

# Introduction of China NMPA Submission Platform



Bryan Zhou Senior Regulatory Consultant, CIRS



# CONTENT

Cosmetic ingredient management in China

How to process NMPA submission

Practical case analysis



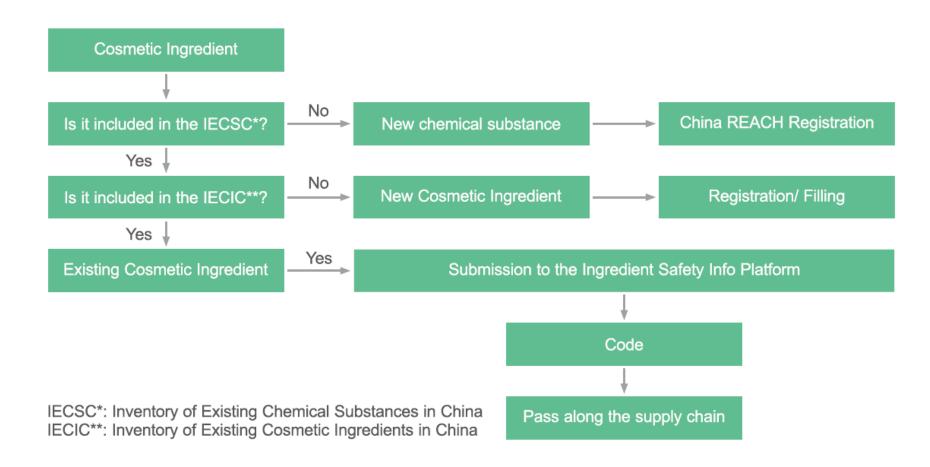
# Overview of Cosmetic Ingredient Management in China

- Regulatory Body for Cosmetic Ingredients in China: National Medical Products Administration (NMPA)
- Regulation for Cosmetic Ingredients in China: Cosmetic Supervision & Administration Regulation (CSAR)
- A cosmetic ingredient is considered "new" in China if it is <u>not</u> included in the IECIC 2021\*
- Existing cosmetic ingredients <u>are</u> included in the IECIC 2021 and <u>from a practical perspective</u>, their safety information should be reported to the <u>NMPA via the Cosmetic Ingredient Safety Information Platform</u>

IECIC 2021\*: Inventory of Existing Cosmetic Ingredients in China



# How to ensure your Cosmetic Ingredient are Compliant in China?





# New Mandatory Requirement under the CSAR Regulation

- From 1<sup>st</sup> Jan, 2021, the filer/registrant\* should provide the safety information of cosmetic ingredients in their product formula with anti-corrosion, sun protection, colouring, hair dying, freckle removal & whitening functions
- From 1<sup>st</sup> Jan, 2023, the filer/registrant should provide safety information of all cosmetic ingredients
- For cosmetic which have been filed/registered before the above deadlines, supplementary safety information of all cosmetic ingredients in the product formula should be provided before Jan 1<sup>st</sup>, 2024

<sup>\*</sup>The filer/registrant here refers to the person responsible for filing/registering cosmetic finished products in China, be they ordinary or special cosmetic products respectively

# How to Submit the Cosmetic Ingredient Safety Information?



There are two options for submitting the safety information of cosmetic ingredients to the NMPA:

Option 1: The filer/registrant should complete Annex 14 (safety information questionnaire) for each cosmetic ingredient when applying for filing/registration

#### <u>Or</u>

Option 2: The filer/registrant can request their ingredient supplier(s) to submit the safety information of the ingredients to the <u>safety information platform</u> and generate a code. The filer/registrant can use the code when applying for filing/registration.



# The Cosmetic Ingredient Safety Information Platform

- On January 1st, 2022, the NMPA launched the cosmetic ingredient safety information platform for <u>existing</u> cosmetic ingredients in China
- An account should be set-up on the platform and the safety information of the cosmetic ingredients used in the product formula can be submitted to generate a code.
- The platform is exclusively in the **Chinese language**
- The code can be provided to the filer/registrant when they are applying for filing/registration of their finished cosmetic products which affiliates the safety information of the cosmetic ingredient used in the product formula.
- Only the NMPA can see the safety information of the cosmetic ingredients submitted which <u>protects the confidential business information</u> of the ingredient supplier.



#### Who can Submit to the Platform?

- Only the role in the supply chain <u>responsible for the safety of cosmetic</u> <u>ingredients</u> can submit to the platform. In general, this is the cosmetic ingredient manufacturer.
- The cosmetic ingredient manufacturer can also appoint an authorized representative (via Power of Attorney) such as a cosmetic ingredient distributor/trader or third party such as CIRS Beijing to submit on their behalf.



#### **Practical Workflow for Submission to the Platform**

#### **Step 1: Account Set-up & Notarization**

Select a Chinese name for the company (Transliteration or other)

- Notarization of original business licence by the local Chinese Embassy or Chinese Public Notary (overseas company only). Domestic companies can submit original business license.
- Translation of the notarized business license to the Chinese language
- Fill in company information form (Annex 13) & complete account set-up
- Step 2: Submission of Cosmetic Ingredient Safety Information & Code Generation

Complete cosmetic ingredient safety information form Translate from original language to the Chinese language Submit to platform & code is generated

- Code can be provided to downstream cosmetic brands <u>Please note:</u> the platform is exclusively in the Chinese language and so all information submitted should be in Chinese.



# **Information Requirements on the Platform**

User Account Set-up on the Platform	Submission of Cosmetic Ingredient Safety Info				
Stamped company information sheet (Annex 13)	Basic info & brief description of production process				
Notarized Business Licence by Chinese Embassy & Translated to Chinese (overseas company only). Domestic companies can submit original business license.	Identification & characterization index of raw materials				
Power of Attorney (if authorized company appointed)	Risk information & control indicators				
Company Name in Chinese	International authority & evaluation conclusion				
Note: All items above should be in Chinese	Brief description of use requirements in other industries				
	Other issues to clarify				
	Note: All items above should be in Chinese				



# **Case Study**

**Company A** is a cosmetic ingredient manufacturer based in France responsible for the safety of their cosmetic ingredients. They supply their ingredients to **Company B**, a cosmetic skincare brand in Germany.

**Company B** now wants to sell one of their skincare products in China but they need to report the safety information of the cosmetic ingredients used to make the finished product to the NMPA when applying for filing/registration. **Company B** does not have the safety information available of the cosmetic ingredients because **Company A** wants to keep this information confidential.

How should Company A & Company B to act?



### **Case Study Analysis**

Step 1: Company B should check if all cosmetic ingredients in the product formula are existing in China (included in the IECIC 2021)

Step 2: Company B should request Company A to generate a code on the Cosmetic Ingredient Safety Information Platform which Company A can then use for filing/registration

Step 3: Company A should set up an account on the platform:

- i. Select a Chinese name
- ii. Notarize their original business licence at local Chinese Embassy & translate the doc. to Chinese
- iii. Complete Annex 13 in Chinese & submit with notarized, translated business licence to set-up an account on the NMPA platform
- iv. Company A should complete cosmetic ingredient safety info form and submit with Annex 13 & the notarized translated business licence to the platform to generate the code

Step 4: Company A can share the code with Company B for their finished product filing/registration in China



### **Latest Information Update from the NMPA**

- The safety code is generated automatically by the system after submission
- The code consists of a 5-digit manufacturer code + 6-digit ingredient code + 3digit quality specification of raw material code
- The NMPA discloses some information of raw material composition & safety information code on the public system (<a href="http://ciip.nifdc.org.cn/hzpYL/ylgsInfo">http://ciip.nifdc.org.cn/hzpYL/ylgsInfo</a>)
- If you already have a code and the cosmetic ingredient safety information is changed, it is mandatory to start a new application on the platform and generate an updated code.

化妆品原料安全信息

原料报送码: 0(■371-1/179-8580

一、基本信息和工艺简述】

原料商品名*	io dominioning impuno!			版本号				
原料组成*	序号 中文名称		INCI 名称/英			含量		
			文名称	备注		値/目	范围	
	1	1 PE+E Bh			1	00%		
原料基本属性	a.主成分 本特征		来源 c.原料生	产方式 d.其f	地特征	e.复配	混合原因	
	其他混合物 以 工 主			· 加州)			其他	
化妆品中使用 目的								

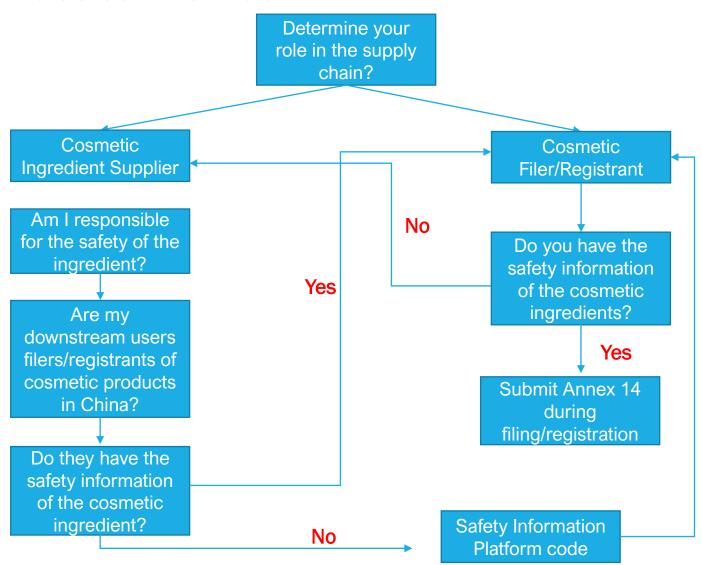


### **Summary**

- Language: Chinese ONLY
- Person responsible for filing/registering cosmetic finished products in China:
  Manufacturers/ Distributors
- Account set-up may take some time: 2-3 weeks, mainly because of the notarization
- Consider limitations set on downstream users (use, quantity used in final cosmetics etc.)
- Once you submit the info, the ingredient info cannot be updated



#### **Practical Advice**



Code can be shared with downstream cosmetic filer/registrant directly for filing/registratio n in China



### How can we help you with Cosmetic Services

- Technical Assistance for Submission to the NMPA Safety Information Platform
- Notarization of original business license & Translation in China
- Act as authorized representative for platform submission
- New Cosmetic Ingredient Registration/Filing in China
- Cosmetic Registration/Filing in China
- NMPA accredited Lab Testing Service
- Domestic Responsible Person Service
- Global Cosmetic Regulatory Update Monitoring and Reporting
- Global Cosmetic Registrations



Your Seamless Extension in Global Regulatory Compliance.



IDEON Science Park, Beta 5. Scheelevägen 17, 223 63 Lund, Sweden



compliance@gpcregulatory.com



+ 46 (0) 46 211 46 15



www.gpcgateway.com

