certified by the notarial deeds or other certificates

□出生证 Birth certificate; □结婚证 Marriage certificate; □无犯罪记录证明 Certificate of non-criminal record;
□健康证明 Health certificate; □学历证明 Diploma; □委托书 Authorization letter; □声明书 Statement;
□商业文件 Business documents; □其他（请注明）Other (please specify) :

4、认证办理目的和文书使用地点 Purpose and Destination of Legalization

办理目的 Purpose of legalization: □婚姻 Marriage; □寄养 Fosterage; □房产 Real estate;
□诉讼 Litigation; □签证 Visa; □领养 Adoption; □商务贸易 Business and trade;
□其他（请注明）Others(please specify):

文书使用地 Destination of legalization:

Submission Requirements

Enterprise Information Submission

- Enterprise information sheet (Attachment 13)
- ID document
- POA (If required)

Ingredient Safety Information Submission

- Ingredient classification and key characters
  - *Main components and key characters;*
  - *Source of raw ingredient;*
  - *Manufacturing methods of ingredient;*
  - *Other characters*
  - *Reasons for compound ingredient or mixture*
- Ingredient safety information
  - *Names of main components of the ingredient;*
  - *Content of the components in percentage;*
  - *Others, including use in cosmetics, restrictions, quality control requirements and character indicators. If applicable, limit requirements for risky substances, assessment conclusion, use in other industries*
  - *If it is oligopeptide raw material, amino acid sequence*

Submission Procedures

No tonnage band distinction!

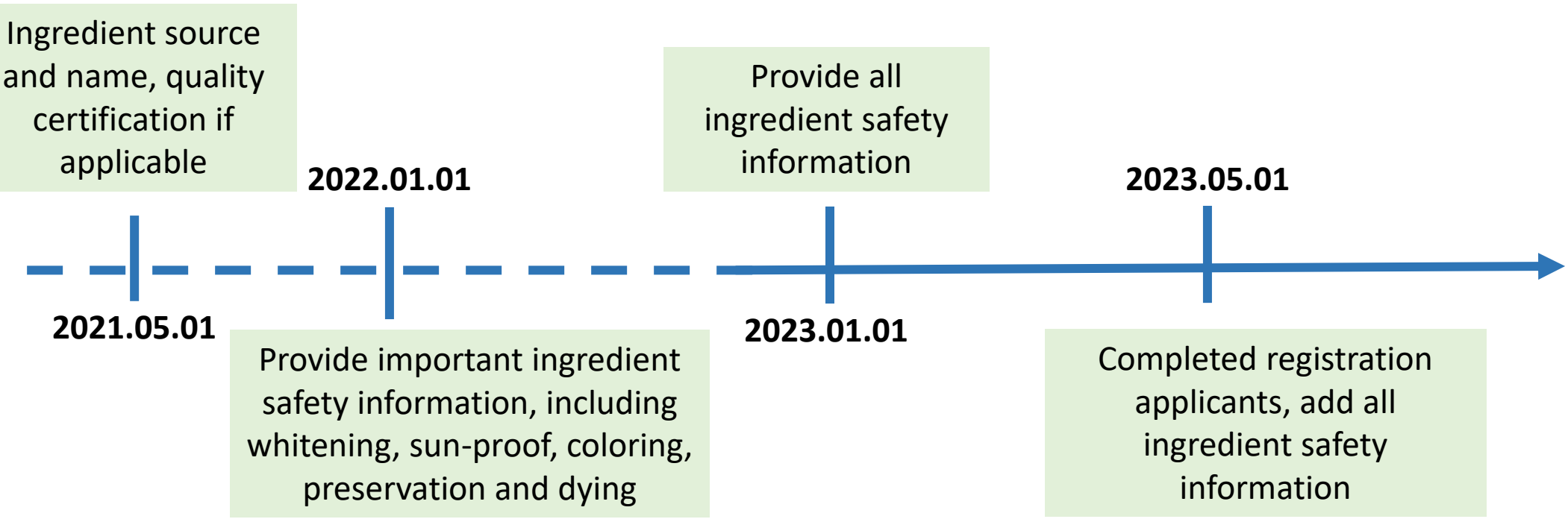
Account application for foreign manufactures → Account application at NMPA online service center → Fill in and submit enterprise information → Fill in and submit ingredient safety information

Code Generation

Unique ID for ingredient！ ！ ！

xxx xx	**yyy yyy**	**zzz**
(five numbers of company code)	(six numbers of ingredient code)	(three numbers of ingredient quality code)

Why Submission Code Is Important?



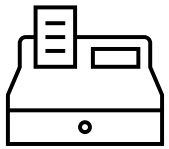
For those raw ingredient manufactures who has already done the ingredient submission, they only need to share the ingredient code to the importers / upstream users!

Your business secretes can be protected!

Cosmetic New Ingredients

1. Submission requirements
2. Submission procedures
3. Timeline

Submission Documents



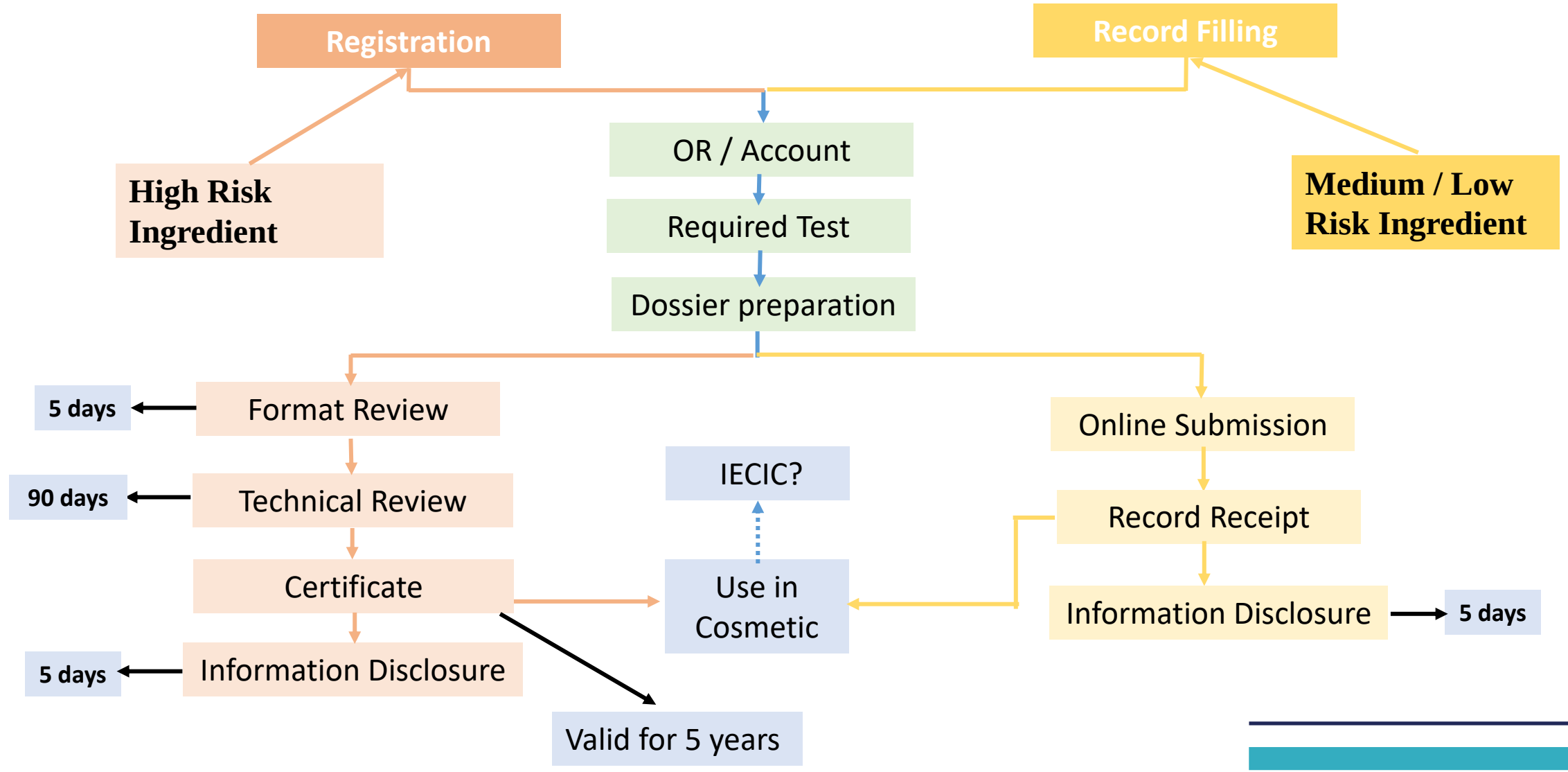
Account application:

1. Information of registrant and notifier of new cosmetic ingredient.
2. Safety risk monitoring and evaluation system overview of registrant and notifier of new cosmetic ingredient.
3. Original authorization letter of the domestic responsible person and the original notarial certificate (for overseas registrant/notifier).

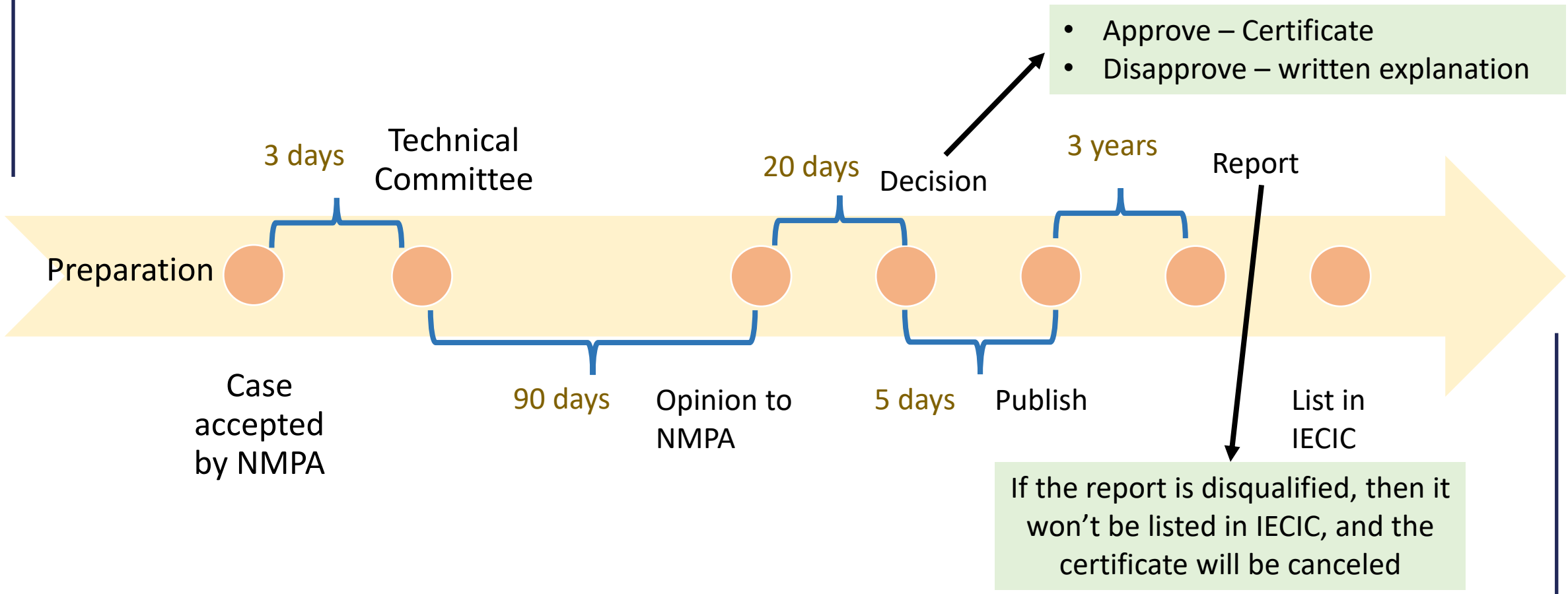
Dossier preparation

1. The name, address, and contact information of the registrant, notifier, and domestic responsible person.
2. New cosmetic ingredient R&D report.
3. Research documents on the NCIs preparation techniques, stability, and quality control standards.
4. Safety assessment documents for NCIs.
5. Technical requirements (available for the public).
6. Other supportive documents.

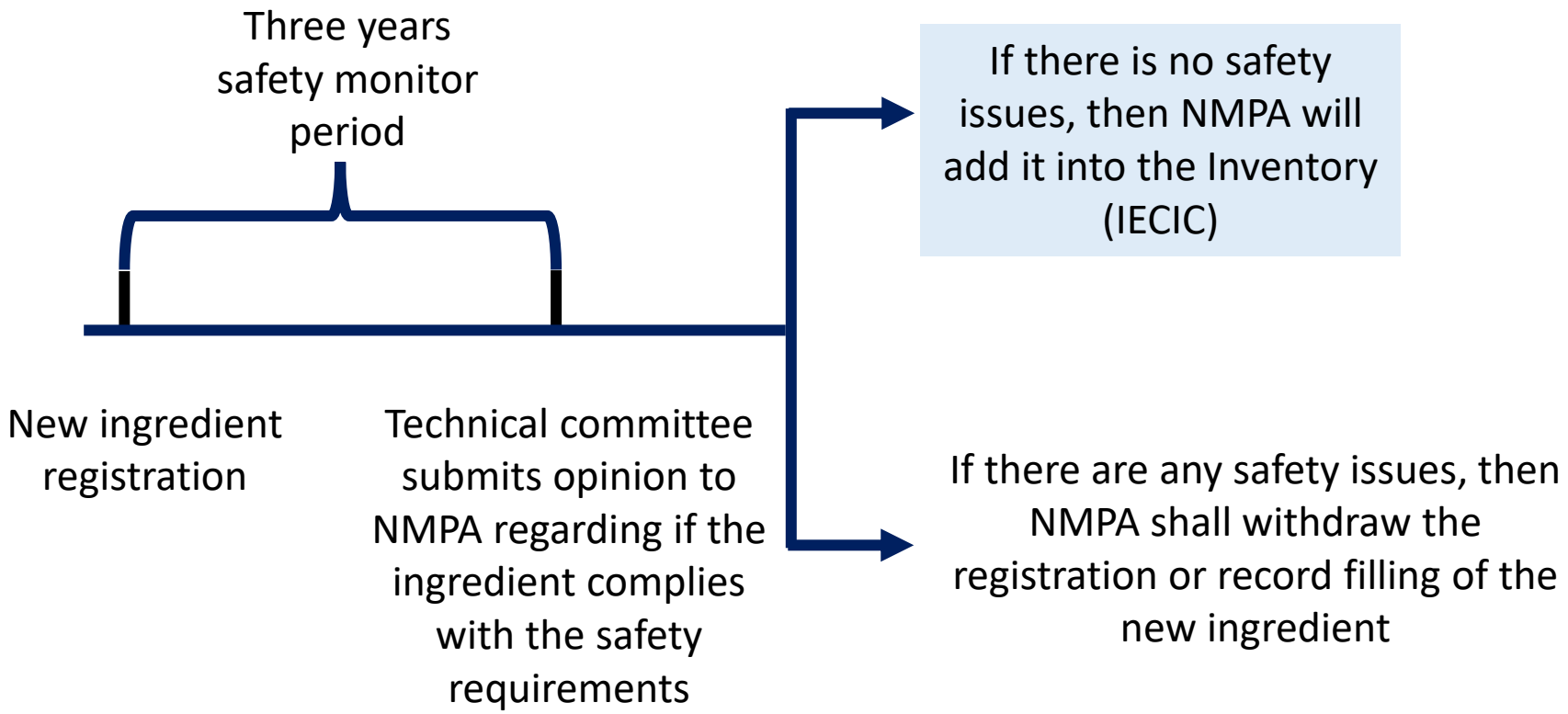
Submission Procedure



New Ingredients Registration Timeline



IECIC Inclusion (cosmetic Ingredients inventory)



Main Content 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

Take Away

1. Cosmetic ingredients are still chemical substances, do check REACH compliance requirements
2. For existed cosmetic ingredients,
    - Check if your cosmetic ingredients are listed in IECIC
    - You can submit by yourself as overseas manufactures
    - As long as the trade names of the products are different, new submission is required
    - There is no expiration date on the code
3. For new cosmetic ingredients,
    - Check the function(s) of your substances first
    - Tests may take long time, so prepare in advance
    - 3-year’s monitoring period is important

Thank You!

“Your Seamless Extension in Global Regulatory Compliance.”

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COSMETIC PRODUCT COMPLIANCE IN CHINA

Webinar COSMED & GPC – 20 October 2022

COSMED
L'ASSOCIATION DES PME DE LA FILIÈRE COSMÉTIQUE

GPC
Global Product Compliance

Marie MAGNAN - Regulatory Affairs

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LOBBYING FOR COSMETIC COMPANIES

→ French National Agency for Medicines and Health Products Safety (ANSM)
→ European Commission
→ ISO, CEN , AFNOR
→ Foreign countries authorities

SHARED SERVICES

→ Regulatory watch
→ Free Sale Certificates
→ Training
→ Purchasing group
→ Events, Congress

WORLDWIDE REGULATORY WATCH

120 Countries monitored (Europe & international).
On-line available databases 24 hours, 7 days

1500 Updated factsheets and summary tables

48h Deadline answer to your regulatory requests from a specialized team

7 days a week Email alerts at each regulatory amendment

CHOOSE your tailored solution

1 database France / Europe OR International
2 databases France / Europe AND International

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SAVE THE DATE!

REGULATORY DAYS by Cosmed

21 & 22 March 2023 (in Paris or remote)

<u>European regulation</u>

Review of national and European institutions (French DGCCRF, European Commission)

Updates on environmental challenges (green deal, eco-design and sustainability, environmental claims, compliance of recycled packaging)

Marketing trends and influence on regulation (bulk sales, CBD and hemp)

Round table: labelling of "new" allergens

<u>International regulation</u>

Round table - China: End of transition periods, how to be ready?

Overviews (category of your product for export: cosmetic or not?, Inspections world tour with focus on claims, Latin America: marketing requirements)

Country news (Middle East - Changes in regulations, Korea - environmental regulations, Asia - news outside China)

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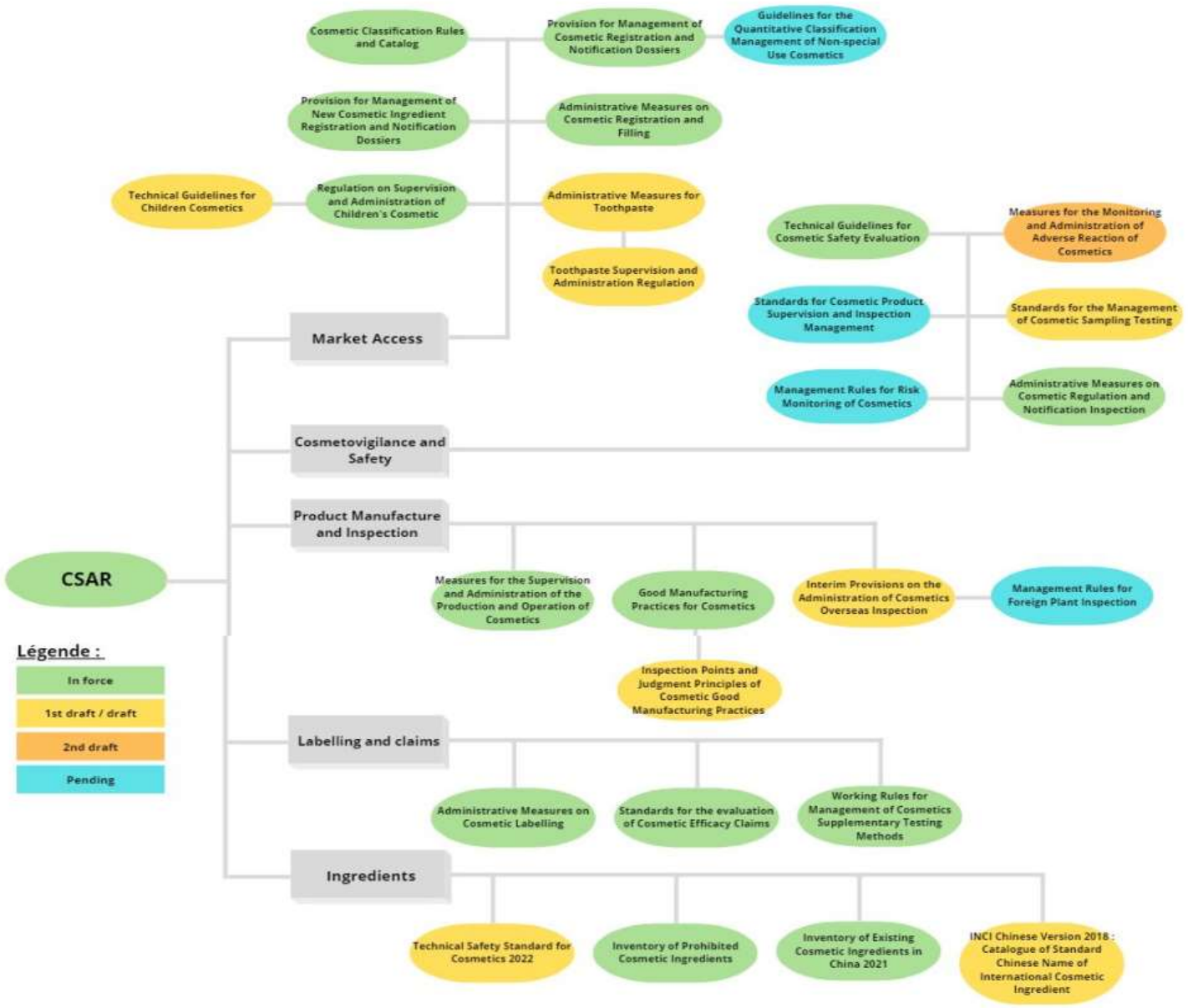
REGULATORY LANDSCAPE FOR COSMETICS



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CATEGORIES

DEFINITION

The term "cosmetics" refers to « daily chemical industrial products applied to the skin, hair, nails, lips and other surfaces of the human body by spreading, spraying or other similar methods for the purpose of cleaning, protecting, beautifying and altering appearance".

Special use cosmetics

Hair colouring products, perm products, anti-freckles products, whitening products, sun protection products, anti-hair loss products, products claiming new effects

General cosmetics

Others

Special cases: toothpastes, soaps without cosmetic claims

CLASSIFICATION

Text
"Cosmetic Classification Rules and Catalogue"

Entry into force 1 May 2021 / Update for existing dossiers: 1 May 2022

⇒ 26 efficacy/claims categories + 1 « new effect »

⇒ 10 body part categories + 1 « other part »

⇒ 3 population categories + 1 « other »

⇒ 11 product forms

⇒ 2 uses

Type product code :
01-02/03-04-05-06

Letter = new effect / population / body part

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CLAIMS

Efficacy of cosmetic products

Article 22 of the CSAR : general requirements on efficacy

- Sufficient scientific evidence
- Summary of literature, research data or efficacy tests published on a specific authority's website

Claims

Any claim outside claims categories considered as "new" => product reclassified as a special purpose cosmetic.

Words prohibited

⇒ medical terms, names of medical personalities, names of medicines ; imply that the product could have a medical efficacy

⇒ Unverifiable or counterfeit scientific data; terminology or mechanisms not validated by the scientific community

⇒ False information or denigration of other products

⇒ Use of the name and image of public authorities or institutions

⇒ Fictitious, invented, absolute, misleading or exaggerated terms

⇒ Use of the properties of a raw material to imply that the finished product would have those same properties

⇒ Terms that are contrary to good morality or offend public order ; superstitious meaning

Contents

NOTIFICATION REGISTRATION

New notification/registration platform

https://zwfw.nmpa.gov.cn/web/index

→ Migration of all dossiers on 1 May 2022

REGULATION

Provisions for Management of Cosmetic Registration and Notification Dossiers

⇒ Documents and information needed

Administrative Measures for Cosmetics Registration and Filing

Cosmetics Supervision and Administration Regulation

⇒ Change management, renewal requests, document format, numbers, responsibilities

Technical Guidance for Submission of Cosmetics Registration and Notification Dossiers

⇒ File format, mandatory/optional

One Domestic Responsible Person per product

CHINESE RESPONSIBLE PERSON

DOMESTIC RESPONSIBLE PERSON (DRP), LEGAL ENTITY IN CHINA

- Notify and register on behalf of the applicant
- Support the quality and safety of cosmetic products in the Chinese market (quality management system)
- Manage cosmetovigilance, adverse reactions and a possible product recall
- Cooperate in case of control by the authorities

FOREIGN APPLICANT

COMPANY / FOREIGN APPLICANT

- Information sheet: passport numbers and CVs of the legal responsible person and the person responsible for quality
- Summary of the **quality management system**
- Summary of the **cosmetovigilance management system**
- **Legalized authorization letter for the Chinese responsible person**
- Information sheet of the production company (also in case of subcontracting).
- Certification required for a company located outside China.

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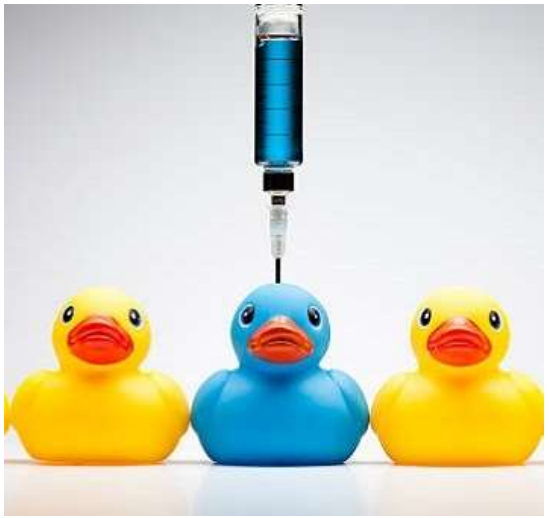
DOCUMENTATION PRODUCT

(IN CHINESE)

- **Form** (with classification code)
- Product **name,** Chinese name and trademark registration certificate
- **Detailed** product **formula** (name of the raw material, INCI and percentage)
- Product specifications **("product standard"**): description of the production process, organoleptic, physico-chemical and microbiological specifications, control methods, storage conditions, shelf life.
- Original **labelling** and Chinese labelling. **3D views of** the product in its packaging.
- **Test reports**: microbiological, physico-chemical, toxicological, efficacy (carried out by a laboratory approved by the NMPA; all products from the same batch).
- **Safety assessment**
- **Free Sale Certificate (imported products)**

EXEMPTION FROM ANIMAL TESTING



CRITERIA

⇒ General cosmetics category

⇒ GMP certification from the authorities (ANSM in France)

⇒ Safety assessment confirming the absence of risks

⇒ Target population does not include children

⇒ Formula without new ingredients (under review)

⇒ Good score (social credit) of the company and the responsible person with the NMPA

Text: Provisions for Management of Cosmetic Registration and Notification Dossiers
ARTICLE 33

CONTENTS

LABELLING

Text "Administrative Measures for Cosmetic Labeling"
From 1 May 2022: compliant labelling for new products
From 1er May 2023: compliant labelling for all products

MANDATORY LABELLING - in Chinese

- Chinese name of the product
- Registration number (special use cosmetics)
- Name and address of the company applying for registration/notification. In case of a foreign company, add the name and address of the Chinese responsible person.
- Name and address of the manufacturer
- Number of « Product standard »
- List of ingredients in Chinese INCI in descending order of concentration. Ingredients with a concentration of less than 0.1% will be listed separately, in any order and preceded by the words: "trace ingredients".
- Net quantity
- [Production date and shelf life] or [batch number and expiry date].
- Instructions for use - Precautions for use, preceded by "caution" or "warning"

On the PRIMARY PACKAGING, Chinese name of the product and expiry date are mandatory

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SIMPLIFIED TIMELINE

1er January 2021: implementation of the CSAR

1er May 2021: Opening of the registration and notification platform
Mandatory classification code for new registrations/notifications

1er January 2022: annual report on cosmetic products to be provided (every year)
Efficacy and simplified safety evaluation for any new registration/notification

1er May 2022: migration of already registered/notified cosmetic products to the new platform with addition of labelling, product visuals, formulas, classification codes
Efficacy for cosmetics notified or registered between 1er May and 31 December 2021

1er May 2023: Efficacy data for all products
Labelling according new regulation (all products)

1st May 2024: Full safety assessment

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CONCLUSION

CHANGE OF REGULATION

- More complex
- More documentation : confidential information?
- More controls

⇒ Quick adjustments needed
⇒ Decrease of numbers of notification/registration
⇒ Increase of prices

WORLDWIDE REGULATORY WATCH on COSMETICS

EUROPEAN DATABASE

. French and E.U regulations
. Specificities of E.U
. Summary Tables of regulated ingredients
. Product Information File
. Assessment of ingredients
. Notification of cosmetic product
. Labelling, Claims
. Cosmetovigilance
. PAO tool
. REACH, CLP
. Actors' Obligations ...

INTERNATIONAL DATABASE

. Classification of products: cosmetics, quasi-drugs, OTC, Natural Products
. Fact sheets on regulations
. Summary tables of regulated substances
. Labelling, Claims
. Registration / Notification of products ...
. Comparative substances tables (UV filters ...)

Contact: regulatory2@cosmed.fr

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