



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



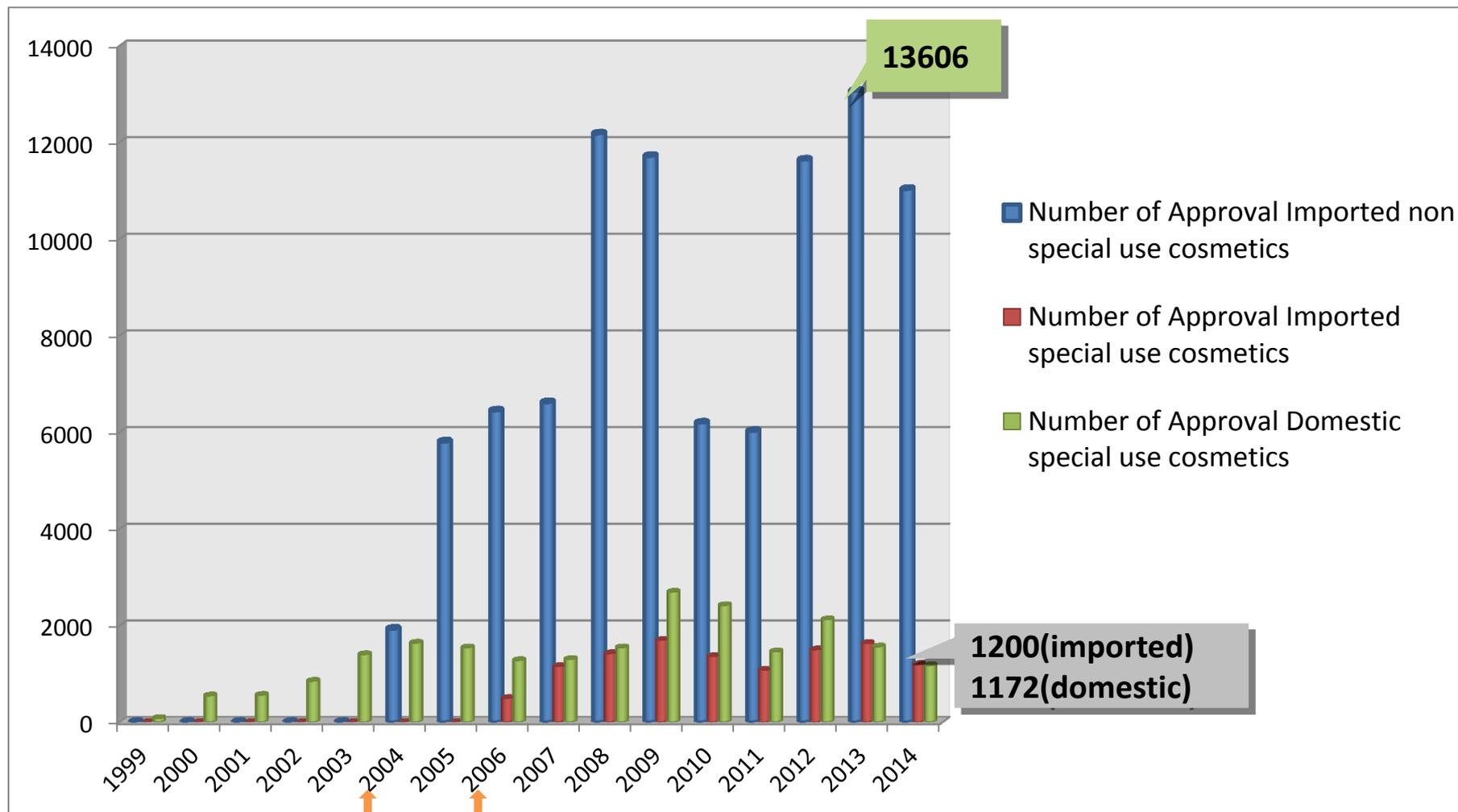
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Registration status of cosmetics in China (1999-2014)

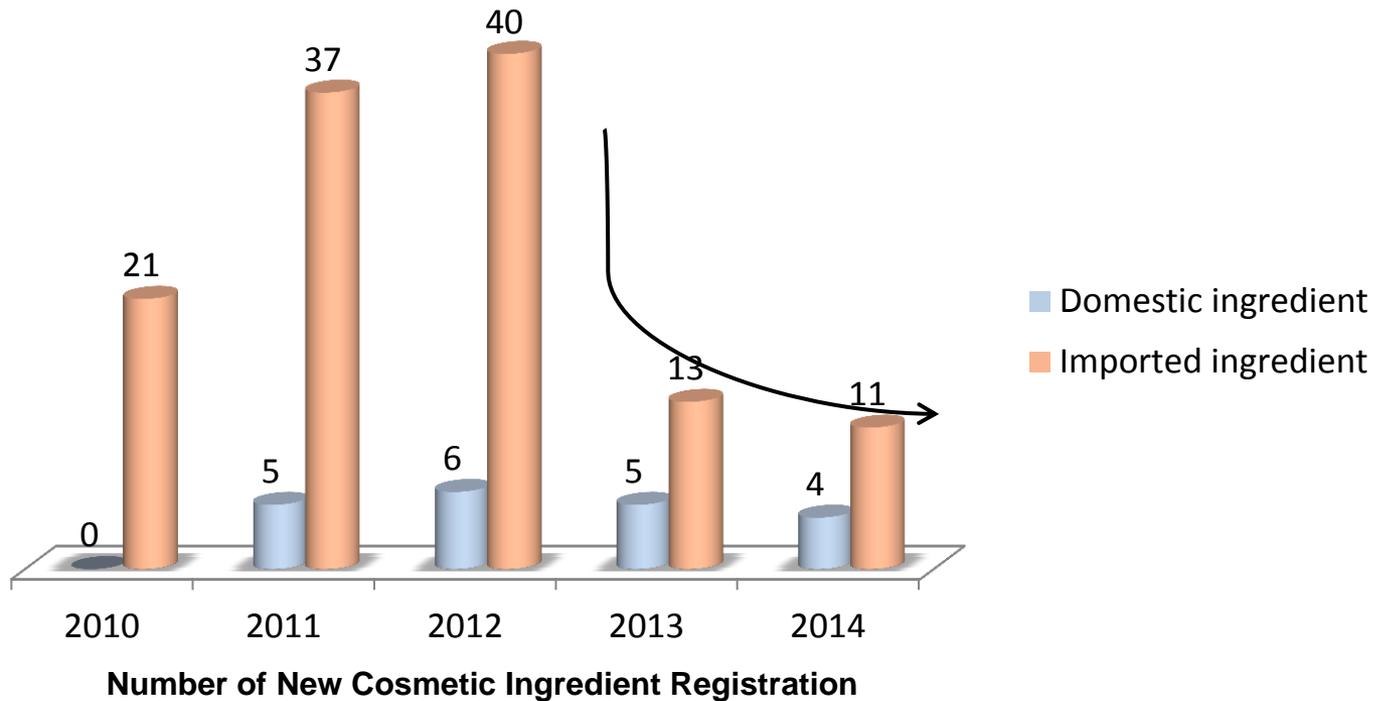


Registration Status of Special use Cosmetics in 2014

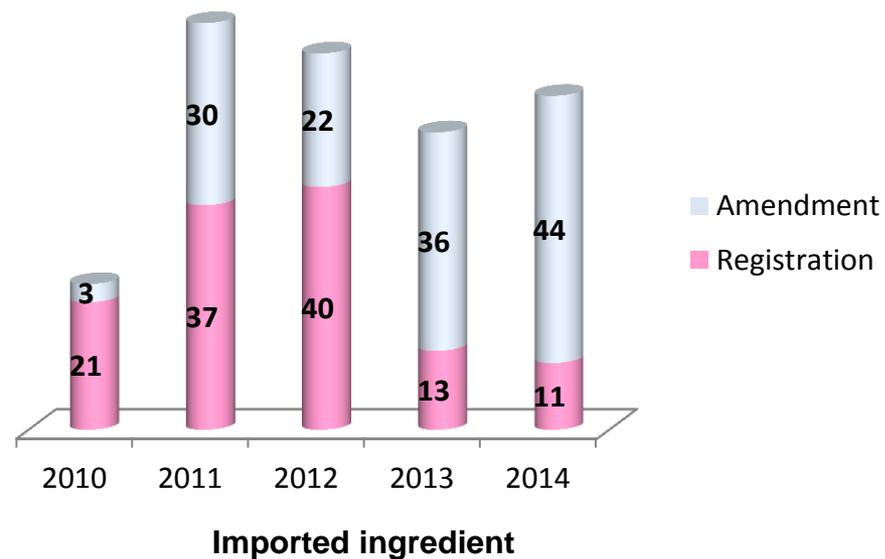
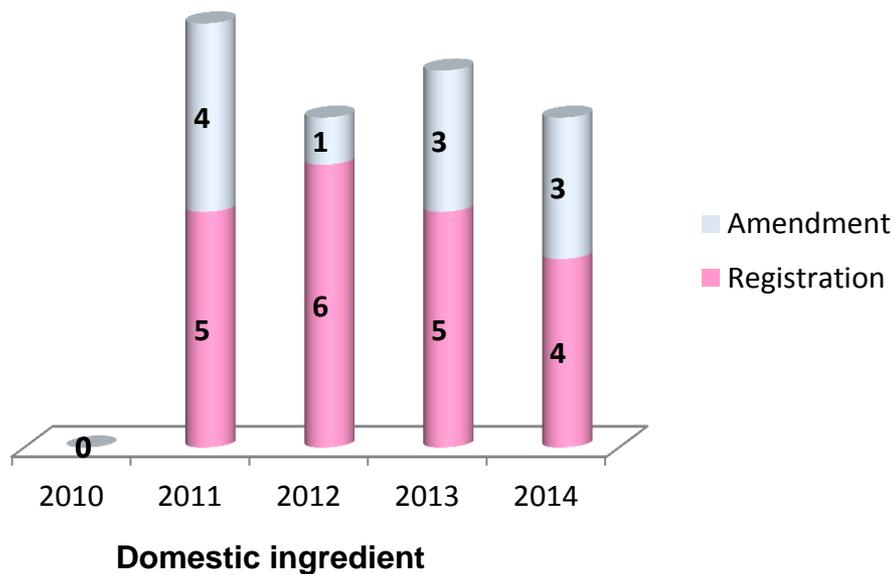


Subcategory	Domestic cosmetics	Imported cosmetics
Hair growth	30	11
Hair dye	411	222
Hair perm	25	9
Depilation	52	7
Breast shaping	5	0
Fitness	9	7
Deodorization	34	10
Anti-freckle	235	264
Sunblock	303	591

Registration status of new cosmetic ingredient in China(2010-2014)



Comparison with the number of amendment and registration between domestic and imported new cosmetic ingredient



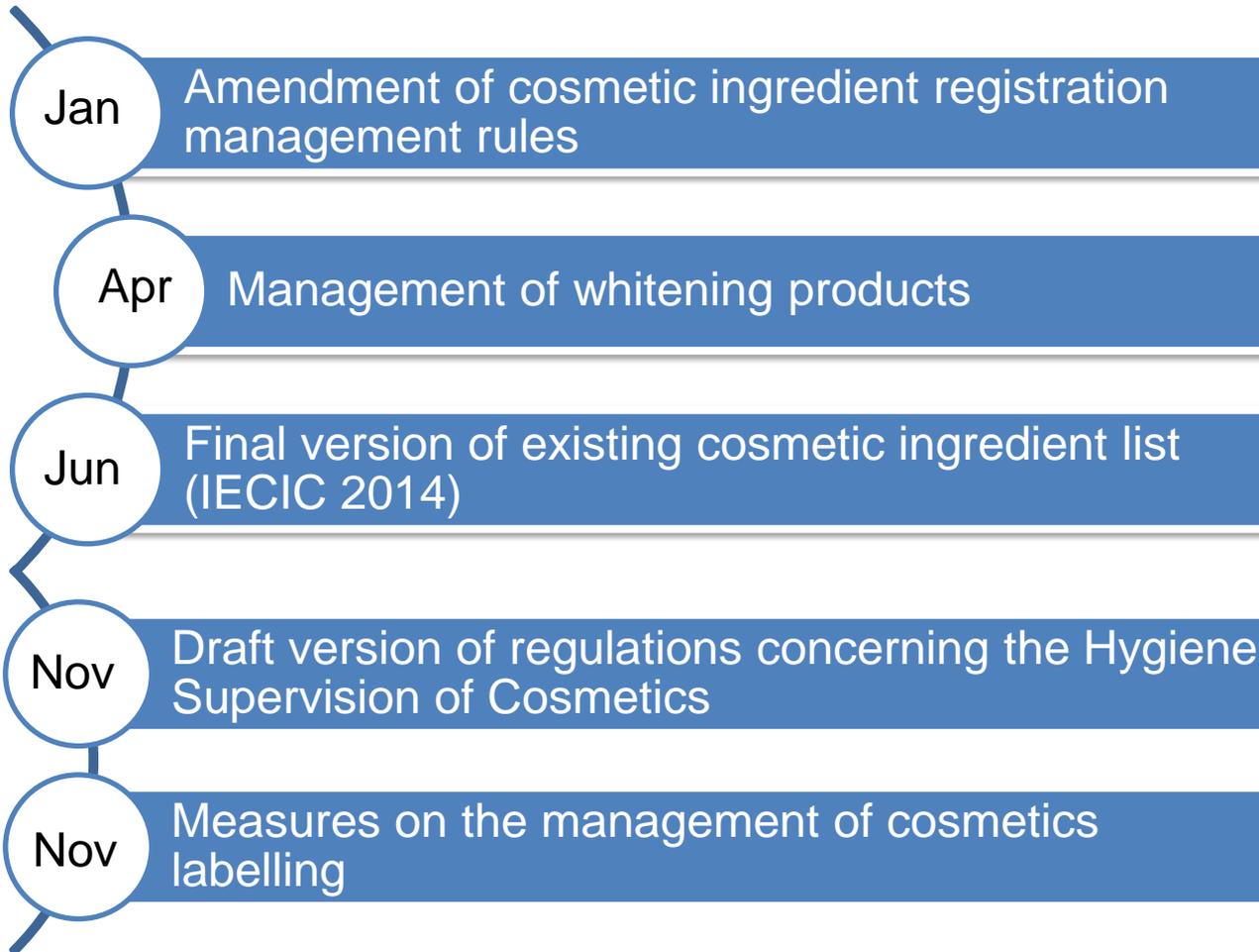
Approval new cosmetic ingredients since 2004



Approval new cosmetic ingredient	Approval time
ALKYL(C12-22)TRIMONIUM CHLORIDE(BROMIDE	14th Jun 2004
Potassium Methoxysalicylate	26 th Apr 2007
9.69% Methylisothiazolinone	28 th May 2007
CARNITINE TARTRATE	3 rd Jun 2008
LATHYRUS ODORATUS FLOWER EXTRACT	6 th Aug 2008
FRUCTOOLIGOSACCHARIDES	6th Aug 2008
POLYMETHACRYLOYL LYSINE	19 th Mar 2012
Dimethoxytolyl Propylresorcinol	19 th Mar 2012
Phenylethyl Resorcinol	5 th Dec 2012
Elaeagnus mollis diel Oil	30th Oct 2014

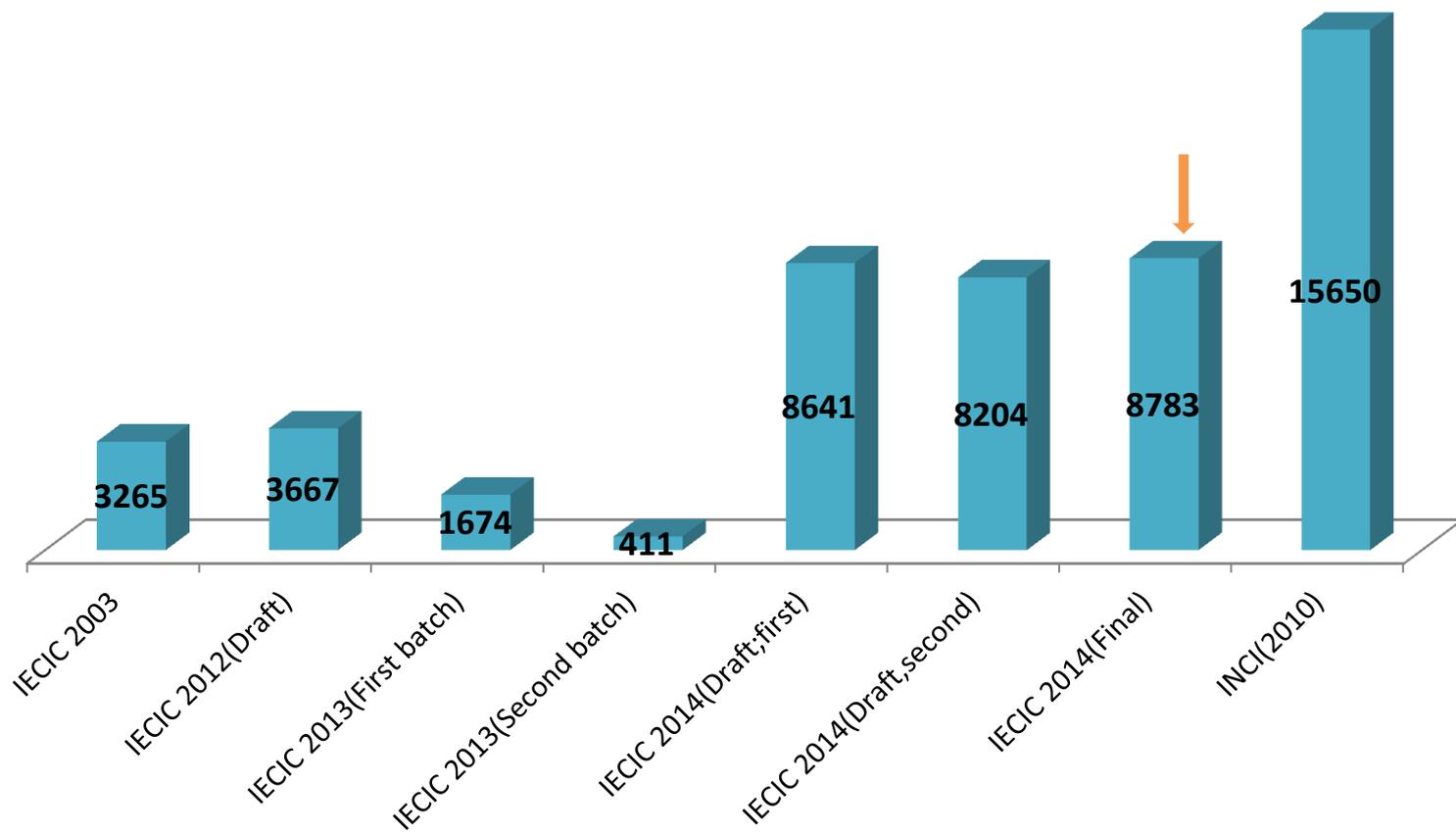
- ❑ The quantity of imported non special use cosmetics approved in 2014 reduced slightly;
- ❑ The quantity of imported and domestic special use cosmetics is nearly equivalent each year;
- ❑ CFDA taking a cautious attitude to approve special use cosmetics for breast shaping and fitness;
- ❑ The number of registering imported new cosmetic ingredient reduced sharply since 2013.
- ❑ The number of registering new cosmetic ingredient since 2010 is **122** for imported products and **20** for domestic products. Only **4** ingredients approved since 2010 and **10** new ingredients approved in 10 years;
- ❑ More and more foreign applicants taking negative attitude for new cosmetic ingredient registration

Latest Update of Cosmetic Regulations in China since 2014



Latest Update of Cosmetic Regulations in China





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



Old 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.**

New 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 are no longer be allowed in domestic non-special use cosmetics.**

Main issues of new cosmetic ingredient registration

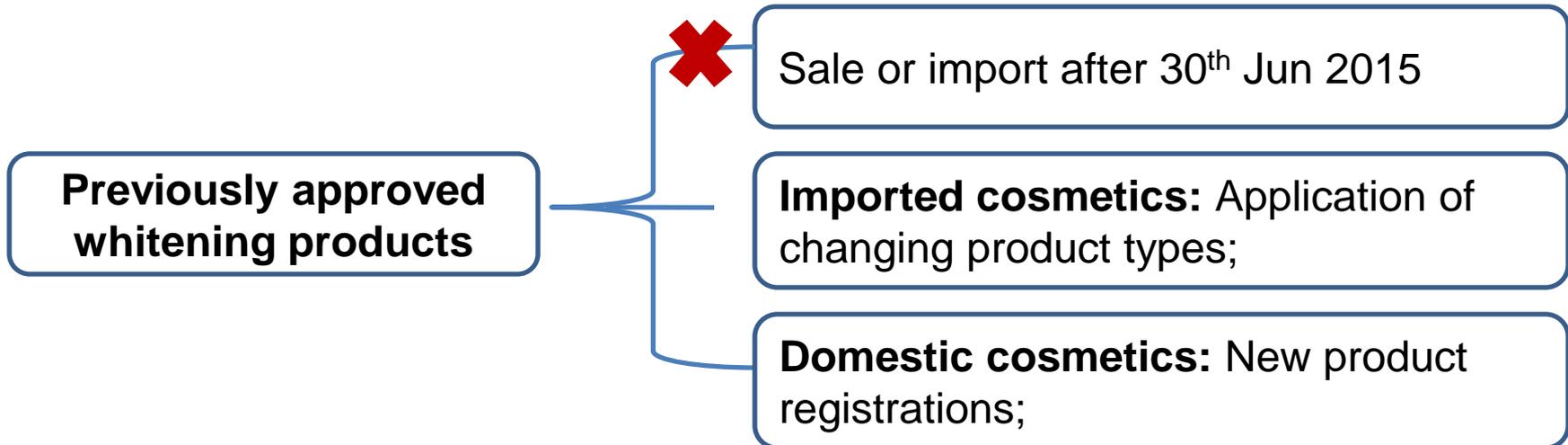


- ◆ Notified ingredient is a mixture
- ◆ Notified info shown on all registration materials is not consistent
- ◆ Non animal testing methods used
- ◆ Stability test performed on finished cosmetics
- ◆ Non supporting doc to prove the maximum use level in cosmetics

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.

Regulations concerning the Hygiene Supervision of Cosmetics(HSC)



Old HSC

1989

- Definition of cosmetics
- Management of cosmetic ingredient
- Management of special use and non special cosmetics
- Management of CFDA license
- Requirements of applicant for the approval of cosmetics
- Supervision of cosmetics sold via E-commerce
- Measures on cosmetics having quality issue
- Monitoring of adverse effect

New HSC(draft)

2014

1) Definition of cosmetics

Old

Daily used industrial chemicals which can be spread on the outer surface of human body (e.g. skin, hairs, nails. Lips etc) for the purpose of cleaning, deodorizing, providing skin care, beauty and make up by way of smearing, spraying or other similar means.

New

Products which can be spread on the outer surface of human body((e.g. skin, hairs, nails. lips etc), **teeth and oral mucosa** for the purpose of cleaning, protecting, beautifying, decorating and keeping in good condition by way of smearing, spraying or other similar means

Comparison between the old and new HSC



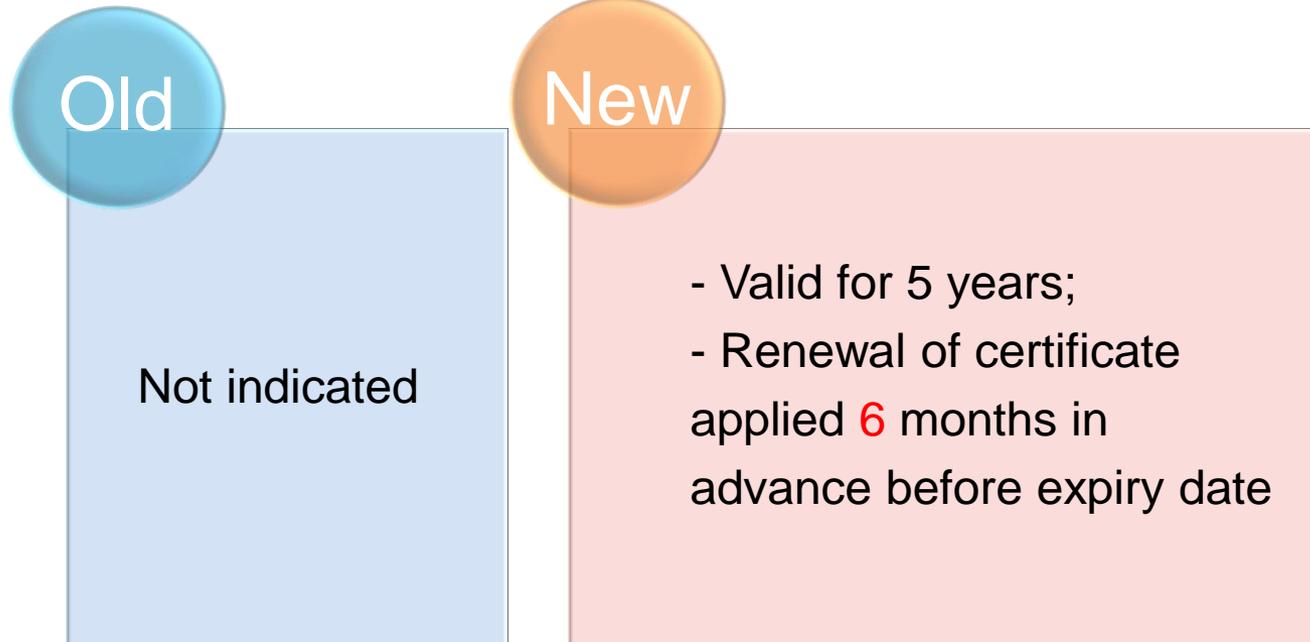
2) Management of cosmetic ingredient

Item	Old HSC	New HSC
Competent authority	MOH	CFDA
Definition of new cosmetic ingredient	The artificial or natural raw materials have never been used in cosmetics in China	The artificial or natural raw materials not listed in the Inventory of Existing Cosmetic Ingredient in China (IECIC)
Sort management	Not indicated	<ul style="list-style-type: none">✓ Banned ingredients✓ Restrictive ingredients✓ Specific ingredients allowed to use✓ Approval ingredients
Evaluation of new cosmetic ingredient	Not indicated	Approval ingredient without the risk of safety will be added into the IECIC list after 4 years

3) Management of special use and non special use cosmetics

Item		Old HSC	New HSC
Special use cosmetics	Competent authority	MOH	CFDA and local FDA
	Scope of special use cosmetics	Hair growth, hair dye, hair perm, deodorization, depilation, fitness, breast shaping, anti-freckle and sunblock	Hair dye, hair perm, whiteness , sunblock and other products with high level of safety risk
Non special use cosmetics	Competent authority	Not indicated	FDA at provincial level
	Import and sale activity of imported cosmetics	Not indicated	Available without receiving any official notice of failed record keeping within 20 working days after format review;

4) Management of CFDA license



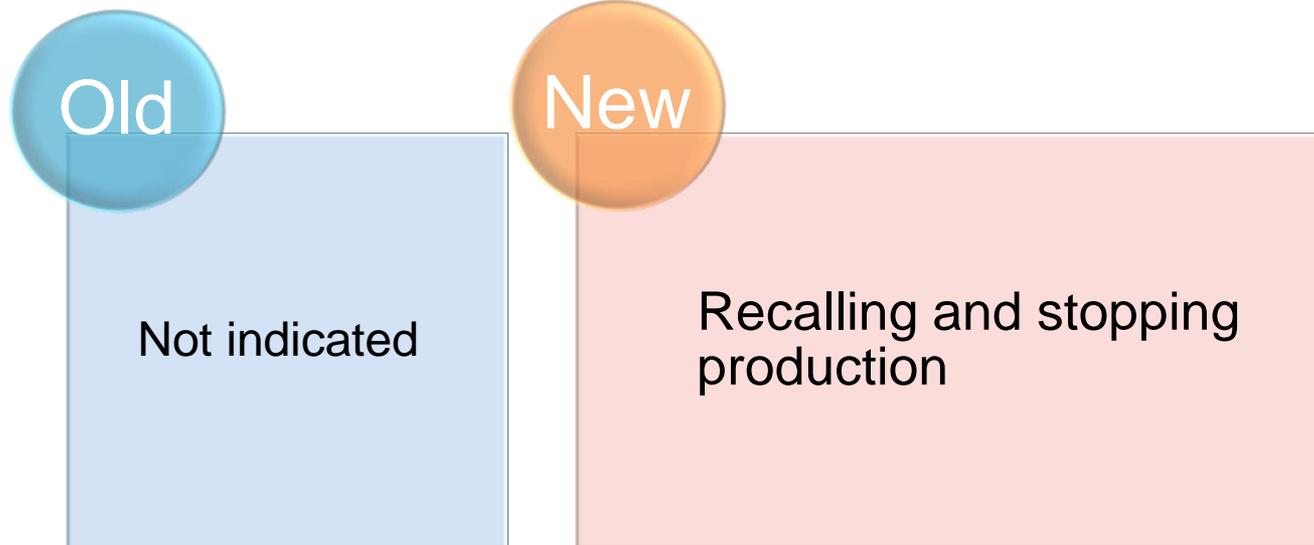
5) Requirements of applicant for the approval of cosmetics



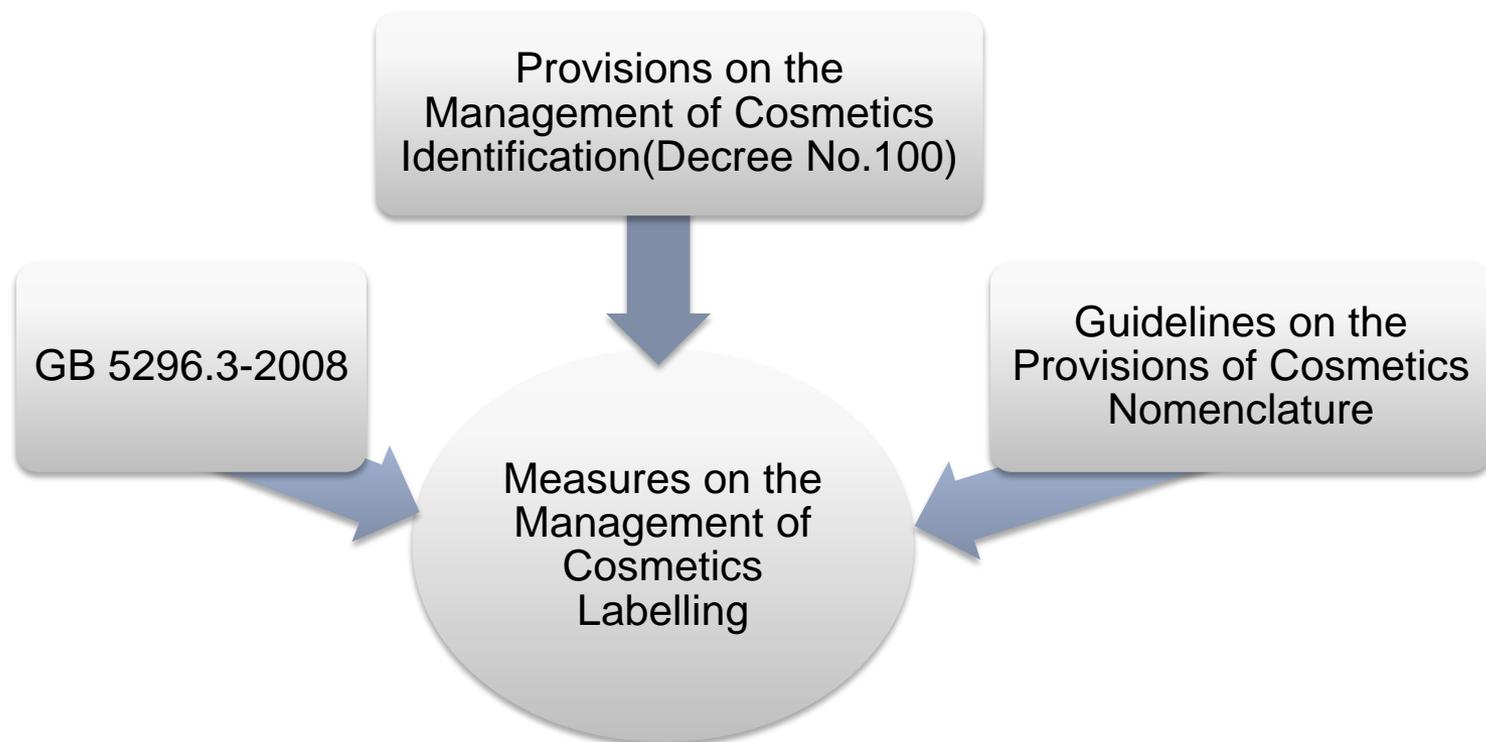
6) Supervision of cosmetics sold via E-commerce

Old	Not indicated
New	<ul style="list-style-type: none">- Each production operator of online cosmetics has to be registered in real name with the third-party platform of e-commerce.- The platform undertake the compensation if not transferring the real name, address and contact info of operator to the sufferers

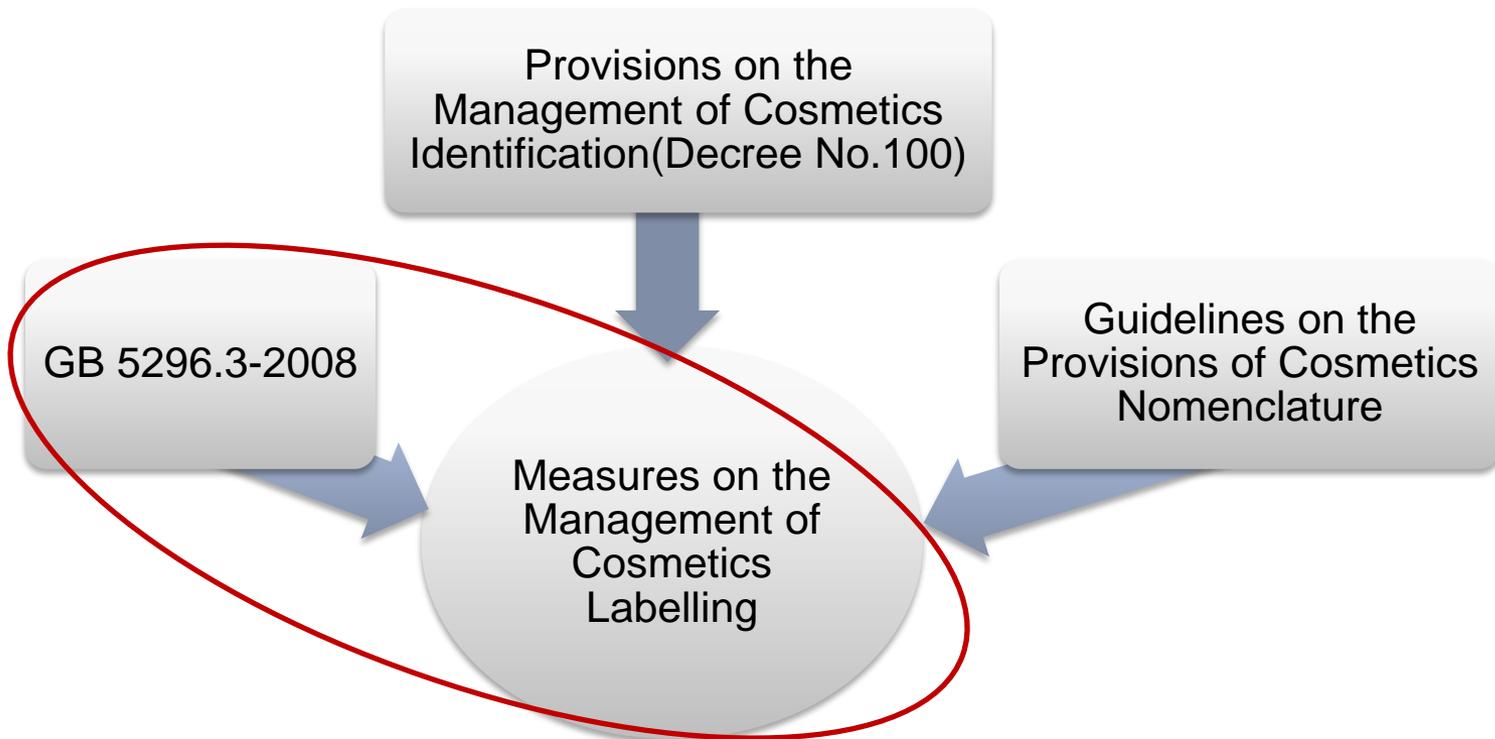
7) Measures on cosmetics having quality issue



Measures on the Management of Cosmetics Labelling



Measures on the Management of Cosmetics Labelling



General information of new cosmetic labelling regulation



Legal basis	Chinese Product Quality Law and Regulations Concerning the Hygiene Supervision of Cosmetics
Applicable scope	Cosmetics produced and sold in China
Supervision body	CFDA
Effective date	1 st Jul 2015
Registered label for public search	Available

Main differences (new labelling regulation, GB 5296.3-2008 and Decree No.100)



Item	Measures on the Management of Cosmetics Labelling	GB 5296.3-2008	Decree No.100
Definition of cosmetics	Not indicated	Products which can be spread on the outer surface of human body((e.g.skin, hairs, nails. Lips etc), for the purpose of cleaning, perfuming, changing appearance, deodorizing, protecting, and keeping in good condition by way of smearing, spraying or other similar means.	Products which can be spread on the outer surface of human body(e.g. skin, hairs, nails. Lips and teeth etc) for the purpose of cleaning, protecting, beautifying, decorating, changing appearance, deodorizing and keeping in good condition by way of smearing, spraying or other similar means.

Main differences (new labelling regulation, GB 5296.3-2008 and Decree No.100)



Item	Measures on the Management of Cosmetics Labelling	GB 5296.3-2008	Decree No.100
Innovative claiming	Clarification of the meaning	Not indicated	Not indicated
Labelling language	All contents are in Chinese except trademark, overseas company address and conventional glossary	Not indicated	Not indicated
Efficacy claiming	Described as “ The efficacy has not been evaluated ” if there is no sufficient testing or evaluation data	Not indicated	Not indicated
Warning words	Requested for specific ingredients, specific group and inflammable cosmetics	Available if needed	Requested for products used in children, easy to damage, or to endanger human

Main differences (new labelling regulation, GB 5296.3-2008 and Decree No.100)



Item	Measures on the Management of Cosmetics Labelling	GB 5296.3-2008	Decree No.100
Name and address of manufacturer	- Required for both imported and domestic cosmetics. - Name and address of Chinese responsible agent for imported cosmetics	Not required for imported cosmetics	Not indicated

Comparison with labelling content between new and current regulation



Labelling content of imported cosmetics

New

- Product name
- Name and address of manufacturer responsible for product quality and safety
- Name and address of actual production enterprise
- Name and address of Chinese responsible agent
- Country(region) of origin
- Approval or record-keeping number of cosmetics
- Full ingredient list
- Net weight
- Shelf life
- Other required info

Current

- Product name
- Name and address of importer, distributor or agent
- Country(region) of origin
- Approval or record-keeping number of cosmetics
- Full ingredient list
- Net weight
- Shelf life
- Other required info

Comparison of labelling content between new and current regulation



Labelling content of domestic cosmetics

New

- Product name
- Name and address of manufacturer
- Name and address of actual production enterprise
- Numbers of sanitary license of cosmetic manufacturer and product standard
- Approval or record-keeping number of cosmetics
- Full ingredient list
- Net weight
- Shelf life
- Other required info

Current

- Product name
- Name and address of manufacturer
- Name and address of actual production enterprise
- Numbers of **production license**, sanitary license and product standard
- **Mark of production license**
- Approval or record-keeping number of cosmetics
- Full ingredient list
- Net weight
- Shelf life
- Other required info

CIRS comments on the change of regulations



1

Oral care products including toothpaste and mouth wash regarded and managed as cosmetics

2

Special use cosmetics classified in terms of the level of safety risk

3

Online record-keeping available for imported non special use cosmetics

4

A qualified assessor of safety evaluation has a professional background of medical science, pharmacy, nursing or a certain period of working experience.

5

The role of Chinese responsible agent is close to the responsible person in EU

6

Safety assessment report has to be signed by qualified assessor or third party

7

The definition of new cosmetic ingredient changes with the issue of final IECIC 2014

CIRS comments on the change of regulations



8

Imported non special use cosmetics available to carry out import and sale activity before certificate issue

9

Market of online cosmetics tend to be more orderly and regulated

10

Chinese sticker not accepted for imported cosmetics sold in China

11

The info of Chinese responsible agent required for the label of imported cosmetics

12

CFDA will not designate lab for the efficacy test. Qualification certificate of lab and efficacy testing report available to search for public

13

“QS” mark and number not needed to label for domestic cosmetics

14

Supervision body of labelling management is changed from AQSIQ into CFDA

16

CFDA adjust the list of banned words (eg.gene, factor, stem cells, interferon, blood capillary, anti-redness, dark circles, cosmeceuticals, etc). Sufficient documentary evidence required for the claiming of sensitivity, nanometre, free of additives, pure nature, pure plant and organic

Thank You!



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