THE DILEMMA

Boss: We need to stop testing our products on animals

Guy: But shampoo companies do it all the time

Boss: Yeah but we make hammers

On the one hand, China is the biggest beauty market and continues to grow rapidly …. But China requires animal testing on imported cosmetic products …

On the other hand, testing on animals will have a strong negative effect upon a brand's Western consumers …

Indeed, selling in China is for many shorthand for "**not** cruelty free"

2021 – the breakthrough – exemption for imported cosmetics from animal testing … in most cases … but there are hurdles

WHIRLWIND HISTORY OF ANIMAL TESTING

BEFORE 2014

- Mandatory animal testing for **ALL** non-special use and special use cosmetic products

JUNE 2014

Announcement of the National Medical Products Administration on Matters Concerning the Modification of the Registration and Record-filing of Cosmetics

- Mandatory animal testing subject to **EXEMPTIONS for non-special use cosmetic products** (i.e. cross-border ecommerce and limited locally manufactured products with an exemption)

FEBRUARY 2021

Administrative Provisions of Cosmetics Registration and Filing Documents

- **EASES UP** animal testing for non-special use imported cosmetic products

PRE-REQUISITES

Beginning May 1, 2021 international cosmetics companies can apply to sell imported non-special use, cruelty-free cosmetics in mainland China through general import and general trade. However, there are two pre-requisites:

QMS

Imported non-special use cosmetics manufacturers need to obtain certification of manufacturing quality management system (QMS – similar to GMP) that is issued by the government authorities or certification organizations of its country (region)

Product safety assessment

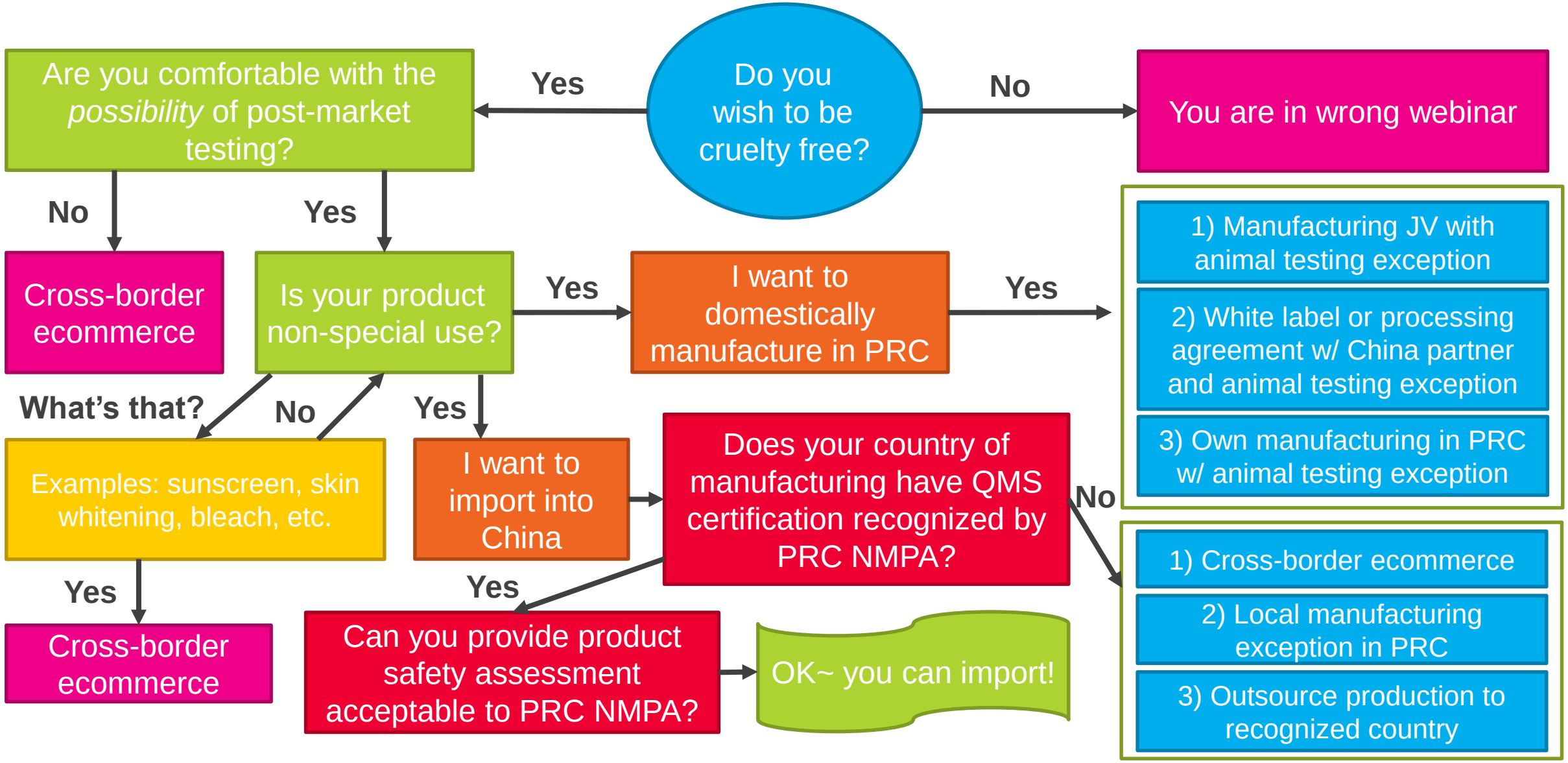
- Provide a product safety assessment that can fully confirm the safety of the products
- Reviewed by the China National Medical Product Administration ("NMPA") based on the risk management materials submitted

EXCEPTIONS

However, the exemption will not be available to imported general cosmetics manufacturers if:

1. Products claim to be used for children or infants
2. Products which contain any new cosmetic raw materials or new ingredients that are still under the safety monitoring period
3. Any of the brand applicant, its Chinese responsible agent or manufacturer has been listed as being subject to supervision (i.e. the NMPA has such watch list In place)

PATH TO AVOID ANIMAL TESTING



OTHER POINTS TO CONSIDER

Greater obligations and paperwork

- Increasingly strict regulations
- Improved health and safety standards
- Expanded role and potential liability for the domestic representative

Recognition of QMS

- Recognition of QMS is on a bilateral basis between China and the relevant manufacturing country
- Issue for countries that are politically out of favor with China

Potential overseas inspection?

- NMPA may notify inspection institution to carry out inspection of overseas manufacturing sites
- Similar, to infant formula, this is NOT necessarily a pre-requisite for registration

Multiple Manufacturing Sites

- Each site that exports needs QMS and safety assessment
- Where to outsource production?

Outsourcing to China

- China wants its own massive cosmetics industry
- Domestic exemption from animal testing is available
- Relocating production to China may be the easiest option but many companies may not feel comfortable

knudsen & crc
Certification & Regulatory Compliance

Cosmetic Supervision & Administration Regulation (CSAR)

The Most Important Changes

April 2021

Our Company

Knudsen &CRC is a team of pharmacists, nutritionists, legal compliance experts, government relations advisors, and business consultants

But most importantly: we are a team working "hands-on" with our clients in China

Cosmetics & Skincare

- Preliminary Product Evaluation
- NMPA Filing/Registration
  - Ingredient & Packaging Consulting
  - Application Dossier Preparation
  - Sample Test Preparation
  - Documentation Submission
  - Raw Material Declaration
- New Raw Material Registration
- Domestic Responsible Person

General Food

- Preliminary Product Evaluation
- GB Regulation Check
- Importation Consulting
- BQS Filing
  - Ingredient & Packaging Consulting
  - Application Dossier Preparation
  - Documentation Submission

Domestic Product Filing

- Preliminary Product Evaluation
- NMPA Domestic Product Filing
  - Ingredient & Packaging Consulting
  - Application Dossier Preparation
  - Sample Test Preparation
  - Raw Material Declaration
  - Documentation Submission
- Manufacturing Process Management & Auditing
- Domestic Responsible Person
- Packaging & Sustainable Material Sourcing

Health Food

- Preliminary Product Evaluation
- SAMR Filing/Registration
  - Ingredient & Packaging Consulting
  - Application Dossier Preparation
  - Sample Test Preparation
  - Documentation Submission

Medical Device & Drug Filing/Registration

- Preliminary Product Evaluation
- NMPA Filing/Registration
  - Product & Packaging Consulting
  - Application Dossier Preparation
  - Sample Test Preparation
  - Documentation Submission

Infant Formula & FSMP

- Preliminary Product Evaluation
- SAMR Registration
  - Ingredient & Packaging Consulting
  - Application Dossier Preparation
  - Sample Test Preparation
  - Documentation Submission

Additional Services: •Trademark Registration Application; • Government Affairs; • Market Research Report

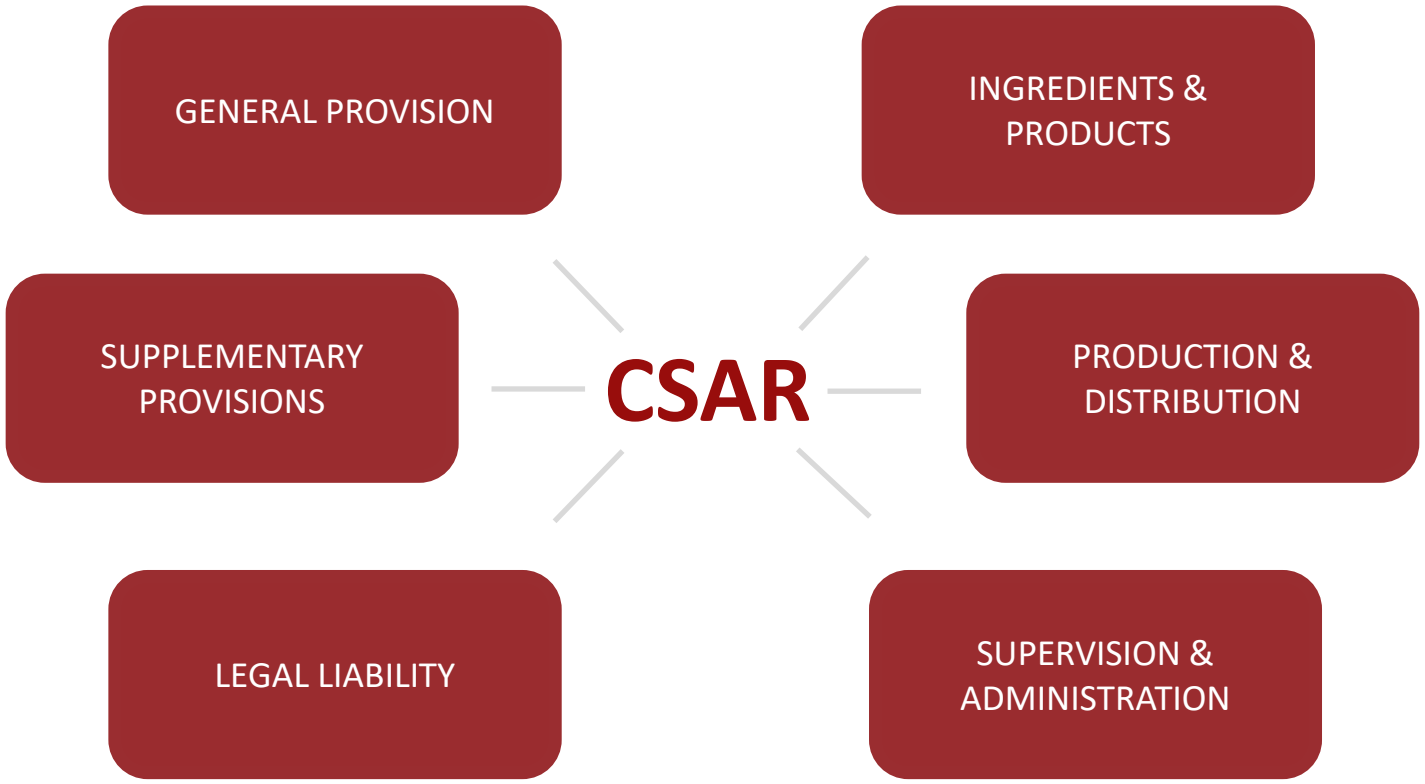
Contents

Cosmetic Supervision & Administration Regulation – CSAR

01

On 30 June 2020, the State Council announced the New Cosmetic Supervision and Administration Regulation (CSAR) that came into effect on January 1st, 2021

Authority in Charge: NMPA

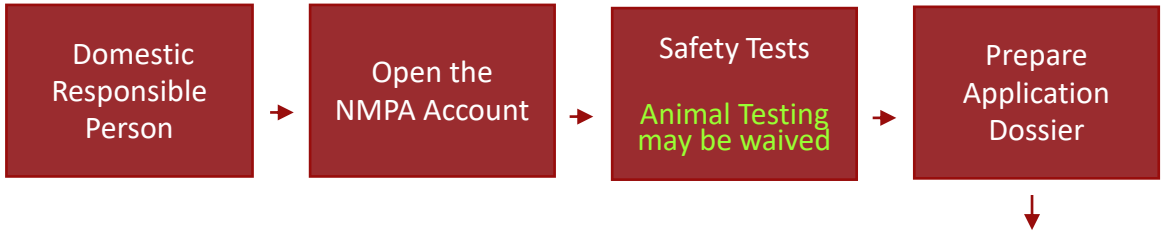


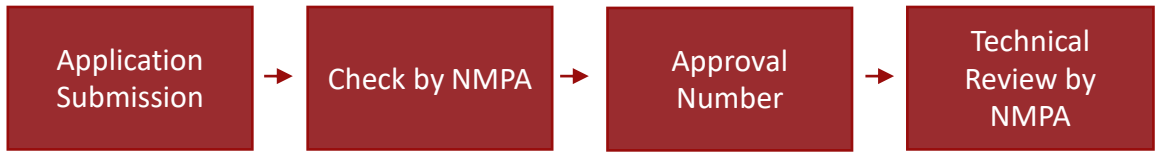
CHSR 1989	CSAR 2020
35 ARTICLES	80 ARTICLES
HYGIENE	QUALITY & SAFETY
KEY RESPONSIBILITY RESTS ON AUTHORITIES	KEY RESPONSIBILITY RESTS ON COMPANIES
QUALITY SUPEVISION RESTS ON AUTHORITIES	QUALITY SUPERVISION PARTIALLY MOVES TO CONSUMERS
LACK OF INNOVATION	INNOVATION ENCORAGEMENT

Product Filing Process & Dossiers

02

Product Filing Process





Old Regulation – Product Filing Dossier

- Application Form
- Product Name Explanation & Trademark certificate
- Product Formula
- Product Packaging & Product Sample
- Quality & Safety specification
- Manufacturing Process & Flowchart
- Free Sale Certificate (imported)
- Sample Testing report
- Safety Assessment Report
- Efficacy Claim Evaluation - Only limited to sunscreen
- Product Implementation Standard - Only limited to domestic cosmetics
- Raw material information (COA) – if requested

NOTE: The product filing doesn't have an expiration date but requires regularly updates

New Regulation – Product Filing Dossier

- Application Form
- Product Name Explanation & Trademark Certificate
- Detailed product formula with raw material supplier information
- Detailed raw material information declaration
- Product Packaging & Product Samples
- Quality & Safety specification
- Manufacturing Process & Flowchart
- Free Sale Certificate (imported)
- Sample Testing Report
- Safety Assessment Report
- QMS/GMP/Manufacturing license of the production entity
- Efficacy Claim Evaluation
- Product Implementation Standard

**Finalised*

Applicant & Responsible Person

03

One of the latest additions to the cosmetics regulation is the rather extensive list of requirements to the “domestic responsible person”.
The responsible person is a legal entity that carries the responsibility for the safety of the cosmetic products sold in China.
No cosmetic product can be filed in China without a responsible person and the decision of a responsible person is thus the first step in a product filing process.

ROLE OF THE RESPONSIBLE PERSON IN CHINA

- Product Filing
- Distribution
- Sales
- Quality Management Control
- Product Quality and Safety
- Warehouse Control
- Complaint Handling and Other Customer Support
- Adverse Reaction Reporting & Product Recalls

Located in China

Must have an office (as officials conduct office inspections)

REQUIREMENTS

Must have or be renting a warehouse

Must have a cosmetic business scope

Suggested to have import/export license

At least 4-5 employees to be responsible for marketing, sales, distribution, product quality and safety, warehouse.

Establish well-structured quality management system, complaint handling system, recall system, etc.

There are totally **50 inspection items** according to which the officials will grade and evaluate the qualification of the responsible person during the on-site inspection.

DOMESTIC RESPONSIBLE PERSON GRADING SYSTEM

- CLASS A - **EXCELLENT**
- CLASS B - **GOOD**
- CLASS C – **SATISFACTORY**
- CLASS D - **UNQUALIFIED**

Entities graded as Class D will be regarded as unqualified and wouldn't be allowed to act as the Domestic Responsible Person

SOME OF THE INSPECTION ITEMS

- Business Operation Compliance
- Quality Management and Product Traceability System
- Incoming Goods Verification Record System
- Sales/Distribution Record System
- Procurement and Acceptance Record System
- Storage/Warehouse Inspection
- Product Shelf-Life Management System
- Product Safety& Quality System (goods return management, etc.)
- Cosmetics Adverse Reaction Reporting
- After-Sales Service Archiving

You can transfer the rights of your cosmetic product filings **between responsible person**.
E.g., transfer back to your own WFOE from your current responsible person.
Documents required:

- Completed application form
- Notarised POA
- Consent Letter stamped by previous responsible person

Efficacy Claim

04

EFFICACY CLAIM LIST

Code	Efficacy Claims
A	Others
01	Cleaning
02	Make-Up Remover
03	Moistening
04	Moisturizing
05	Beautifying/Decorating
06	Hair Style
07	Fragrance
08	Hair Care
09	Sunscreen
10	Freckle Whitening
11	Freckle Whitening (only physical coverage)
12	Anti-wrinkle
13	Tightening
14	Repairing
15	Soothing
16	Acne (including removing blackheads)
17	Oil controlling
18	Exfoliating
19	Cooling (including antiperspirant)
20	Hair dyeing
21	Hair Perming
22	Preventing Hair Loss
23	Preventing Hair Breakage
24	Anti-dandruff
25	Colored Hair Care
26	Depilatory
27	Deodorizing
28	Auxiliary Shaving

NOTE

Claim "others" is an indication of "cosmetics with new efficacy claim", i.e., cosmetics with the efficacy claim falling under "other" category will be classified as ***special cosmetics*** *in CSAR.*

NEW REQUIREMENT

Additional substantiation, such as testing, scientific evidence, consumer research: REQUIRED for all cosmetics apart from the exempted categories

Example:

"*Moisturising*" claim: REQUIRES Scientific Literature or Human test or Consumer survey or additional lab test

**Draft*

No.	Efficacy claim	Human evaluation test	Consumer trial test	Lab Test*	Literature or research data
1	Anti-hair loss	√			
2	Anti-Freckle& whitening ①	√			
3	Sunscreen	√			
4	Anti-Acne	√			
5	Nourishing ②	√			
6	Repair ②	√			
7	Anti-wrinkle	°	°	°	△
8	Firming	°	°	°	△
9	Soothing	°	°	°	△
10	Oil controlling	°	°	°	△
11	Exfoliation (non-physical)	°	°	°	△
12	Hair breakage prevention	°	°	°	△
13	Anti-dandruff	°	°	°	△
14	Moisturising	°	°	°	°
15	Hair care (conditioning)	°	°	°	°
16	Tear-free formula	√			
17	Suitable for sensitive skin	°	°		
18	Mild formula (no irritation)	°	°	°	△
19	Claiming quantitative indicators (time, statistics, etc.)	°	°	°	△
20	A new efficacy declaration	Choose the appropriate evaluation evidence based on the specific efficacy claims.			

DESCRIPTION:

√: Items marked with a **√** in the bar are mandatory items

°: The items marked with ° in the bar are optional items, but at least one of them must be selected

△: The items marked with △ in the bar are compatible items, but they must be used in conjunction with consumer trial test or lab test

① Only if anti-freckle & whitening effect is achieved by “physical application method” (such as foundation, face powder, etc.) and “physical coverage” is clearly stated on the label, the product efficacy evaluation **can be exempted**

② If the effective site is only hair, real hair in vitro can be selected for evaluation

NOTES:

*Lab test may include but not limited to animal tests, in vitro tests (in vitro organ culture, tissue culture, cells culture, microbial culture, etc.), physical tests, chemical tests, etc.

For special claims, such as anti-hair loss, sunscreen, etc. the efficacy claim tests shall be conducted in China by the NMPA authorized laboratories.
For general claims the efficacy claim tests can be conducted overseas

**Draft*

Cosmetic Efficacy Claim Declaration Form

The following information is required for the efficacy claim declaration form:

1. Product Chinese name
2. Product classification code
3. Basic information of the applicant
   - Name, address and contact information
   - Basic information of the responsible person in China if the applicant is overseas
4. Declare if it's a baby/children product
   - Usage method
   - Type of product – Rinse-off/Leave-on
5. Product form & usage area
6. Efficacy claim – Must be consistent with the one in codification system
7. Select the evaluation items
   - Scientific evidence
   - Data research
   - Human test
   - Consumer trial test
   - Lab test
8. Name and address of the evaluation institution

For human test evaluation:

1. Method name
2. Source of Method
3. Efficacy determination indicators
4. Timeline
5. Results

For consumer trial:

1. Method name
2. Source of Method
3. Test method – Research, interview, other
4. Data collection – Questionnaire, video, other
5. Timeline
6. Results

For lab test:

1. Method name
2. Source of Method
3. Test item
4. Timeline
5. Results

For literature & research data:

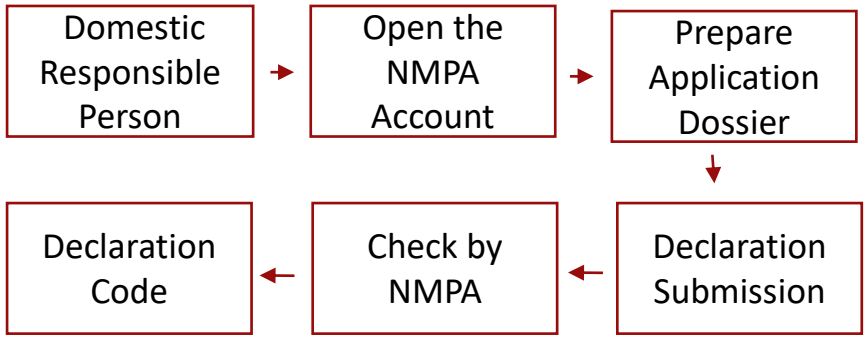
1. The method name, source, brief description of the research process, research results, etc.
2. For Literature materials: name of the literature and traceable source information
3. For regulatory reference: name of the regulation, source of basis, legal effect, etc.

Raw Material Declaration

05

Raw Material Declaration Process & Dossier

Declaration Process



Raw Material Declaration – Dossier

- Commercial name of raw material
- General information of raw material
- Brief description of production process
- Quality control requirements, such as identification method, quantitative control indexes & characteristic indexes test method, microbiological indicators, etc.
- Evaluation conclusions from International authoritative institutions
- Usage limit requirements of risky substances, etc.
- Water from special/polluted origin area shall be declared

NOTE: After the information submitted successfully, a "declaration code" for each raw material will be provided that would be used for cosmetics filing and registration.

**Finalised*

Animal Testing

07

OLD REGULATIONS

IMPORTED COSMETICS

Animal Testing is required for all the Imported Cosmetics

DOMESTIC NON-SPECIAL USE COSMETICS

Domestic Non-Special Use Cosmetics (apart from baby, other special categories) is exempted from animal testing

VS

NEW REGULATIONS

SPECIAL COSMETICS

Animal Testing is required for all Special Cosmetics

DOMESTIC & IMPORTED GENERAL COSMETICS

Might be exempted from animal testing if the applicant can comply with the exemption points:

- Certification of the production quality management system compliance issued by the cosmetics supervision authority of the country (region) of origin (**The requirements are not specified clearly)*
- Manufacturer shall conduct safety risk assessment confirming the safety of the products
- Products are not aimed at children or infants
- Products do not contain any new raw materials that are not included in the approved list of cosmetic raw materials
- Applicant , RA as well as actual manufacturing facility should not be target of additional supervision by the Chinese authorities (due to the score of the quantitative classification grading system)
- Applicant , RA as well as actual manufacturing facility have not been investigated and prosecuted for cosmetic quality and safety issues before

**Finalised*

Required application documents for manufacturing license in China:

1. Application form
2. Copy of business license
3. Copies of the identity certificates of the legal representative
4. Photocopies of the qualifications of the person in charge of quality and safety, such as the identity certificate, certificate of academic background or professional title, etc.
5. Certificate or evidence to prove legality of the used production site
6. The test report for air cleanliness and production water sanitation issued by the qualified inspection agency within one year
7. For the production of eye care products, infant and children skin care, the production site shall meet the requirements for the clean area of the production workshop specified in "*Guidance on Cosmetics Production and Quality Management*"
8. The general plan of the production site and the plan of the production workshop (including the layout of each functional workshop)
9. A brief description and flowchart of the production process
10. Document catalog of production quality management system and main equipment
11. Authorization letter of the handler

NOTE: The Cosmetic Manufacturing License regulation is based on ISO 22716

Foreign governments or relevant consulate/associations can take these requirements into consideration to apply for QMS/GMP certificate

Knudsen&CRC Checklist

08

- ☑ Secure your Trademark
- ☑ Ensure the ingredients belong to the approved ingredient list
- ☑ Ensure the packaging is compliant with the new requirements
- ☑ Secure CoA & Supplier information for the product raw materials
- ☑ To avoid animal test → secure the certification of the production quality management system & product safety assessment in due time
- ☑ Secure efficacy claim support & evidence
- ☑ Establish a legal entity
- ☑ Recruit the qualified team members to enable a fully functioning responsible person in China
- ☑ Set up Quality Management System & Handling systems in China
- ☑ Set up Adverse Reaction Monitoring & Evaluation system in China

Q&A

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www.knudsencrc.com

"You are welcome to contact us anytime with your questions and considerations"

How Brands Should Be Viewing China's Loosening Cruelty-Free Regulations

chinaskinny

8 April 2021

2020 Domestic Retail Sales

-3.9%

Imported Cosmetics

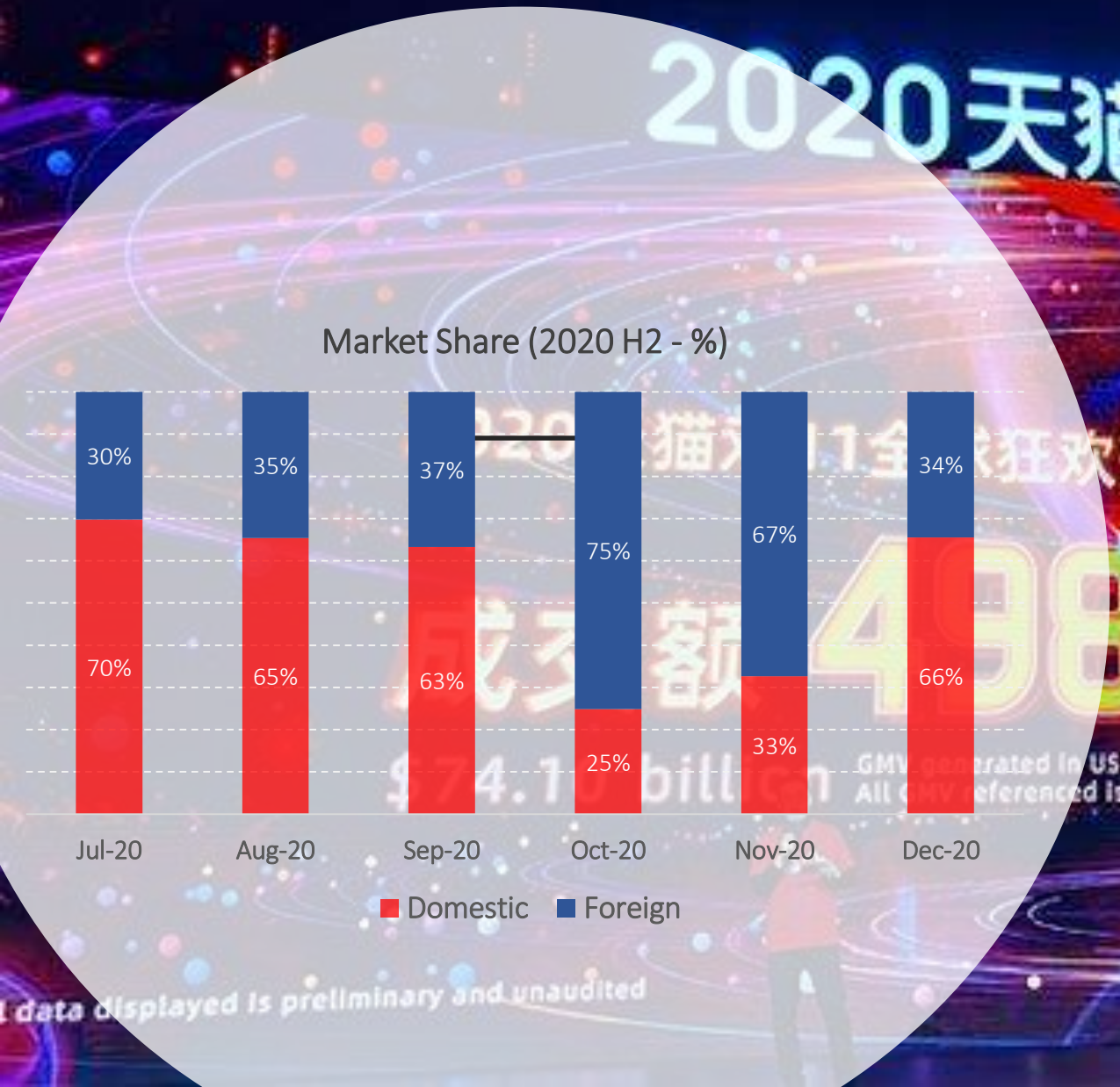
+30%

Source: China Ministry of Commerce

Cruelty-Free No Silver Bullet

chinaskinny

Foreign Brands Need to Create Habit



Foreign Skincare Brands' Claims are Less Personal than Domestic Brands

chinaskinny

SHISEIDO
GINZA TOKYO

官网购物理由 | 品牌故事 专柜导航

Mentions

Suits Chinese skin specifically

Big, global brand

Functional benefits (anti-aging, fights black heads, anti-wrinkles etc.)

endation

Friend/colleague recommendation

State-of-the-art technology

oducts

Organic certification

Additive-free/natural ingredients

Ave. Rank Value

Superior quality (regulations, high-quality ingredients)

ndorsement

Value for money

Beauty endorsement

Scandal-free record

fically proven results

f ingredients

Origin is important

Product discount

Eco/sustainable production

Eco-sustainable practices

cting

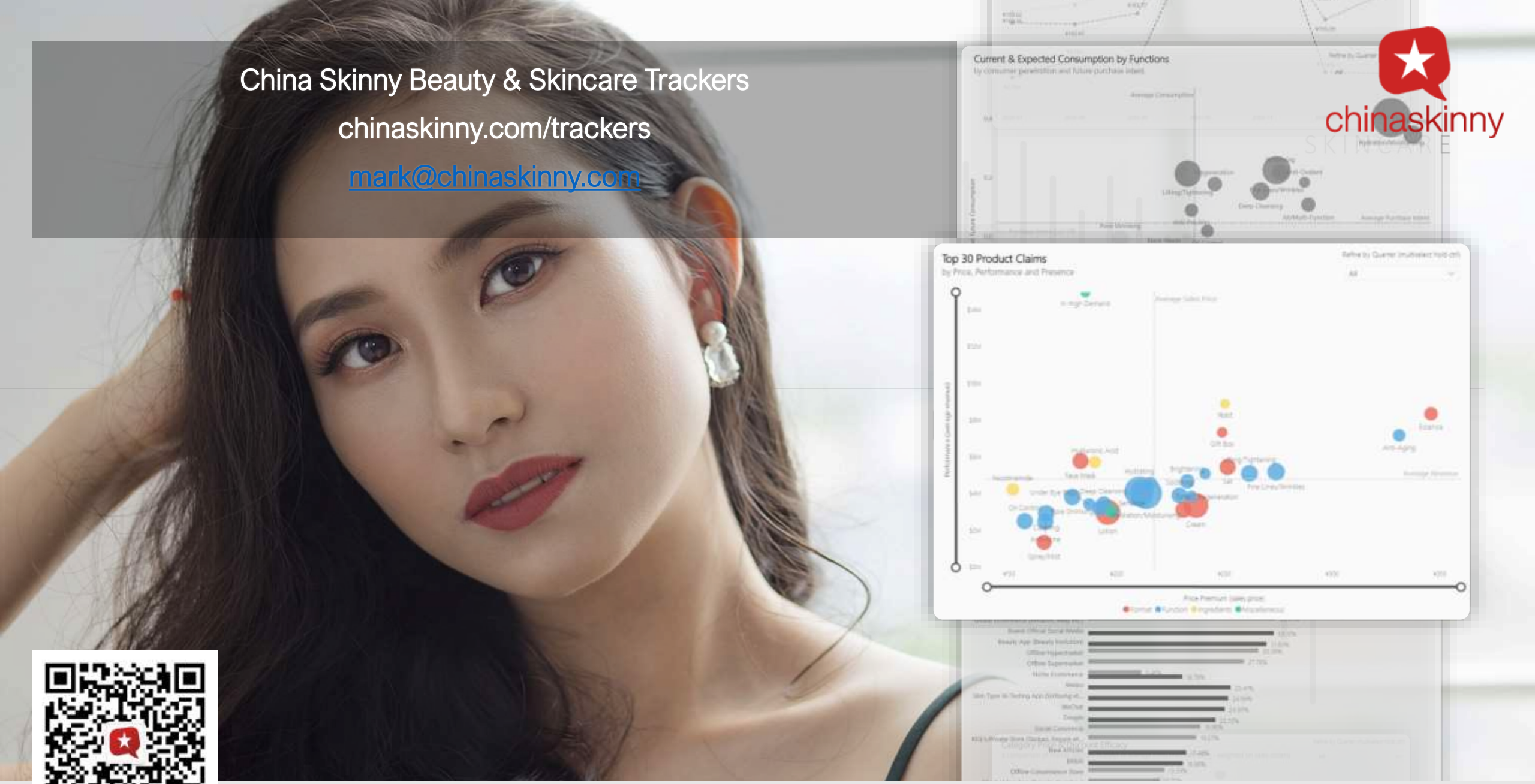
chinaskinny


chinaskinny
Quicker to Market
+ More SKUs

China Skinny Beauty & Skincare Trackers

chinaskinny.com/trackers

mark@chinaskinny.com



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