Investigation Report on Regulation Status of Domestic Non-special Use Cosmetics Related Animal Testing

REACH24H Consulting Group China

To: Humane Society International

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Report No: REACH24H-2016-E28592-01

Date: 18th May 2016

Catalogue

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1. Background

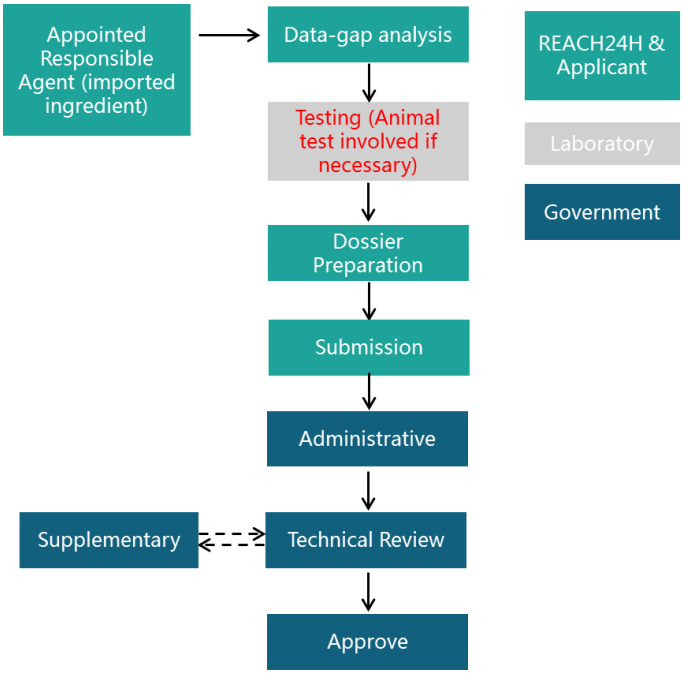
1.1 Definition and Category

Currently, the Chinese cosmetic market ranks as the third largest globally and is also the worlds' emerging market, exhibiting the greatest average annual growth rate. Before being used, marketed or imported into China, cosmetic products must get approval from China Food and Drug Administration (**CFDA**) or provincial FDAs according to the product category. In China, cosmetic products are divided into two categories, non-special use cosmetics (**Non–SUC**) and special use cosmetics (**SUC**). Non–SUC means skin care products, hair care products, nail (toe) care products. Special use cosmetics contain 10 kinds which is hair growth products, hair dyes, hair perming products, depilating products, breast beauty product, slimming products, deodorant, freckle-removing products, sunscreens, whitening and anti-spot products. Also, cosmetics in China will be divided into domestic products and imported products based on the manufacture place. If the final manufacturing procedure is undertaken in China, e.g. repack in China, these cosmetics should be defined as domestic cosmetics. At present, imported cosmetics, domestic special use cosmetics and new cosmetic ingredients are required for pre-market registration with CFDA, while domestic Non-SUC are subject to post-market filing with the provincial FDA.

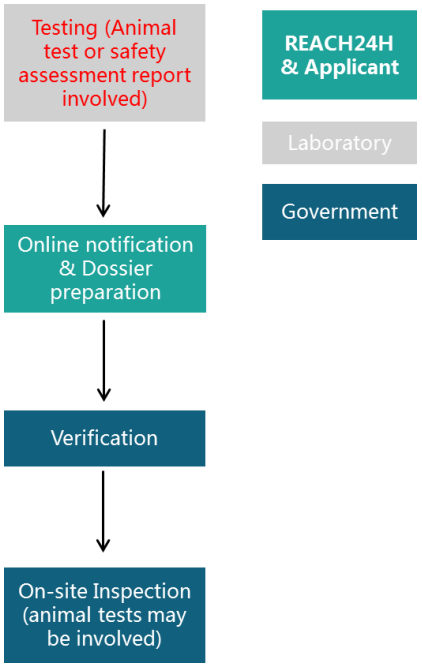
1.2 Regulation Status on Domestic Non–SUC

Cosmetics manufacturers shall notify provincial FDA through an online platform of the product formula and sales packaging (including labels and instructions for use) prior to marketing. Applicants are required to record the product information, including formula, packaging, description of production process, product technical requirements and testing reports for future examination. In order to assist producers in China, CFDA has prepared a guidance document, **Administrative Measures on Filing of Domestic Non-Special Use Cosmetics** in 2011, which details all information required and the filing procedures. And from 30 June 2014, **Requirements for Record Keeping Documents of Domestic Non-Special Use Cosmetics** came into force to replace the above measurement. Therefore, according to Requirement, although for imported cosmetics, animal testing is still necessary for registration with China Food and Drug Administration (CFDA), for the domestically manufactured non special use cosmetics, there are some other options to substitute the animal testing when some rigorous requirements are met for different situations.

There will be two different scenarios on the notification depending on whether new ingredients involved. One is that domestically manufactured non-SUC that contain new ingredient to China, which means it will need to register the new ingredient first (**Scenario 1**), another one is domestically manufactured non–SUC using only ingredients listed in the Inventory of Existing Cosmetic Ingredients in China 2015 (**Scenario 2**).



Procedure of scenario 1: New ingredient registration



Procedure of scenario 2: Domestic non-SUC notification

For both scenarios, the companies can still choose to submit the traditional animal test report. Since for some small and medium enterprises, follow traditional and conservative ways to finish the notification is an easier way. They don't need make any change from past. After all, they have to spend some time researching the new regulation articles, hiring a toxicological expert or finding a professional and trustful third party to help them finish safety assessment report if they choose the new way. And the passing rate won't be influenced no matter what approach they choose.

Based on our investigation, the safety assessment reports have been well accepted by Zhejiang FDA, Guangdong FDA, Shanghai FDA, and Jiangsu FDA, Beijing FDA and Fujian FDA without triggering any animal test. The percentage of domestic non-SUC notified in these provinces is nearly 90%. Indeed, it is difficult for small and medium enterprises to build a team or even hire a toxicological expert to finish the safety assessment report. However, now many professional third parties and testing agencies which have been authorized by CFDA can provide a complete set of service, and no matter based on price or time period, choosing safety assessment has advantages. For example, the price of the whole test including toxicological test for a domestic non-SUC is more than 4000rmb in a common test agency, by contrast, choosing safety assessment report only needs less than 1000rmb.Therefore, a third party like REACH24H, the experts have finished more than 400 safety assessment report in less than 5 months and all well accepted by different province FDAs mentioned above. Apparently, manufacturers prefer safety assessment report to animal test for now.

2. Requirements for Domestic Non-SUC Containing New Ingredients

2.1 Toxicological Endpoints Requirement

Based on article 9 of the < Regulation of Hygienic Supervision over cosmetics> (1989) requires that any new cosmetic ingredients should be approved by Ministry of Health (MoH),currently CFDA, prior to firstly being used in cosmetic products for commercial purpose . The new ingredients are defined as a natural or artificial ingredient that is firstly used in cosmetic products in China and the sole source of check list, Inventory of Existing Cosmetic Ingredient in China (IECIC 2015), also have been issued by CFDA. Currently, the application dossier required by CFDA should contain a detailed toxicological profile.

The generally required toxicological endpoints are 10 items:

1. Acute toxicity (oral and dermal)
2. Irritation/Corrosion (dermal and eye)
3. Skin sensitization
4. Photo-induced toxicity and sensitization
5. Mutagenicity/Genotoxicity
6. Sub-chronic toxicity (oral and dermal)
7. Teratogenicity toxicity
8. Chronic toxicity/Carcinogenicity
9. Toxicokinetics
10. Based on the properties and usage of raw materials, other necessary tests might be included. If the raw material has similar chemical structure and properties with a raw material that has been used in cosmetics, the tests might be reduced.

The specified toxicology data is a principled requirement. The tests might be increased or reduced based on the physico-chemical properties, quantitative structure-activity relationship, toxicology data, clinical trials, human epidemiological study and the toxicity of similar compounds.

According to Guidance on Application and Review of New Cosmetic Raw Materials (2011), 5 categories of ingredients could reduce toxicological requirement.

1. General ingredient: Ingredient without intention to be listed as restricted substance, preservative, UV filter, colorant or hair dye.
2. Listed general ingredient: Above general ingredient which have been included in related list of regulated ingredient for over 4 years and have not been reported that it can cause any human health hazard.
3. Edible ingredient: Ingredient with edible history or approved by Chinese or other national authorities for food.
4. Polymer ingredient: Polymer that one or more than one structure units linked by covalent bond and average relative molecular mass is over 1000 Da.
5. Reviewed new ingredient: any new ingredient which has been subject to safety evaluation by oversea recognized institutes, such as SCCS or CIR, or approved by the authorities.

The exempted endpoints (marked as 'X') related the special new ingredients present below

Exempted Endpoint	General ingredient	Listed general ingredient	Edible ingredient	Polymer ingredient	Reviewed new ingredient[3]
Acute toxicity (oral and dermal)	√	√	X	X	X
Irritation/Corrosion (dermal and eye)	√	√	√	√	X
Skin sensitization	√	√	√	X	X
Photo-induced toxicity and sensitization[1]	√	√	√	√	X
Mutagenicity/Genotoxicity	√	√	X	X	X
Sub-chronic toxicity (oral and dermal)[2]	√	X	X	X	X
Teratogenicity toxicity	X	X	X	X	X
Chronic toxicity/Carcinogenicity	X	X	X	X	X
Toxicokinetics	X	X	X	X	X

Note:
1. Only required if the ingredient has UV absorption properties (For polymer, only photo-induced toxicity is required)
2. If oral intake is highly possible, sub-chronic oral toxicity should be chosen.
3. Evaluated reported, result and other documents should be submitted. If the ingredient has been approved, the approval certificates should also be submitted.

2.2 Test method requirement

Although testing report, scientific literature, published information on the website of government or international organization can be used to replace the animal test, the animal testing alternatives including 3T3 NRU photo toxicity test (OECD No.432) still are not able be accepted by CFDA. In other words, if a safety evaluation with in-vitro data offered by even an overseas recognized institute is used for the safety assessment, those tests mentioned before would not be waived for a reviewed new ingredient. Nowadays, the only source of test method accepted by CFDA is from <Cosmetics Hygienic Standard (2007 version)>, and <Safety and Technical Standard for Cosmetics> will come into effect to replace it from 1st, December, 2016.

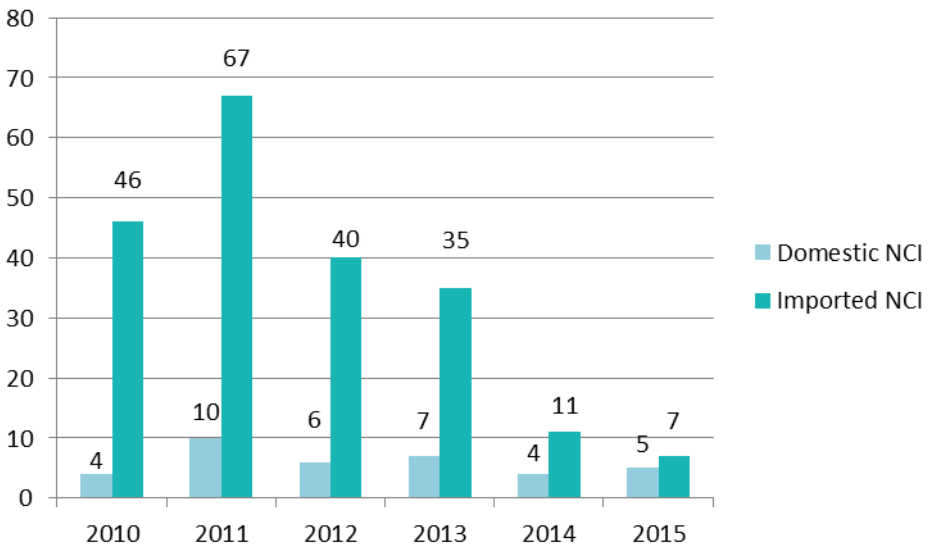
Test item	Test category	Reference (if available)	Duration (Month)	Number of animal per test
Acute oral toxicity test	In Vivo	OECD No.401 UESPA OPPTS Series 870.1100	2	40-60 adult rats or mice
Acute dermal toxicity test	In Vivo	OECD No.402 UESPA OPPTS Series 870.1200	2	40-60 adult rats or mice

Dermal irritation/corrosion test	In Vivo	OECD No.404 USEPA OPPTS Series 870.2500	1.5 / 2.5 (Repeated dermal irritation test)	At least 4 albino rabbits
Acute eye irritation/corrosion test	In Vivo	OECD No.405 USEPA OPPTS Series 870.2400	2	At least 3 albino rabbits
Skin sensitization test	In Vivo	OECD No.406 USEPA OPPTS Series 870.2600	3	A minimum of 20 animals is used in the treatment group and at least 10 animals in the control group
Skin photo toxicity test	In Vivo	/	1.5	6 animals
Salmonella typhimurium/Reverse mutation assay	In Vitro	OECD No.471	2	/
In vitro mammalian cells chromosome aberration test	In Vitro	OECD No.473	3	/
In vitro mammalian cell gene mutation test	In Vitro	OECD No.476 GB15193.12;20-2003	4	/
In vivo mammalian bone marrow cell chromosome aberration test	In Vivo	OECD No.475	2.5	At least 5 mice or rats per sex per group
Mammalian erythrocyte micronucleus test	In Vivo	OECD No.474 GB 14924	2.5	At least 50 rats or mice
Testicle cell chromosome aberration test	In Vivo	GB15193.8-2003	3.5	At least 25 mice
Subchronic oral toxicity test	In Vivo	OECD No.408	9	At least 80 rats
Subchronic dermal toxicity test	In Vivo	OECD No.411	9	At least 80 animals
Teratogenicity test	In Vivo	GB15193.14-2003	6.5	At least 48 adult rats
Combined chronic toxicity / carcinogenicity test	In Vivo	OECD No.453 GB14924	36-48	At least 400 animals

2.3 Case Analysis

Based on the different ingredient types mentioned before and our experience, for the edible ingredient and polymer ingredient, the testing time is about 3 months, on the other hand, for the general ingredients it's about 6 months considering the sub-chronic toxicity test. The "worst "case, if total test items should be taken, 2-3 years is a conservative estimate.

Since the risk of new ingredient and conservative attitude of CFDA, the approval standard is rigorous. During 2004-2015, only 10 new ingredients have been approved by CFDA and MoH. The chart of new application case in every year was shown below. Around July 2013, Kanebo Skin-whitening Products, which is expected to be around 450,000 products, are recalled in Asia and UK because the active ingredient, Rhododendrol, caused skin problem, and over 8000 customers were affected except Chinese Mainland Market since the application of problematic ingredient Rhododendrol did not get approval of CFDA[1].



The first application of every year new cosmetic ingredients

Except for impurity substance, toxicological study is vital part of application dossier. Missing some endpoints is the main reason for some failure case. For example, an ingredient without data of photo-induced sensitization and toxicity did not illustrate its UV absorption properties, either.

After getting approval, the ingredient can be used in cosmetic products. However, if the substance has not been listed in the Inventory of Existing Chemical Substance manufactured or Imported in China (IECSC), it should be notified under China New Chemical Substance Notification (China NCSN) based on "Measures for the Environmental Management of New Chemical Substances" (MEP Order 7) before imported as raw material. Fortunately, waiving requirements have been specified in the MEP new chemical substance guidance document. Test data may be obtained from domestic Chinese laboratories or suitably accredited or Good Laboratory Practice (GLP) laboratories outside China. Data generated using Quantitative Structure Activity Relationships (QSAR) or

read-across are now acceptable under the Measures. Otherwise, the ingredient only can be imported as part of cosmetic product.

3. Requirements for Domestic Non–SUC Containing Existing Ingredients

3.1 Safety Assessment Report Requirement

China Food and Drug Administration (CFDA) released the revised rules on notification of domestically non-special use cosmetic products in 16-Dec-2013, which specified the information requirements on notification and highlighted that the toxicological test (including the animal tests) can be exempted if the safety of the finished products can be substantiated in accordance to the Safety Assessment Guidance on safety risk concerned substance, which was issued by CFDA in 2010.

The basic risk assessment procedure contains 4 steps:

1. Hazard identification
2. Hazard characterization (Dose –response relationship)
3. Exposure assessment
4. Risk characterization

Required assessment data on risk concerned substance includes:

1. Origin
2. Description (physicochemical ,biology)
3. Content and test method
4. Content limitation in literatures or regulations
5. Toxicological data
   - 5.1 Toxicological data description (whether have been classified as carcinogen by IARC)
   - 5.2 Based on the General Principle of Method of Toxicological Test in <Cosmetics Hygienic Standard (2007 version)>, the toxicological data summary should be provided.
6. Specific assessment and conclusion
7. If the ingredient is from plant, pesticide residue should be provided.
8. Advanced manufacture technology if it can reduce the content on risk concerned substance

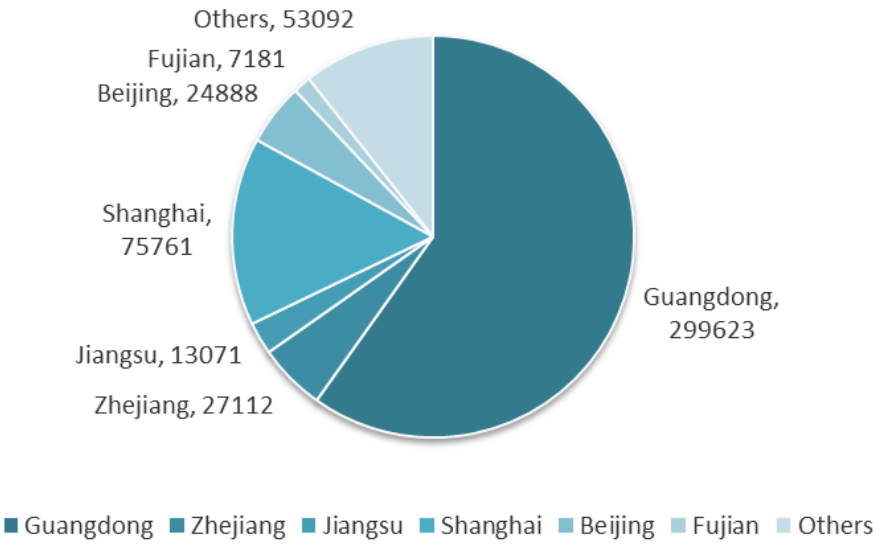
As for the ingredient that have specified the limitation in the annex of Safety and Technical standards for cosmetics, there is no need to provide risk assessment data mentioned above, on the other hand, if the foreign authority have been issued assessment conclusion of the ingredient, only the safety assessment report should be provided.

Moreover, in November 2015, CFDA released the last draft Guidance for the cosmetic safety risk assessment, which will apply to both finished product and ingredient. It demands higher requirements more in line with EU SCCS's guidance and specify the requirements of safety assessor. Due to the uncertainty before final version, it won't be detailed in this report.

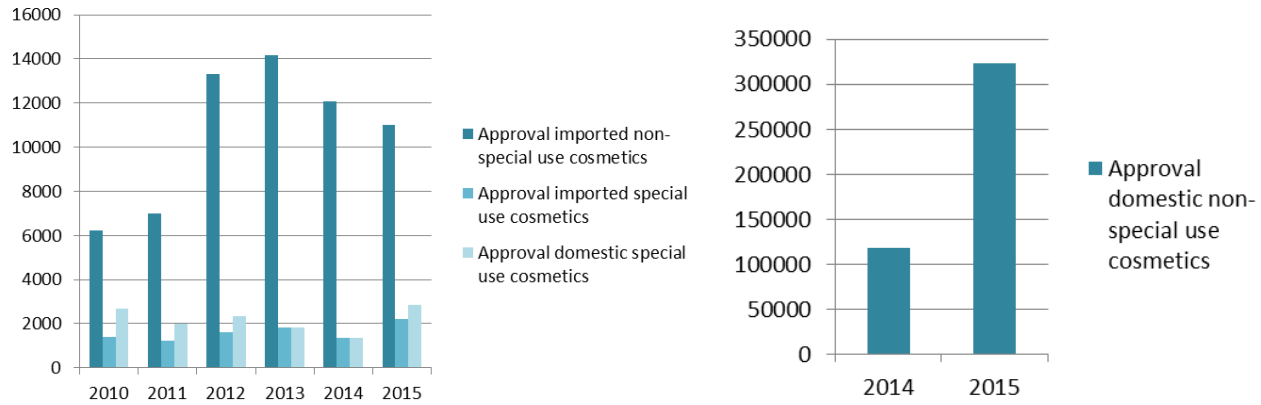
Like requirement of new ingredient registration, based on our experience, analogue data such as read-across and other in vitro test methods have not been listed in <Cosmetics Hygienic Standard (2007 version)>won't be accepted in these safety assessments.

3.2 Post-market surveillance

The revised notification rules were effective in 1st, July, 2014, and there has around 500000 online notification records since the effective date[2], including some made-in-China non-special use cosmetic products from oversea brands that are against animal testing globally, which is much more than the number of imported non- SUC cosmetics registration records.



Pie chart of notified records in different province

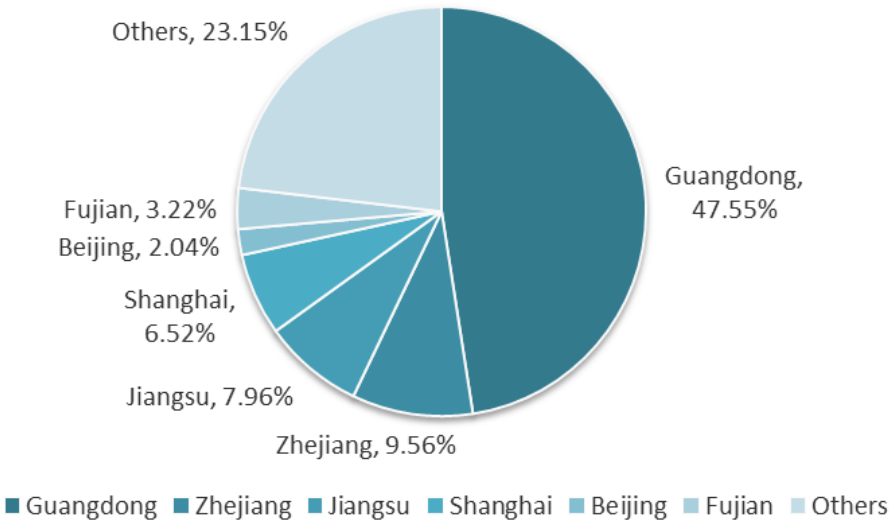


Bar chart of number of China cosmetic product registration and notification

In theory, after manufacturers finish on-line submission successfully, local FDA will verify the notification information for completeness and correctness, not technical review, and the verification will be finished within 5 working days after the notification is completed. Products can be put on the market immediately after verification. The local FDA will carry out the on-site inspection within 90 working days after the notification.

Since the safety assessment report will only be checked after notification, the risk around animal testing requested from CFDA or Province FDAs can only happen after notification, and Province FDA (like CFDA) can take sample inspection on any products sold in their region.

For now, the number of domestic cosmetic manufacture companies that have got product licenses is 3800[3], and nearly 50% of them are in Guangdong, 9.6% of them are in Zhejiang, 8.0% of them are in Jiangsu, 6.5% of them are in Shanghai.



Pie chart of domestic cosmetic manufacture companies that have got product licenses

To supervise the cosmetic in market, CFDA held a conference on 11-9-2014 on deployment of sampling inspection work in 2014[4].

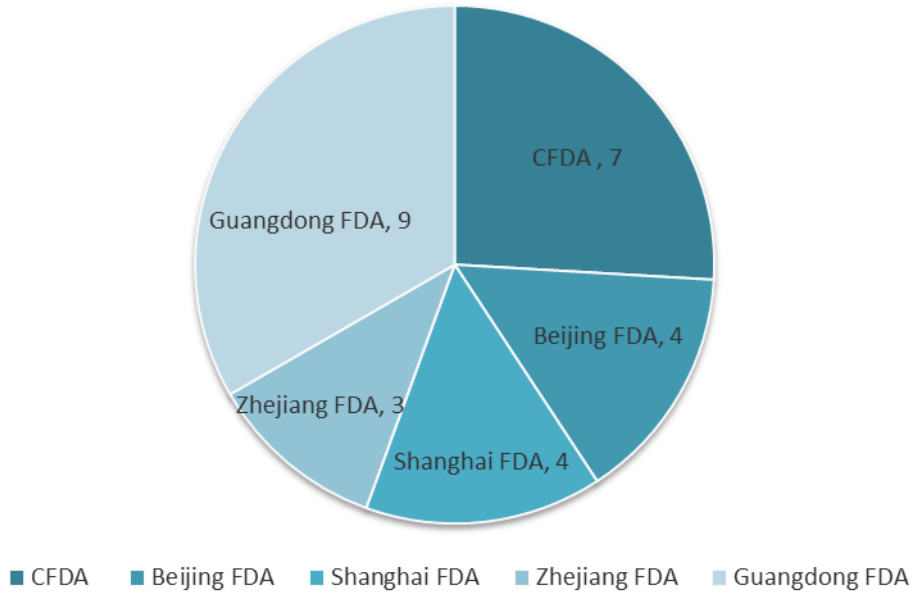
The in-market surveillance of CFDA will focus on the chemical and microbiological test, not animal tests, and the specific requirement present below:

No.	Product type	Quantity(batch)	Test Type	Test Item
1	Hair product(claim anti – dandruff)	20	Sampling Inspection	Anti-dandruff agent
2	Skin care product(claim acne)	20	Sampling Inspection	Antibiotics and metronidazole (7 kinds)
			Sampling Inspection	Ofloxacin, Ketoconazole
			Sampling Inspection	Glucocorticoid
			Risk Monitor	Lincomycin, Clindamycin
3	Fragrance product (Perfume)	15	Sampling Inspection	Methanol

			Risk Monitor	Phthalate
			Risk Monitor	Volatile organic solvents
4	Nail product(paint)	15	Sampling Inspection	Methanol
			Risk Monitor	Phthalate
			Risk Monitor	Volatile organic solvents
			Risk Monitor	Cadmium
5	Make-up product (Lip product)	20	Sampling Inspection	Mercury, Arsenic, Lead, Microorganism(5kinds)
			Risk Monitor	Cadmium
6	Make-up product (Eye product)	25	Sampling Inspection	Mercury, Arsenic, Lead, Microorganism(5kinds)
			Risk Monitor	Volatile organic solvents
			Risk Monitor	Cadmium
7	Skin product (claim baby product)	15	Sampling Inspection	Mercury, Arsenic, Lead, Microorganism(5kinds)
			Sampling Inspection	Acrylamide
8	Skin product (claim skin whiting)	10	Sampling Inspection	Mercury, Arsenic, Lead, Microorganism(5kinds)
			Sampling Inspection	Acrylamide
			Sampling Inspection	α-hydroxy acid
9	Skin product (claim under 3 years old baby powder product)	10	Sampling Inspection	Mercury, Arsenic, Lead
			Risk Monitor	Cadmium
10	Skin product (Bath product)	20	Sampling Inspection	Dioxane
			Sampling Inspection	Formaldehyde
			Sampling Inspection	Preservative(11kinds), Triclosan, Triclocarban
			Risk Monitor	Preservative(Methylchloroisothiaolinone)

The statistical data shown that the illegal addition of some prohibited ingredients, such as mercury, are the priority concerns of CFDA and main reason for fine, and there has no signals or evidence that CFDA has sampled any in-market product for animal tests to assess the eye or skin effects.

However, in addition to post-market inspection conducted by CFDA, Provincial FDAs also carry out inspection at irregular intervals, according to incomplete statistics:

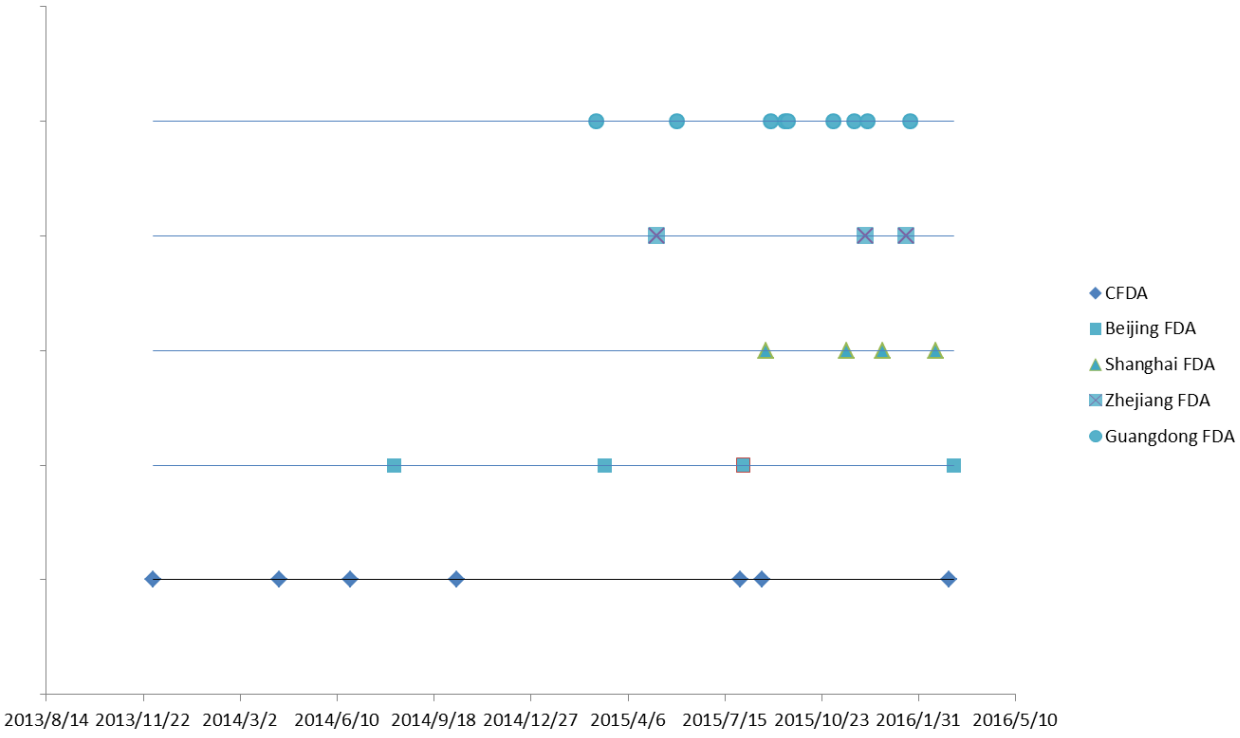


Pie chart of the number of sampling inspection

Authority	Inspection reporting date (From 2014 To now)	Result
CFDA[5]	02/12/2013	Prohibited ingredients were found in 4 batches, restricted ingredients exceeded were found in 2 batches.
	11/04/2014	Prohibited ingredients were found in 6 batches, restricted ingredients exceeded were found in 2 batches.
	24/06/2014	Prohibited ingredients were found in 6 batches
	11/10/2014	Prohibited ingredients were found in 6 batches
	31/07/2015	Prohibited ingredients were found in 8 batches
	22/08/2015	Prohibited ingredients were found in 11 batches
	02/03/2016	Prohibited ingredients were found in 39 batches
Beijing FDA[6]	07/03/2016 (the second half of 2015)	Microorganism content over standard was found in 4 product of 399
	03/08/2015 (the first half of 2015)	Total 254 batches were all pass
	13/03/2015 (the second half of 2014)	Total 374 batches were all pass
	08/08/2014 (the first half of 2014)	Total 276 batches were all pass

Shanghai FDA[7]	18/2/2016	Total number of colonies over standard was found in 3 of 489 products.
	25/12/2015 (the third quarter of 2015)	Prohibited ingredients were found in 17 products, restricted ingredients exceeded were found in 1 product (total 517 products).
	18/11/2015(the second quarter of 2015)	Prohibited ingredients were found in 4 of 1171 products.
	26/8/2015(the first quarter of 2015)	Prohibited ingredients were found in 2 products, total number of colonies over standard was found in 2 products (total 309 products)
Zhejiang FDA[8]	18/01/2016	Prohibited ingredients were found in 15 products, Microorganism content over standard was found in 2 product (total 818 batches)
	07/12/2015	Prohibited ingredients were found in 2 of 239 batches.
	06/05/2015	Prohibited ingredients were found in 6 batches.
Guangdong FDA[9]	04/03/2015	Prohibited ingredients were found in 1 batches
	26/05/2015	Prohibited ingredients were found in 7 batches, restricted ingredients exceeded were found in 2 batches.
	31/08/2015	Prohibited ingredients were found in 24 batches, restricted ingredients exceeded were found in 42 batches.
	15/09/2015	Prohibited ingredients were found in 4 batches, restricted ingredients exceeded were found in 6 batches.
	18/09/2015	Prohibited ingredients were found in 4 batches.
	04/11/2015	Prohibited ingredients were found in 1 batch.
	25/11/2015	Prohibited ingredients were found in 3 batches, Total number of colonies over standard was found in 4 batches, restricted ingredients exceeded were found in 5 batches, pH value over standard was found in 1 batch.
	09/12/2015	Prohibited ingredients were found in 2 batches, restricted ingredients exceeded were found in 6 batches.
	22/01/2016	Prohibited ingredients were found in 3 batches， restricted ingredients exceeded were found in 12 batches

Jiangsu FDA[10]	11/2014	Microorganism content over standard was found 1 in 83 sample
AQSIQ[11]	Every month	Pay attention to imported cosmetics in recent years (From 2014), and only pay attention to the product label, heavy metal, microorganism without toxicity test.



Scatter diagram of inspection timeline

However, to supervise and inspect commercial cosmetics from four regions in Jiangsu Province, heat resistance and freeze resistance test, microbiological test ,and toxicology test were performed ,contents of lead ,arsenic, mercury, hydroquinone, phenol, preservative, oxidative hair dyes and antibiotics were determined ,and the results were statistically analyzed in 93 batches of cosmetic samples of three categories (cleaning products, skin care products and make-up products) were conducted according to <Cosmetics Hygienic Standard (2007 version)> and People's Republic of China Light Industry Standard Series (cosmetics volume) for Yangzhou Institute for Drug Control in Jiangsu Province. The 93 batches samples are from 61 manufacture companies and include low, medium and high level of characteristic bands. 24 batches in all three categories of cosmetic samples are conducted toxicological tests that contain acute eye irritation test, acute skin irritation test, repeated skin irritation test, and based on <Cosmetics Hygienic Standard (2007 version)> they are all animal tests, and result presents below.

	Acute skin irritation test	Repeated skin irritation test	Acute eye irritation test
Nonirritating	3	12	4
Slightly irritating	-	-	5
Mildly irritating	-	-	3
Total	3	12	12

For now, this is the only post- market surveillance contained animal testing we could find. Since Province FDAs have the right to conduct animal test during inspection, we don't think the authorities need to hide such information. Although the result was not issued on the official website of Jiangsu CFDA, it was published in the journal. On the deployment meeting of sampling inspection work for last 4 months of 2015, Jiangsu FDA emphasizes that improve supervision of skin whiting product[12],however the results have not been issued.

4. Conclusion

In summary, we draw the conclusion that a company cannot provide a 100% assurance of no new animal testing for the Chinese market. New animal testing can still be required or undertaken for new ingredient registration, and provincial FDAs or related authorities have the authority to conduct sampling inspection including animal testing in post-market surveillance, no matter whether the submitted data is animal test report or safety assessment report.

There are multiple reasons for such insistence. Firstly, compared with SCCNFP firstly issued the guidance on safety assessment in 1990, CFDA did not publish similar guidance until 2010. No matter how rapid scientific development in China, 20 years is such a huge gap that can hardly catch up easily. Secondly, both the valid of animal testing alternative experiments and ethical issues on human trials are still the main barriers for conservative authority to adopt these method for safety assessment on cosmetics since human safety still be a priority for all. Last but not least, the test labs are at varying levels of expertise, without a harmonized standard, the repeatability for alternative test method cannot be guaranteed. Therefore, imported non special use cosmetics can use the new safety assessment instead of traditional toxicological testing or only need notify prior to marketing is just rumor, which hardly come into effect officially recently.

However, many scientists and experts in China devoted themselves to promote alternative method development. Guangdong CIQ and other research and application organizations have established the Center for Alternatives Research & Evaluation (**CCARE**) and have held Workshops of Alternative Method regularly[13]. To promote the harmonious interactions among human, animal and environment, CCARE is committed to be the leading force of promoting and disseminating 3R principles and alternative methods in China. Except for this, National Institutes for Food and Drug Control and IIVS have co-hosted Workshop of In Vitro Animal Test in Cosmetics in 2015 to introduce the cutting-edge technology and research in alternative method[14].

2014 witnessed a turning point for animal testing policy in China. Although it is still uncertain whether the change will be extended to all cosmetic products, it is nonetheless a major milestone for China on its way to modernization of its animal testing policy and alignment of its regulatory framework with the global cruelty free trends.

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