

Welcome!



# Latest Updates of CFDA Regulations on Cosmetics and New Cosmetic Ingredients in China



Date: 18 March 2014  
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CIRS China



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CHEMICAL INSPECTION  
& REGULATION SERVICE



# Latest Updates of CFDA Regulations on Cosmetics and New Cosmetic Ingredients in China 2013-2014



全球化学品法规  
服务专家

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# Summary of Main Changes - 2013-2014



- ❑ Imported non special use cosmetics will be registered with FDA at provincial level;
- ❑ Toothpaste is regarded as cosmetics;
- ❑ Online record-keeping will be available to domestic non special use cosmetics on 30<sup>th</sup> Jun 2014;
- ❑ Whitening product is considered as special use cosmetics;
- ❑ Animal tests no longer mandatory for non-special use cosmetics produced in China;
- ❑ IECIC 2014 draft version issued;
- ❑ New rules proposed for the management of new cosmetic ingredient registrations.

# Registration of imported non special use cosmetics

## Authority Change: CFDA -> Provincial FDA



Effective date	Authority	Dossier	Testing	Duration
30 Jun 2014*	CFDA -> Provincial FDA	No change	No change	Might be shortened

- \* Will be delayed as CFDA will take more time to assess if the provincial FDA is qualified to manage imported non special use cosmetics;
- \*\* Not all provincial FDAs are qualified at the moment.

## How to manage toothpaste in China?

### Before

- Not regarded as cosmetics;
- CFDA registration not required;
- Only customs clearance required.

### Now

- Regarded as cosmetics since Oct 2013.
- CFDA registration may be required in the future;
- CFDA is drafting detailed guidance.

## New record-keeping requirements for domestic non special use cosmetics

### New system

- Both pre-market record-keeping and post-market inspection;
- Online record-keeping of formula and packaging only;
- Other documents kept by manufacturer for future reference/inspections;
- No record-keeping certificate
- Available for search on CFDA's website

### Old system

- Post-market record-keeping.
- All materials are submitted to provincial FDA in hard copies;
- Record-keeping certificate issued;
- Not available online.

## Latest IECIC list

### □ IECIC 2014 draft

- 8641 ingredients
- Extracted from IECIC 2003 and finalized two batches of IECIC 2012

### □ IECIC 2014 final

- Time: no available
- Composition: IECIC 2003, IECIC 2012(final) and part of [new cosmetic ingredients listed in domestic non special use cosmetics](#)
- Quantity: More than 8641
- Regarded as the sole list to identify new cosmetic ingredient.

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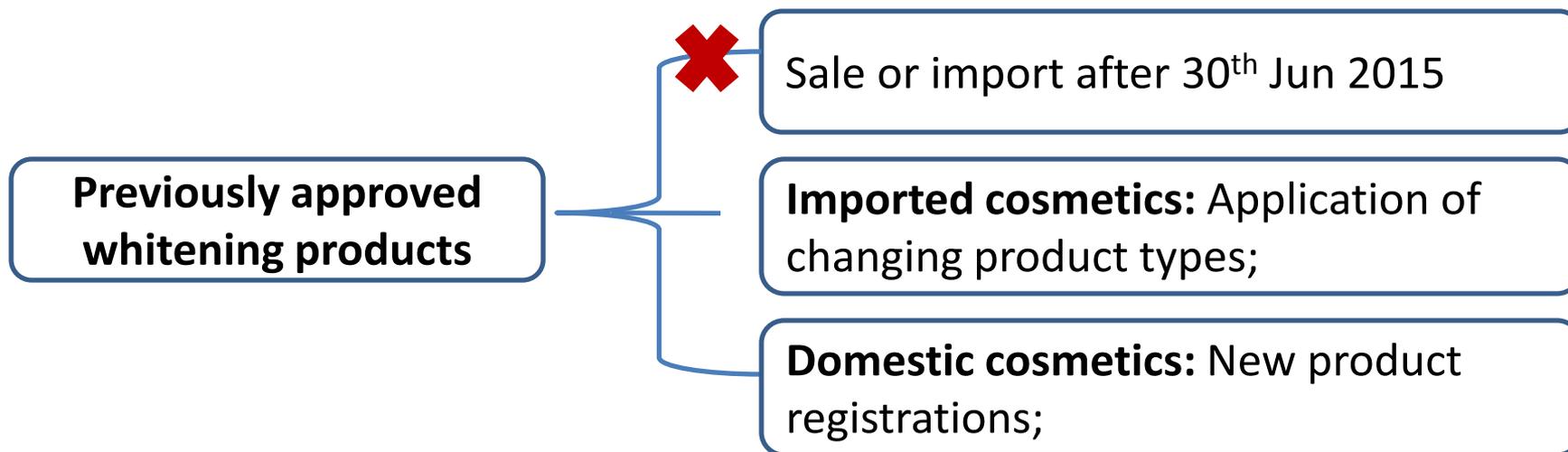
- Time: no available
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- Regarded as the sole list to identify new cosmetic ingredient.

**Existing cosmetic ingredient nominations open until 31 March 2014.**

# Management of Whitening Products



## □ Implications



# Registration Requirements for Whitening Products with Different Claims



Item	CFDA license	Testing items	Review process	Labeling
Type I*	Hygiene license for anti-freckle	As special use cosmetics for anti-freckle	As special use cosmetics for anti-freckle	n/a
Type II**	Hygiene license for anti-freckle marked with "Only for physical covering"	As non special use cosmetics	As non special use cosmetics	Marking with "Only for physical covering"

\* Having the claims of whitening skin or reducing skin pigment

\*\* Achieving the whitening effect via physical covering.

# Animal Testing Requirements for Cosmetics in China – Current System



## Imported and domestic non special use cosmetics\*

- Eye irritation
- Acute skin irritation
- Repeat skin irritation

## Special use cosmetics

- Eye irritation
- Acute skin irritation
- Repeat skin irritation
- Skin sensitization
- Skin phototoxicity
- Reverse mutation assay
- In vitro mammalian cell chromosome aberration

## Domestic non special use cosmetics for export only

- Testing is not required

\* Domestic non special use cosmetics consist of products manufactured in mainland China or products packed in mainland China.

# Animal Testing Requirements for Cosmetics in China – New System from 30 June 2014

## Imported non special use cosmetics

- Eye irritation
- Acute skin irritation
- Repeat skin irritation

## Special use cosmetics

- Eye irritation
- Acute skin irritation
- Repeat skin irritation
- Skin sensitization
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- Reverse mutation assay
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## Domestic non special use cosmetics for export only

- Testing is not required

## Domestic non special use cosmetics

- Testing can be waived based on the safety assessment result of ingredients.

# How to manage the registration of new cosmetic ingredient in the future?



## Current system

- **Existing cosmetic ingredient list for reference to determine new ingredient:**
  - IECIC 2003
  - IECIC 2012(Two final versions plus one draft version)
- **Each user or producer can use a new ingredient once it has been approved;**
- **No post-registration obligations on registrant.**

## Future system

- **Existing cosmetic ingredient list to determine new ingredient:**
  - IECIC 2014
- **4 Years of Protection Period for New Cosmetic Ingredient Registrants**
- **More Post-registration Obligations on Registrant ;**
- **New cosmetic ingredients may no longer be allowed in domestic non-special use cosmetics.**

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- ❑ **Toothpaste** is regarded as cosmetics;
- ❑ Online record-keeping will be available to **domestic non special use cosmetics** on 30<sup>th</sup> Jun 2014;
- ❑ **Whitening product** is considered as special use cosmetics;
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# Special Use vs Non Special Cosmetics



## Special use cosmetics

- Hair growth
- Hair dye
- Hair perm
- Depilation
- Breast shaping
- Fitness
- Deodorization
- Anti-freckle
- Sun block

## Non special use cosmetics

- Hair care
- Skin care
- Make-up
- Nail care
- Perfume

# Thank You!



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