



CHEM **LINKED**

Remove Regulatory Barriers, Expedite Market Access



ChemLinked Workshop in FIAC 2018:

Regulatory Intelligence on Food Ingredients

July 12, 2018,

Shanghai New International Expo Centre (SNIEC)

Agenda

- 13:50-14:30 Theme Speech 1 - China Food Ingredients: Regulatory Interpretation & Case Study
- 14:35-15:10 Theme Speech 2 - China Food Ingredients: Special Foods & Case Study
- 15:10-15:40 *Break*
- 15:45-16:25 Theme Speech 3 - China Food Contact Materials: Regulatory Interpretation & Compliance Challenges
- 16:30-17:00 Q&A
- 17.00 Group Photo
- 17.05 End of Event

2018/7/12

Regulatory Interpretation for China Food Ingredients

Yilia, ChemLinked Editor & Regulatory Analyst
REACH24H Consulting Group

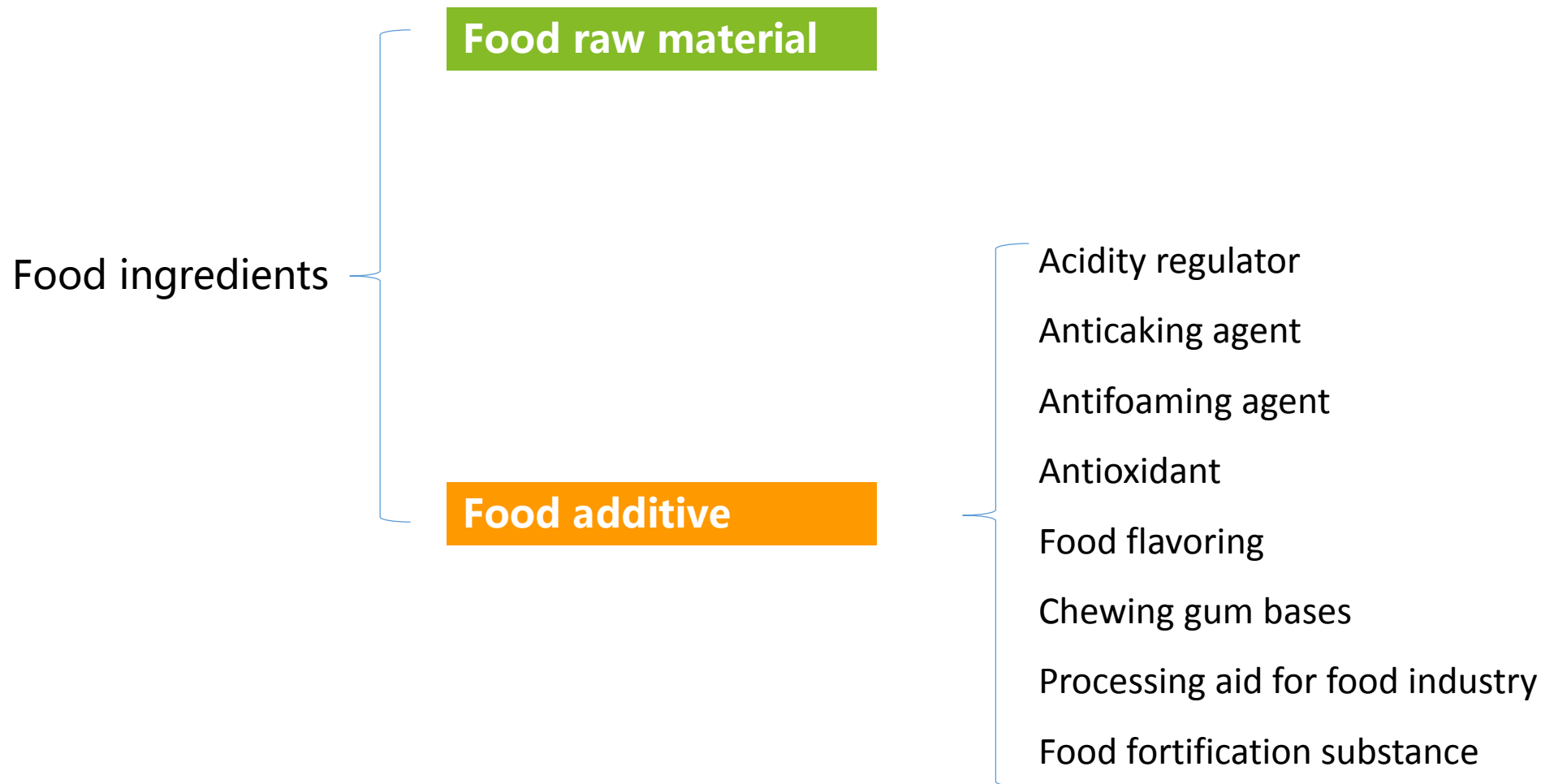
Content

- 01 Food Ingredients Supervision Mechanism
- 02 China' s Regulatory Requirements for Food Ingredients
- 03 How to Apply For New Food Ingredients in China
- 04 Access Requirements of Special Raw Materials

01

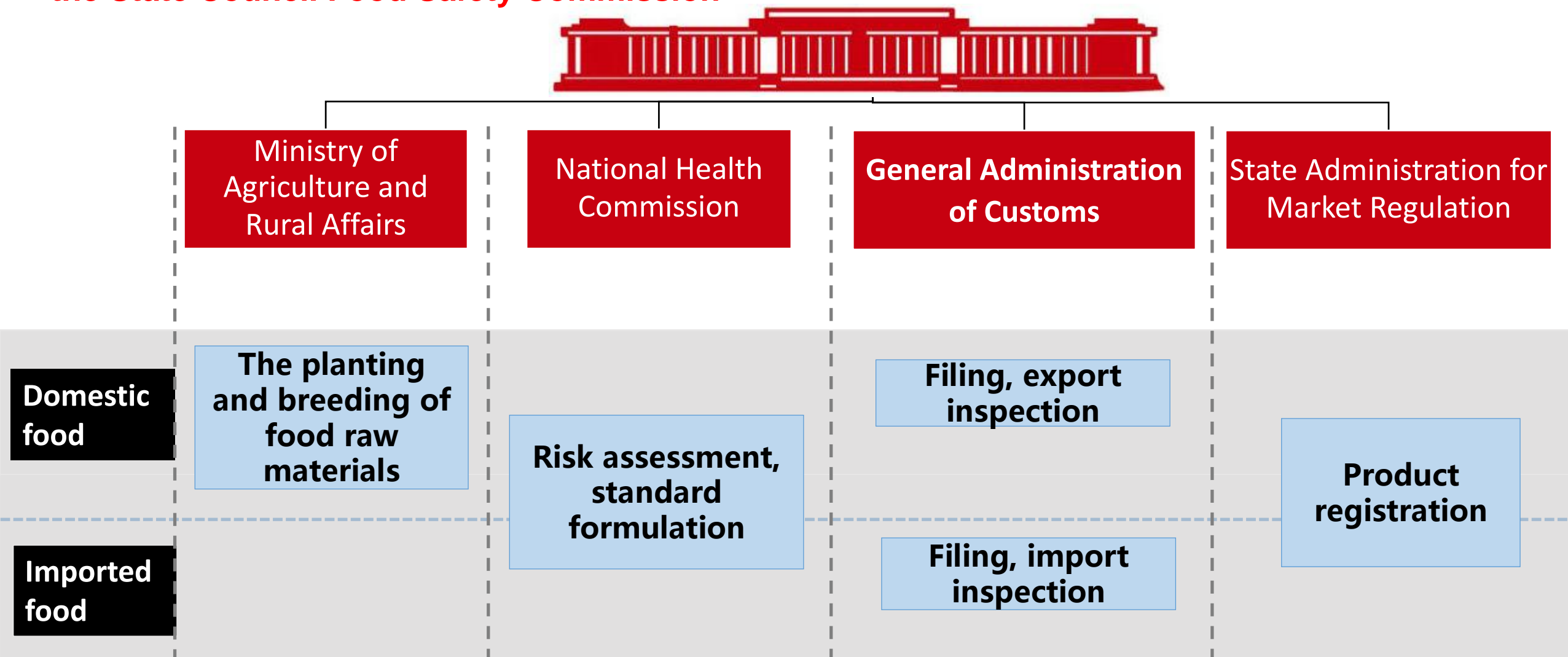
Food Ingredients Supervision Mechanism

Food Ingredients Supervision Mechanism



Food Ingredients Supervision Mechanism

the State Council Food Safety Commission



Food Safety Law

Hygienic standard(general)

- [GB 2761-2017 Maximum Levels of Mycotoxins in Foods](#)
- [GB 2762-2017 Maximum Levels of Contaminants in Foods](#)
- [GB 2763-2016 Maximum Residue Limits for Pesticides in Food](#)
- ...

Product standard

- [GB 19644-2010 Milk Powder](#)
- GB 1886.283-2016 food additive ethyl vanillin
- ...

Usage standard

- [GB 2760-2014 Standard for Uses of Food Additives](#)
- [GB 14880-2012 Standard for the Use of Nutritional Fortification Substances in Foods](#)
- Announcement related to new food raw materials
- ...

Supervision regulation

- Administrative measures on food production permit
- Administrative measures on imported and exported food safety
- [Administrative Measures on Safety Examination of New Food Raw Materials](#)
- [Administrative Measures for New Varieties of Food Additives](#)
- ...

02

China's Regulatory Requirements for Food Ingredients

Regulatory Requirements for Food Raw Material

Permitted food raw materials

Type	Judgement
Common food raw materials (confirm)	<ul style="list-style-type: none"> • Product standard • Announcement issued by NHC • Substances Used as Both Food and Traditional Chinese Medicine
New food raw materials	<ul style="list-style-type: none"> • New food raw material announcement
Bacterial cultures	<ul style="list-style-type: none"> • Bacterial Cultures that Can Be Used in Foods in China • Bacterial Cultures that Can Be Used in Baby Foods in China

Regulatory Requirements for Food Raw Material

Type	Judgement
Prohibited	
Raw materials that can only be used in health food	<ul style="list-style-type: none"> • Substances that can be used in health food
Raw materials that can only be used in drug	<ul style="list-style-type: none"> • Pharmacopeia
non-common food raw material	<ul style="list-style-type: none"> • Materials That Should Not be Used as Ordinary Food Raw Materials in China
Risk	
Common food raw materials (public recognized)	<ul style="list-style-type: none"> • Foods that have been consumed for over 30 years in China

Regulatory Requirements for Food Raw Material

一、严格贯彻执行国家食药监总局相关复函要求

2017年1月20日，国家食药监总局办公厅下发了《关于雪菊可否作为普通食品原料的复函》（食药监办食监一函〔2017〕39号），规定雪菊与菊花不同，如需开发为新食品原料，应当按照《新食品原料安全性审查管理办法》规定进行安全性评估。2017年8月9日，国家食药监总局办公厅下发了《关于石楠子可否作为普通食品原料的复函》（食药监办食监一函〔2017〕538号），规定亚麻籽在我国主要作为饲料使用，如需开发为新食品原料，应当按照《新食品原料安全性审查管理办法》的规定申报批准。

The food manufacturers in Shanghai should stop the production of common food that senecio cineraria or flaxseed is contained in.

Shanghai FDA

自以上复函之日起，本市食品生产经营者应当停止生产经营配料中含有“雪菊”、“亚麻籽”的普通食品，对正在销售的产品应当及时召回，召回的产品不得作为食品原料生产普通食品。

食品生产经营者如需开发“雪菊”、“亚麻籽”用于普通食品的生产经营，应当按照《新食品原料安全性审查管理办法》的规定申报批准。



Flaxseed

国家卫生计生委办公厅关于通报亚麻籽适用标准的函

GB 19300-2014 Nuts and Seeds Food is applicable to flaxseed that can be directly consumed.

NHFPC (previous)

质检总局、食品药品监管总局办公厅：

经研究，直接食用的亚麻籽适用《食品安全国家标准 坚果与籽类食品》（GB 19300-2014）。同时，宜在标签标示“熟制后食用”等类似消费提示。

附件：食用亚麻籽研究情况

国家卫生计生委办公厅
2017年12月21日

Regulatory Requirements for Food Additive

Common food additives	GB 2760-2014 and related announcement
Food fortification substance	GB 14880-2012 and related announcement
Food flavoring and fragrance	GB 2760-2014 Annex B
Food processing agent	GB 2760-2014 Annex C
Basic substance and its ingredient in gumbased candy	GB 29987-2014

Regulatory Requirements for Food Additive

Can thaumatin be added in biscuit?

1 GB 2760 Annex E Food category list

07.0	bakery food
07.01	bread
07.02	pastry
07.02.01	chinese pastry (except moon cakes)
07.02.02	western pastry
07.02.03	moon cakes
07.02.04	color decorations of pastry
07.03	biscuit
07.03.01	sandwich biscuit and decorative biscuit
07.03.02	wafer biscuit
07.03.03	egg roll
07.03.04	other biscuits
07.04	bakery food fillings and surface battering
07.05	other bakery food

2 GB 2760 Annex A

thaumatin

CNS No. 19.020

INS No. 957

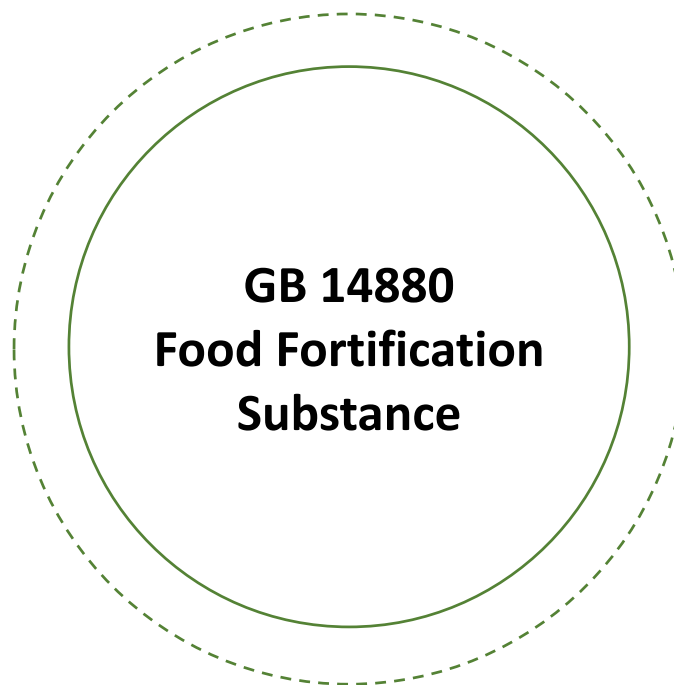
Function: sweetener

Food Classification No.	Food Name	Maximum Limits(g/kg)	Note
03.0	frozen drinks(03.04 edible ice excluded)	0.025	
04.05.02	processed nuts and seeds	0.025	
07.0	bakery food	0.025	
11.04	table sweeteners	0.025	
14.0	Beverage (14.01 packaged drinking water excluded)	0.025	usage can be increased according to dilutions for

Regulatory Requirements for Food Additive

Annex A Regulations on the Use of
Nutritional Fortification Substances

Annex B List of Allowable Compound
Sources of Nutritional fortification
substances



Annex D Description of food categories
(names)

Annex C Nutritional fortification substances
allowable for special dietary foods and their
compound sources

Regulatory Requirements for Food Additive

Modified milk powder for pregnant and lying-in women (vitamin A fortified)

1 Annex D Food categories

Food classification No.	Food category (name)
01.0	Milk and dairy products (except the category of special dietary foods in 13.0)
01.01	Pasteurized milk, sterilized milk and modified milk
01.01.01	Pasteurized milk
01.01.02	Sterilized milk
01.01.03	Modified milk
01.02	Fermented milk and flavored fermented milk
01.02.01	Fermented milk
01.02.02	Flavored fermented milk
01.03	Milk powder and its modified products
01.03.01	Milk powder
01.03.02	Modified milk powder
01.04	Condensed milk and its modified products
01.04.01	Evaporated milk
01.04.02	Modified condensed milk
01.05	Single cream (whipping cream) and similar products
01.06	Cheese and processed cheese
01.07	Instant flavored dessert or its prepared products with milk as the main

2 Annex A Allowable varieties, application scope and dosage of nutritional fortification substances

Vitamins			
Vitamin A	01.01.03	Modified milk	600 µg/kg ~ 1000 µg/kg
	01.03.02	Modified milk powder (except for the milk powder used for children, pregnant women and lying-in women)	3000 µg/kg ~ 9000 µg/kg
		Modified milk powder (only for the milk powder for children)	1200 µg/kg ~ 7000 µg/kg
		Modified milk powder (only for the milk powder for pregnant women and lying-in women)	2000 µg/kg ~ 10000 µg/kg
	02.01.01.01	Vegetable oil	4000 µg/kg ~ 8000 µg/kg
	02.02.01.02	Margarine and similar products	4000 µg/kg ~ 8000 µg/kg

Regulatory Requirements for Food Additive

Modified milk powder for pregnant and lying-in women
(vitamin A fortified)

3

Annex B List of Allowable Compound Sources of Nutritional fortification substances

Nutritional substance	fortification Compound source
Vitamin A	Acetate, retinyl ester (acid vitamin A) Retinyl palmitate ester (palmitic acid, vitamin A) All-trans retinol β -carotene

03

How to Apply For New Food Ingredients in China

How to Apply for New Food Raw Material in China

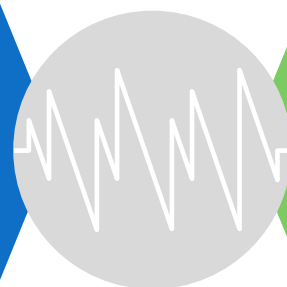
Competent authorities

National Health Commission:

- Inspection on food production/circulation permit
- Organize food's technical review

CFSA:

- Technical review and raise corresponding suggestion



Major regulations

- Administrative Measures on Safety Examination of New Food Raw Materials
- [Regulation for Application and Acceptance of New Food Raw Materials](#)
- [Review Procedures for Safety of New Food Raw Materials](#)

How to Apply for New Food Raw Material in China

New food raw material

Basic principle—possess foods' characteristics; poisonless and harmless

without traditional eating habits in China

01

animal, plant,
microorganism

02

Food extraction

03

The original structure
of food ingredients
has changed

04

Other newly
developed food raw
materials

*Traditional eating habit means that a food has more than **30 years** history of production and operation as a packaged food product in certain region at provincial level and is not included in the **Chinese Pharmacopoeia**.*

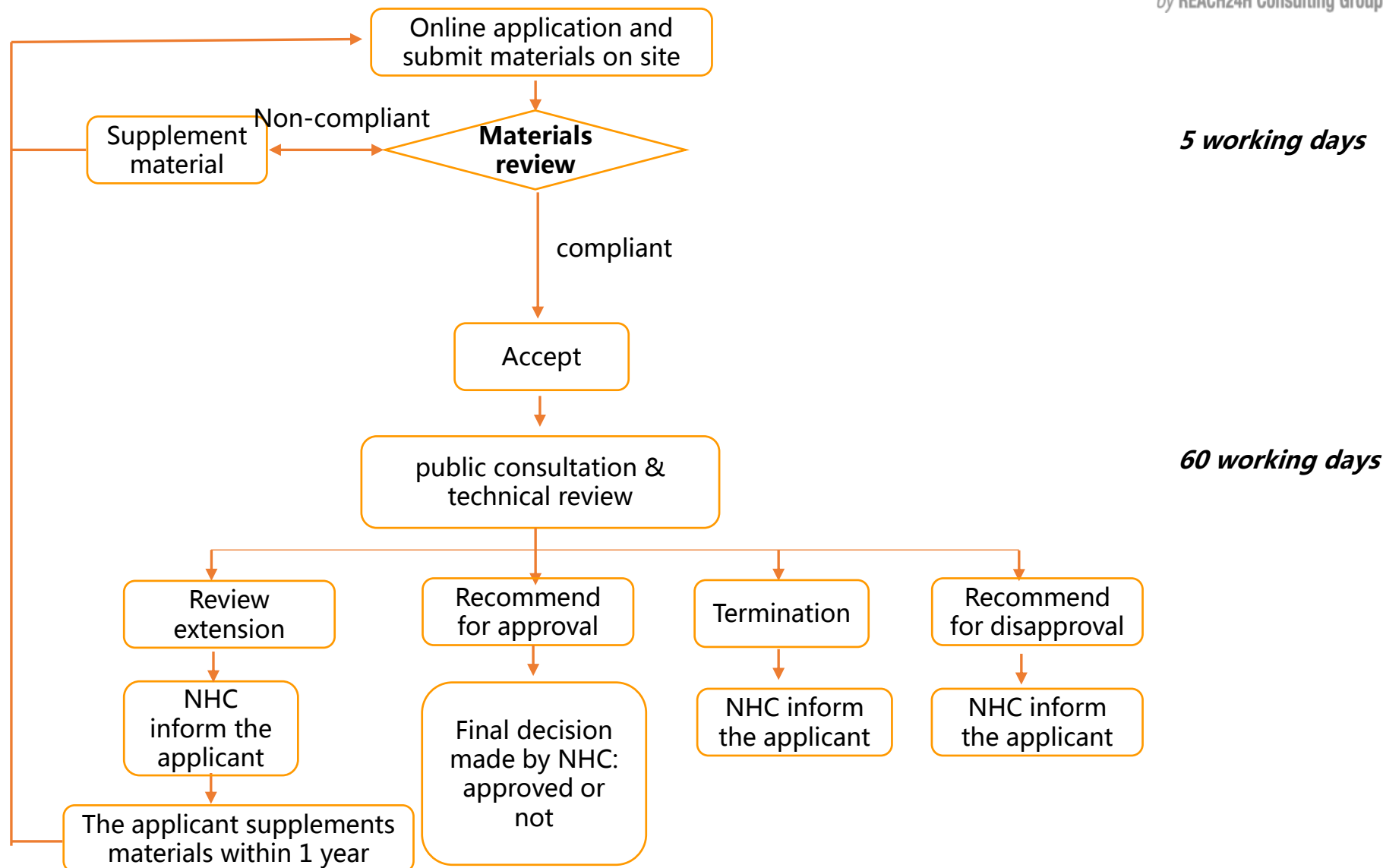
How to Apply for New Food Raw Material in China



How to Apply for New Food Raw Material in China



**Material acceptance-
review results:
5 months**



How to Apply for New Food Raw Material in China

Termination

- Regarded as or **substantial equivalence** to common food

--*Mulberry leaf extraction & Mulberry leaf*

- **substantial equivalence to new food raw materials**

--*Ginseng adventitious roots & Ginseng*

- **Others**

--*Soybean oligosaccharides (GB/T standard unveiled during technical review)*

The following are the same:
species, source, biological
property, major
component, edible parts,
usage amount, application
scope, target group
The processing technique
and quality specification
are primarily the same.

How to Apply for New Food Raw Material in China

国家卫生和计划生育委员会政务大厅

行政许可项目

▶ 新消毒产品

▶ 新涉水产品

▶ 新食品原料

▶ 食品添加剂新品种

▶ 食品相关产品新品种

Online application system

<https://slps.wsjd.gov.cn/>

How to Apply for New Food Raw Material in China

1. application form; ;
2. Research and development report of the new food raw material
- 3. Safety evaluation report;**
4. Production techniques;
5. Reference standard (safety requirements, quality specification, test methods, etc);
6. Labels and instructions;
7. Research and utilization data at home and abroad, as well as safety-related data; ;
8. Other supporting documents conducive to review and examination

How to Apply for New Food Raw Material in China

For imported new substance

1. The document issued by exporting country (region) proving production or sale of the product in the exporting country (region);	Production permit
2. The document issued by original country (region) proving the manufacturer go through certain inspection or certification	HACCP / GMP certificate

Pay attention:

- The supporting document must be the original one (by competent authority of original country or industry association)*
- For those can not be provided with original copy, the document must be confirmed by issuance unit or embassy.*

How to Apply for New Food Additive in China

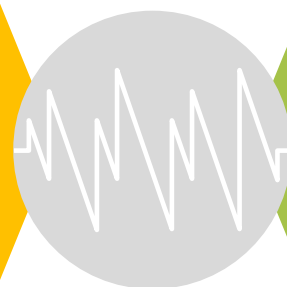
Competent authority

National Health Commission:

- Inspection on food production/circulation permit
- Organize food's technical review

CFSA:

- Technical review and raise corresponding suggestion



Major regulations

- [Administrative Measures for New Varieties of Food Additives](#)
- [Provisions on Application and Acceptance of New Varieties of Food Additives](#)

How to Apply for New Food Additive in China

New food additive

01

food additives that
are not included in
the food safety
national standard

02

food additives that
are not included in
the approval
announcement issued
by NHC;

03

food additives that
require scope
expansion or dosage
increase

How to Apply for New Food Additive in China

1

**Application
procedure**

2

**Materials
required**

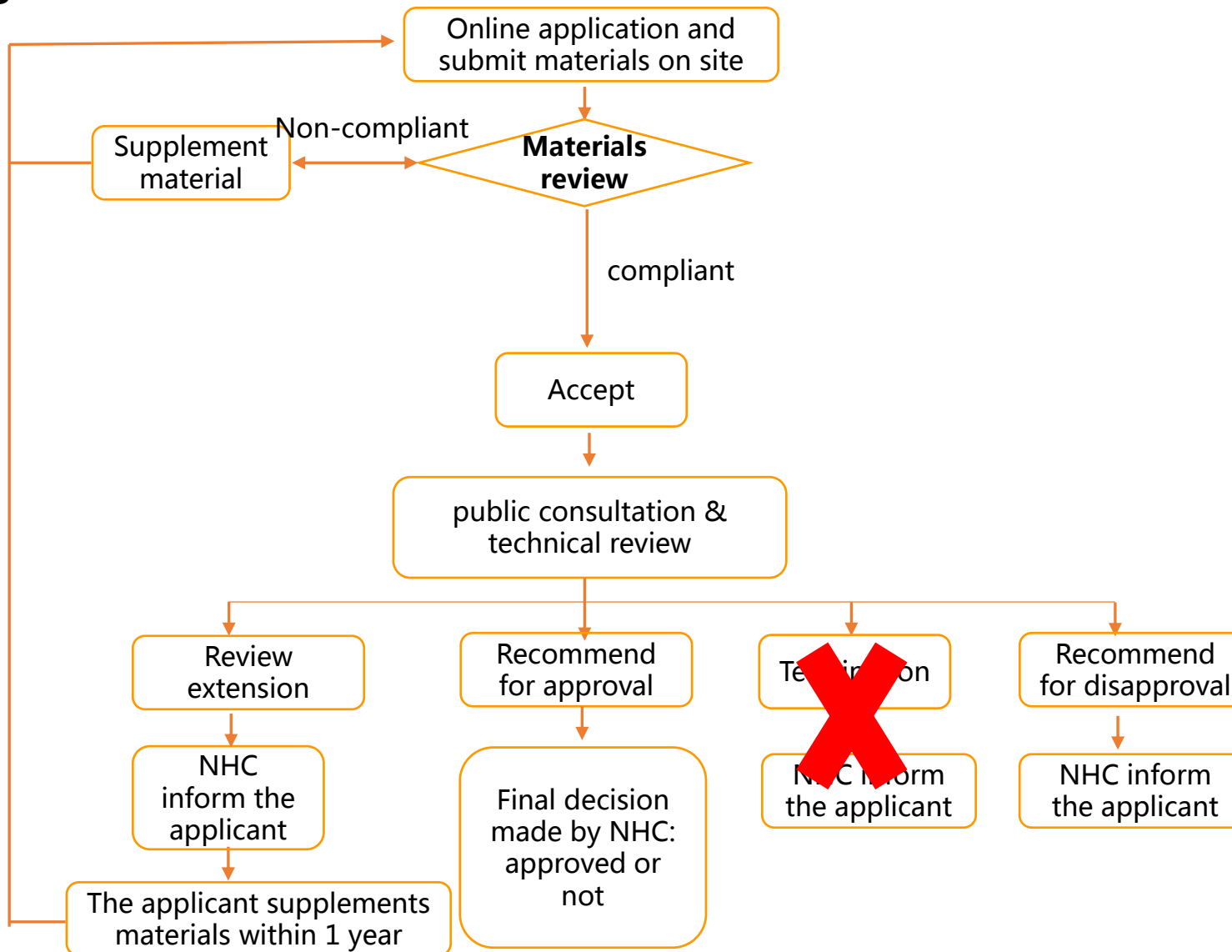
3

Notes

How to Apply for New Food Additive in China



**Material acceptance-
review results:
5 months**



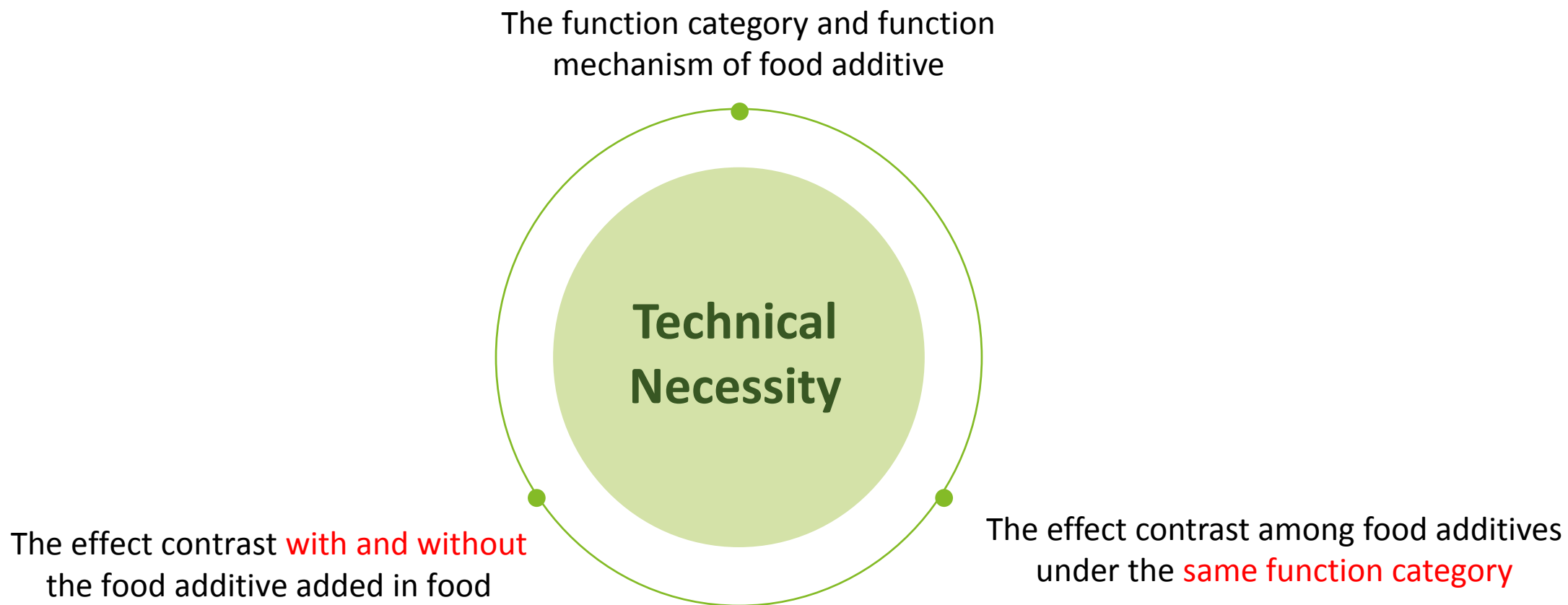
5 working days

60 working days

How to Apply for New Food Additive in China—Material

1. Application form
2. Generic name, function category, dosage and scope of use;
- 3. The supporting document to prove its technical necessity and intended using effects**
4. Quality and specification requirements, production techniques and testing method as well as the method or instructions to test the additive in food
5. Safety evaluation data, including production techniques, toxicological safety evaluation data or testing reports and quality and specification testing report. **(this item is not required for food additives proposed to expand application scope or dosage increase)**
6. Label sample and instruction
7. The supporting document of its production and use issued by other countries (region) / international organizations that are conducive to the safety evaluation

How to Apply for New Food Additive in China—Material



How to Apply for New Food Additive in China—Material

No color agent



1

Monascus red



2

Sorghum red



3

Sensory contrast

The application scope
of monascus red is
extended to frozen
surimi product

How to Apply for New Food Additive in China—Material

1. Application form
2. Generic name, function category, dosage and scope of use;
- 3. The supporting document to prove its technical necessity and intended using effects**
4. Quality and specification requirements, production techniques and testing method as well as the method or instructions to test the additive in food
5. **Safety evaluation data**, including production techniques, toxicological safety evaluation data or testing reports and quality and specification testing report. **(this item is not required for food additives proposed to expand application scope or dosage increase)**
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04

Access Requirements of Special Raw Materials

Food Safety System Inspection Mechanism on Imported Countries/Regions

Imported food catalogue from countries/regions compliant with safety system inspection or having tradition trade with

- Meat product
- Dairy product
- Aquatic product
- Bird's nest
- casing (for sausages)
- plant origin food
- Traditional Chinese medicine
- Honey products



符合评估审查要求及有传统贸易的国家或地区输华食品目录

符合评估审查要求及有传统贸易的国家或地区输华食品目录

为严格落实《食品安全法》等有关规定，进一步规范对境外输华国家或地区食品安全体系评估和审查，便于国内外监管部门、经营主体和广大消费者了解相关信息，更好地服务进出口贸易健康发展，国家质检总局进出口食品安全局开发了“符合评估审查要求及有传统贸易的国家或地区输华食品目录信息系统”（以下简称“目录”）。

目前，本目录包括：肉类（鹿产品、马产品、牛产品、禽产品、羊产品、猪产品）（内脏和副产品除外）、乳制品、水产品、燕窝、肠衣、植物源性食品、中药材、蜂产品等8大类产品信息，国家质检总局将根据评估和审查结果进行动态调整。进口目录以外的食品需符合我国法律法规和食品安全国家标准要求。为便于用户使用，系统提供了进口食品目录查询、产品名称查询、国家或地区查询等多种查询方式，使用过程中，如有问题可通过电子邮件进行咨询。

注1：体系评估：是指某一类（种）食品首次向中国出口前，国家质检总局对向中国申请出口该类食品的国家（地区）食品安全管理体系开展的评估活动。

注2：回顾性审查：是指向我国境内出口食品的国家（地区）通过体系评估已获得向中国出口的资格或虽未经过体系评估但与中国已有相关产品的传统贸易，国家质检总局经风险评估后决定对该国家（地区）食品安全管理体系的持续有效性实施的审查活动。与中国已有贸易和已获准向中国出口的食品均属于回顾性审查的相关食品范围。

进口食品名单

	肉类名单 肉类查询
	水产品名单 水产品查询
	乳制品名单 乳制品查询
	中药材名单 中药材查询

<http://pub.fsciq.cn/approval/SitePages/Home.aspx>

Food Safety System Inspection Mechanism on Imported Countries/Regions

Dynamic management

亚洲

Malaysia

国家和地区	产品名称	准入状态	企业名单
马来西亚	冰糖燕窝等燕窝制品	正常	自2017年6月15日恢复正常
	食用燕窝 Bird's nest	正常	自2017年6月15日恢复正常
泰国	冰糖燕窝等燕窝制品	正常	The trade back to normal since Jun. 15, 2017
	食用燕窝	正常	
印度尼西亚	冰糖燕窝等燕窝制品	正常	The trade back to normal since Jun. 15, 2017
	食用燕窝	正常	

Overseas Food Manufacturer Registration

- [China Approved Overseas Manufacturers-Dairy Products \(except Infant Formula\)](#)
- [China Approved Overseas Manufacturers-Infant Formula](#)
- [China Approved Overseas Manufacturers-Meat](#)
- [China Approved Overseas Manufacturers-Aquatic Products](#)
- [China Approved Overseas Manufacturers-Honey](#)
- [China Approved Overseas Manufacturers-Bird's Nest](#)

<http://www.cnca.gov.cn/bsdt/ywzl/jkspjwscpqzc/>

 **进口食品境外生产企业注册专栏**

[首 页](#) | [通知公告](#) | [法律法规](#) | [文件下载](#) | [常见问题](#)

进口乳品境外生产企业注册名单

婴幼儿配方乳品

欧 洲			
奥地利(2016年05月16日)	比利时(2015年05月07日)	丹麦(2018年02月12日)	英国(2015年11月03日)
法国(2017年12月05日)	德国(2016年06月01日)	爱尔兰(2014年09月11日)	意大利(2014年12月22日)
荷兰(2017年12月29日)	波兰(2017年07月21日)	瑞士(2018年01月11日)	西班牙(2014年05月21日)
白俄罗斯(2016年09月28日)			
美 洲			
美国(2015年11月03日)	阿根廷(2014年12月22日)		
大洋洲			
澳大利亚(2018年02月12日)	新西兰(2017年10月25日)		
亚 洲			
韩国(2017年10月12日)	新加坡(2018年01月18日)		

Overseas Food Manufacturer Registration

Dynamic management



中华人民共和国国家认证认可监督管理局

Certification and Accreditation Administration of the People's Republic of China

澳大利亚婴幼儿配方乳品生产企业在华注册名单

(2018年4月9日更新)

序号 No.	注册编号 Approval NO.	企业名称 Manufacture name	注册地址 Manufacture address	注册类型 Type	注册产品 Products for approval	备注 Remarks
1	1179	Camperdown Powder Pty Ltd	10 Phoenix Court, Braeside, Victoria, Australia, 3195	加工企业 PP	婴幼儿配方乳粉 infant formula milk powder	自2017年08月09日, 恢复在华注册资格。
2	1381	VIPLUS DAIRY PTY LTD	67 TOORA JETTY ROAD TOORA VIC 3962	加工企业 PP	婴幼儿配方乳粉 infant formula milk powder	自2016年12月9日, 恢复在华注册资格。
3	1890	SPHERE HEALTHCARE (ASIA) PTY LTD	12 CHURCH ROAD MOOREBANK NSW 2170	加工企业 PP	婴幼儿配方乳粉 infant formula milk powder	
4	1933	FARMLAND DAIRY PTY LTD	UNIT 1, 360 CHISHOLM ROAD AUBURN NSW 2144	加工企业 PP	婴幼儿配方乳粉 infant formula milk powder	
5	2156	AUSTRALIAN DAIRY PARK PTY LTD	120 FRANKSTON GARDENS DRIVE CARRUM DOWNS VIC 3201	加工企业 PP	婴幼儿配方乳粉 infant formula milk powder	

The suspension on CNCA registration was lifted

Inspection and quarantine system on imported animal and plant origin food

Inspection and quarantine:

- Meat product
- Aquatic product
- Some dairy products
- Some plant origin food
- Bird' s nest

Animal and plant epidemic, laws and regulation, ban, alert, risk assessment report, safety evaluation report



Summary

Product category	Food safety system inspection	Manufacturer registration	Inspection and quarantine
Dairy	★	★	☆ (only raw milk, raw milk products, pasteurized milk, and modified milk processed by pasteurization are required)
Meat	★	★	☆ (excluding cooked meat product)
Grain	★	★	☆ (excluding processed grain like rice and flour)
Vegetable and vegetable products	☆ (excluding canned food)	☆ (excluding canned food)	☆ (fresh solanaceous vegetables only)
casing (for sausages)	★	☆ (Chile only)	★
Traditional Chinese medicine	★	☆ (animal/plant-based traditional Chinese medicine only)	☆ (animal/plant-based traditional Chinese medicine only)
Aquatic and aquatic products	☆	★	☆
Bird's nest	★	★	☆ (edible bird's nest only))
Oil and fat refined from livestock and poultry animal at high temperature	★	★	
Grain products	☆ (rough finish products only)	☆ (access agreement)	
Edible vegetable oil and oilseeds	☆ (oilseeds only)		
Egg and egg products	★		☆ (fresh egg only)
Dried nuts	☆ (the inspection and quarantine condition is P)		☆ (the inspection and quarantine condition is P)

Thank you!

Visit food.chemlinkd.com for more info...

Contact Us

Email: food@chemlinked.com | Skype: ChemLinked Official

Tel: +86 571 8710 3822 | Fax: +86 571 8700 7566

China Food Ingredients: Specialty Foods

July 12, 2018



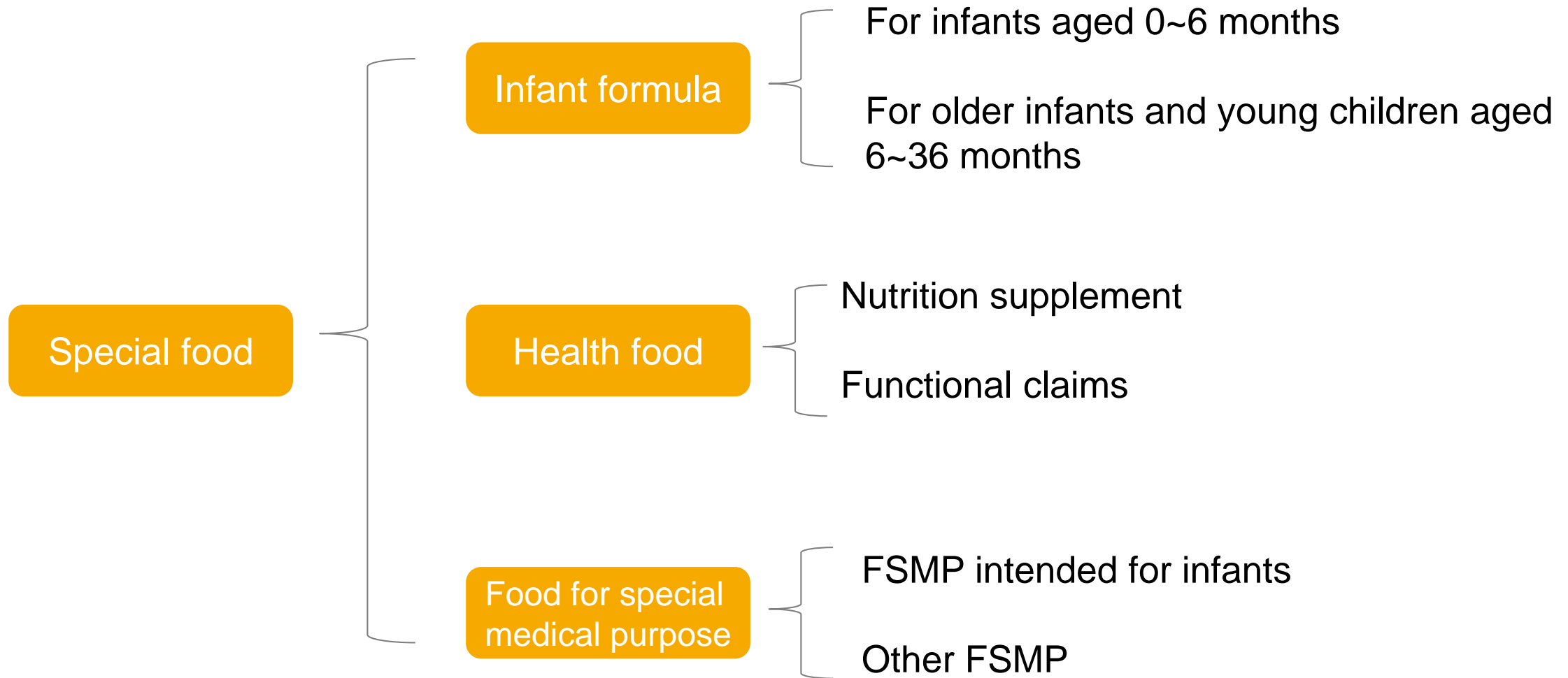
Maxwell Heston from REACH24H Consulting Group

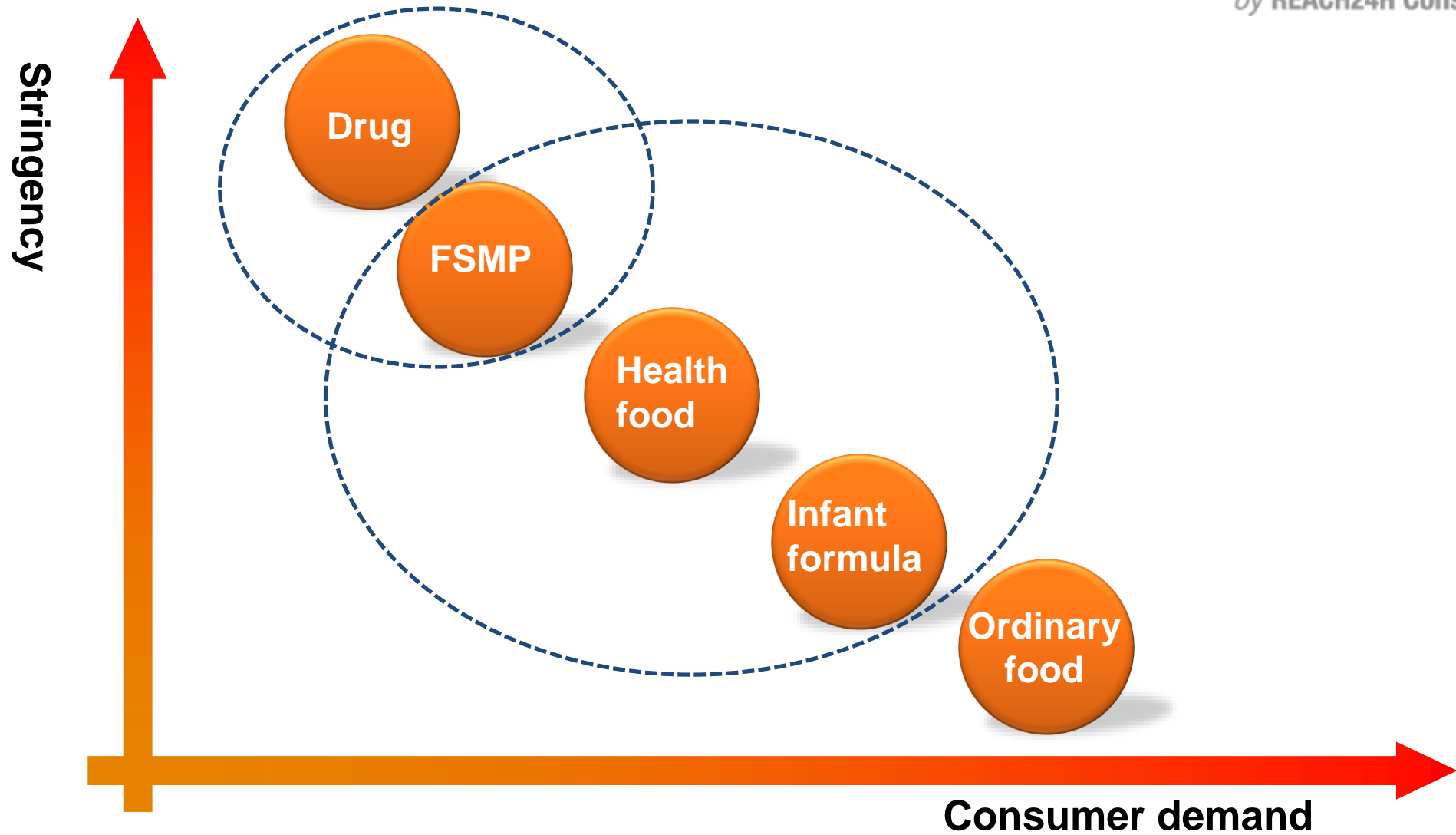
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- 01 Overview of special food supervision system in China
- 02 Regulatory requirements for ingredients used in infant formula
- 03 Regulatory requirements for ingredients used in health food
- 04 Regulatory requirements for ingredients used in food for special medical purpose

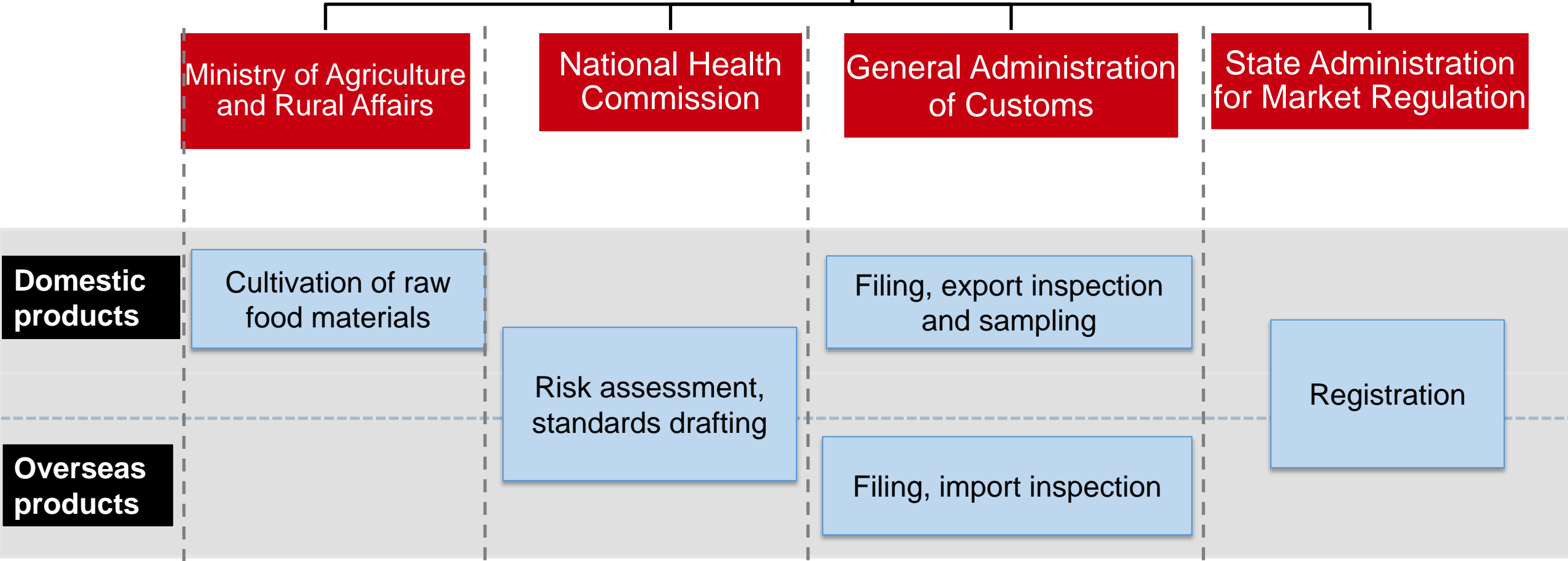
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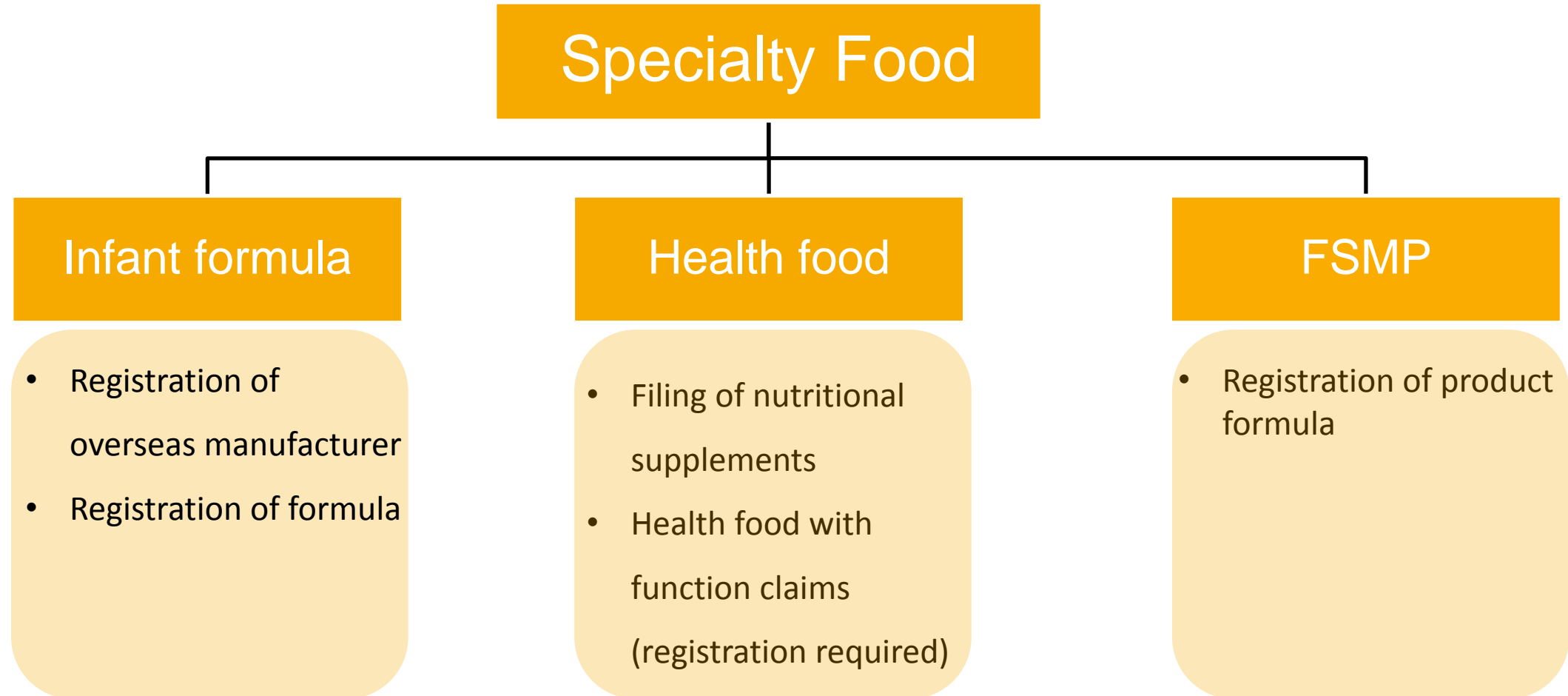
Overview of special food supervision system in China

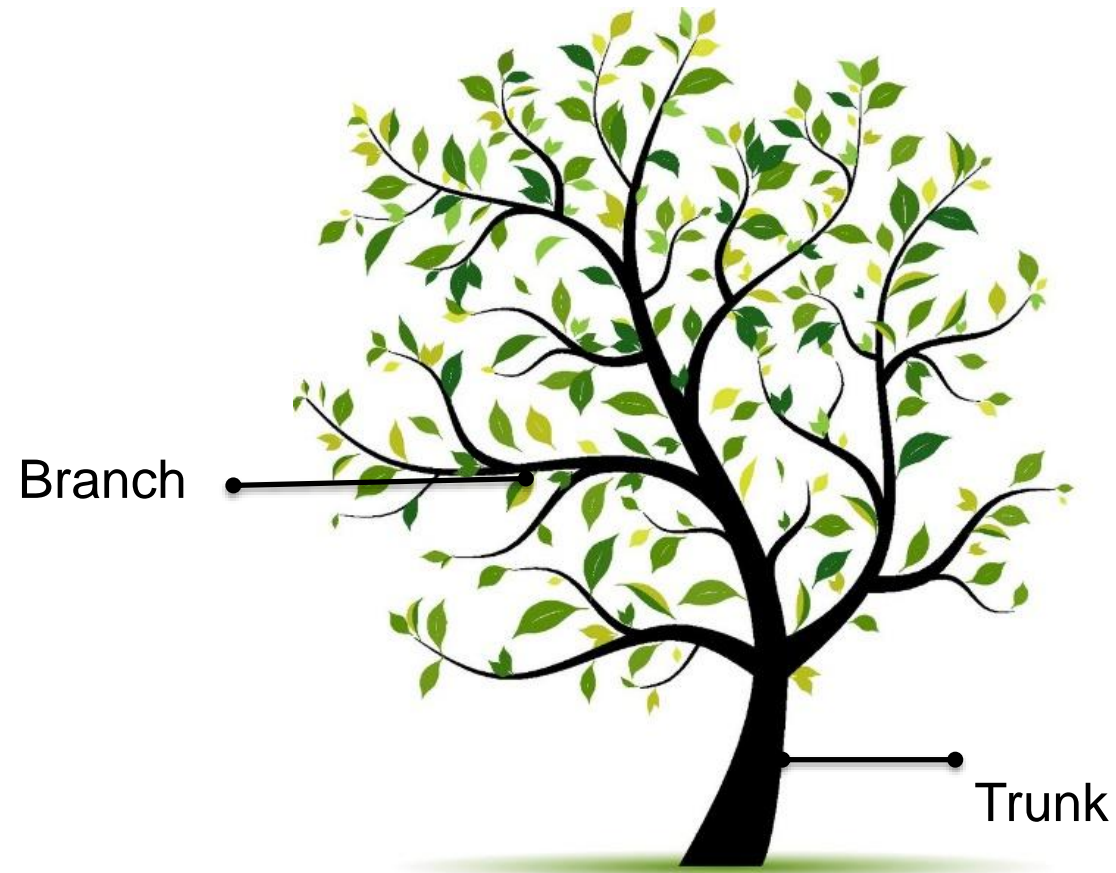




**Commission on Food Safety
of State Council**

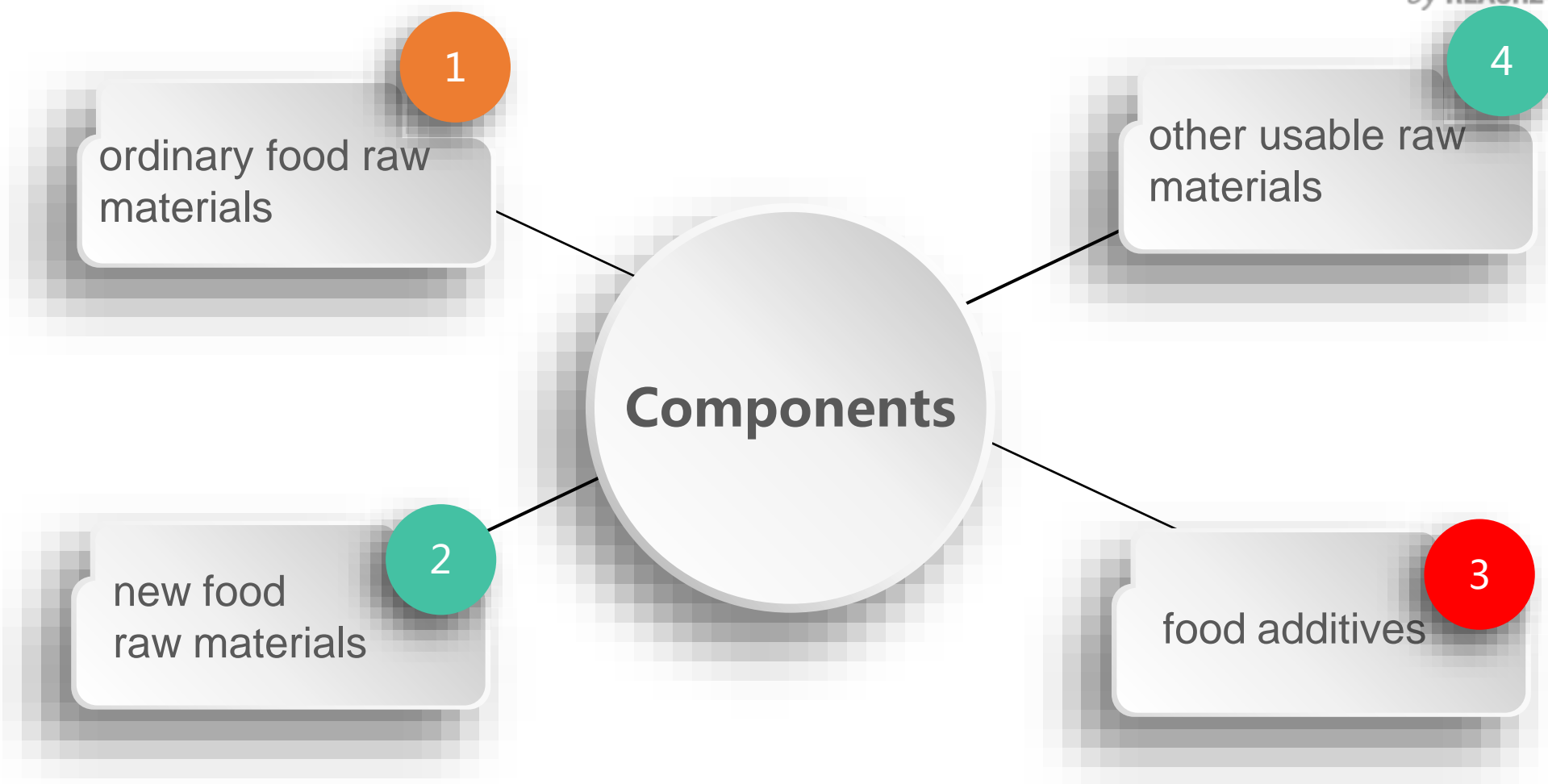






Laws & regulations		Food Safety Law Provisions on the Implementation of Food Safety Law Administrative Measures for the Registration of Product Formula of Infant Formula Milk Powder Administrative Measures for the Registration of FSMP Administrative Measures for the Registration and Filing of Health foods Administrative Measures for the Safety Review of New Food Raw Materials Administrative of New Varieties of Food Additives
Announcements		No.7-2017 Announcement on ten new good raw materials No.8-2016 Announcement on new varieties of food additives
National food safety standards	General standards	GB 2760-2014 Standard for the Use of Food Additives GB 14880-2012 Standard for the Use of nutrition fortification substances
	Product standards	GB 10765-2010 infant formula food GB 10767-2010 elder and young children formula food GB 25596-2010 General Rules for Infant Formula Food for Special Medical Purpose GB 29922-2013 General Rules for Food for Special Medical Purpose GB 16740-2014 health food GB 11674-2010 whey powder & whey protein powder
	Inspection standards	GB 5413 collection GB 5009 collection

The Composition of Special Food



02 Regulatory Requirements for ingredients used in infant formula

Requirements for Infant Formula Ingredients

For infants aged 0~6 months

Raw and auxiliary materials

<u>Milk</u> , bean and their products	Plant oil	Vitamin	Mineral
---------------------------------------	-----------	---------	---------

Requirements

To be safe, meet nutrition demand;
 No gluten contained;
 No bovine colostrum or its products;
 No hydrogenated oil or fats;
 No irradiated raw material;
 Ash of whey powder $\leq 1.5\%$, ash of whey protein powder $\leq 5.5\%$;
 Carbohydrate of dairy based infant formula: first choice is lactose, or the polymer of lactose and glucose;
 Pre-gelatinized starch & No fructose.

Permitted monomer amino acids

L-Phenylalanine	L-Cysteine	L-Leucine	L-Tyrosine	L- Tryptophan	L-Histidine
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Requirements for Infant Formula Ingredients

For children aged 6~36 months

Raw and auxiliary materials

Milk, bean and their products	Plant oil	Vitamin	Mineral
-------------------------------	-----------	---------	---------

Requirements

To be safe, meet nutrition demand;
No bovine colostrum or its products;
No hydrogenated oil or fats;
No irradiated raw and auxiliary materials;

Requirements for Infant Formula Ingredients —— additives

For infants aged 0~6 months

No gluten contained;
In accordance with relevant regulations;
G 2760 & GB 14880 (no flavor and fragrance)

For children aged 6~36 months

In accordance with relevant regulations;
G 2760 & GB 14880

Emulsifying agent, stabilizer, thickening agent

- mono-and diglycerides of fatty acids
- carob bean gum
- carrageenan
- phospolipid

Antioxidant

- Ascorbyl palmitate

Acidity conditioner

- citric acid, trisodium citrate
- calcium hydroxide
-

ADDITIVES

Vitamin

- L-Ascorbic acid
- Vitamin B2
- D-Biotin

Mineral

- Sodium chloride
- Copper sulfate
- Sodium selenite

Others

- Galactooligosaccharide
- DHA/ARA
- OPO
- Lutein
- Nucleotide
- Lactoferrin
- Casein phosphopeptides (CPP)
- Casein calcium peptide (CCP)

Permitted strain

* Confined to formula
food for children above
1 years old

Lactobacillus *
acidophilus
Strain No: NCFM

Bifidobacterium
animalis
Strain No: Bb-12

Bifidobacterium
lactis
Strain No: HN019
Bi-07

Lactobacillus
rhamnosus
Strain No: LGG
HN001

Lactobacillus
reuteri
Strain No: DSM
17938

Lactobacillus
fermentum
Strain No: CECT
5716

Bifidobacterium
breve
Strain No: M-16V

Requirements for Infant Formula Ingredients

Raw material

配料表

配料: Skim milk, 生牛乳、脱盐乳清粉、乳糖、葵花籽油、脱脂奶粉、乳清蛋白粉、大豆油、玉米油、酪蛋白、无水奶油、低聚半乳糖、低聚果糖、牛磺酸、二十二碳六烯酸 (DHA)、花生四烯酸 (ARA)、乳双歧杆菌HN019 (添加量 $\geq 2 \times 10^6$ CFU/g)、乳杆菌Bb-12 (添加量 $\geq 2 \times 10^6$ CFU/g); 食品添加剂: 维生素: Vitamin A (醋酸视黄酯)、Vitamin D (胆钙化醇)、维生素E (dl- α -醋酸生育酚)、维生素K (植物甲萘醌)、维生素C (L-抗坏血酸)、维生素B₁ (硝酸硫胺素)、维生素B₆ (盐酸吡哆醇)、维生素B₁₂ (氰钴胺)、叶酸、烟酰胺、D-泛酸钙、D-生物素、氯化胆碱、维生素B₂ (核黄素); 矿物质: 碳酸钙、硫酸亚铁、硫酸锌、硫酸铜、碘化钾。配料中含有乳及乳制品、大豆制品、鱼油制品。

Strain

Bifidobacterium animals

nutrition fortification substances

phospholipid

Emulsifying agent

03

Regulatory requirements for ingredients used in health food



Raw and auxiliary materials

- Food standards & relevant provisions



Food additives

- Food additives: GB 2760
- nutrition fortification substances: GB 14880 & relevant provisions

Requirements for Health Food Ingredients

— health food for registration

- 01 General food ingredients, food additives, substances in pharmacopoeia;
- 02 New food ingredients;
- 03 Substances traditionally used as both food and Chinese medicine (87 items);
- 04 Substances allowed to be used in health food (114 items);
- 05 Probiotics allowed to be used in health food (10 items);
- 06 Substances prohibited from health food (59 items).

Requirements for Health Food Ingredients

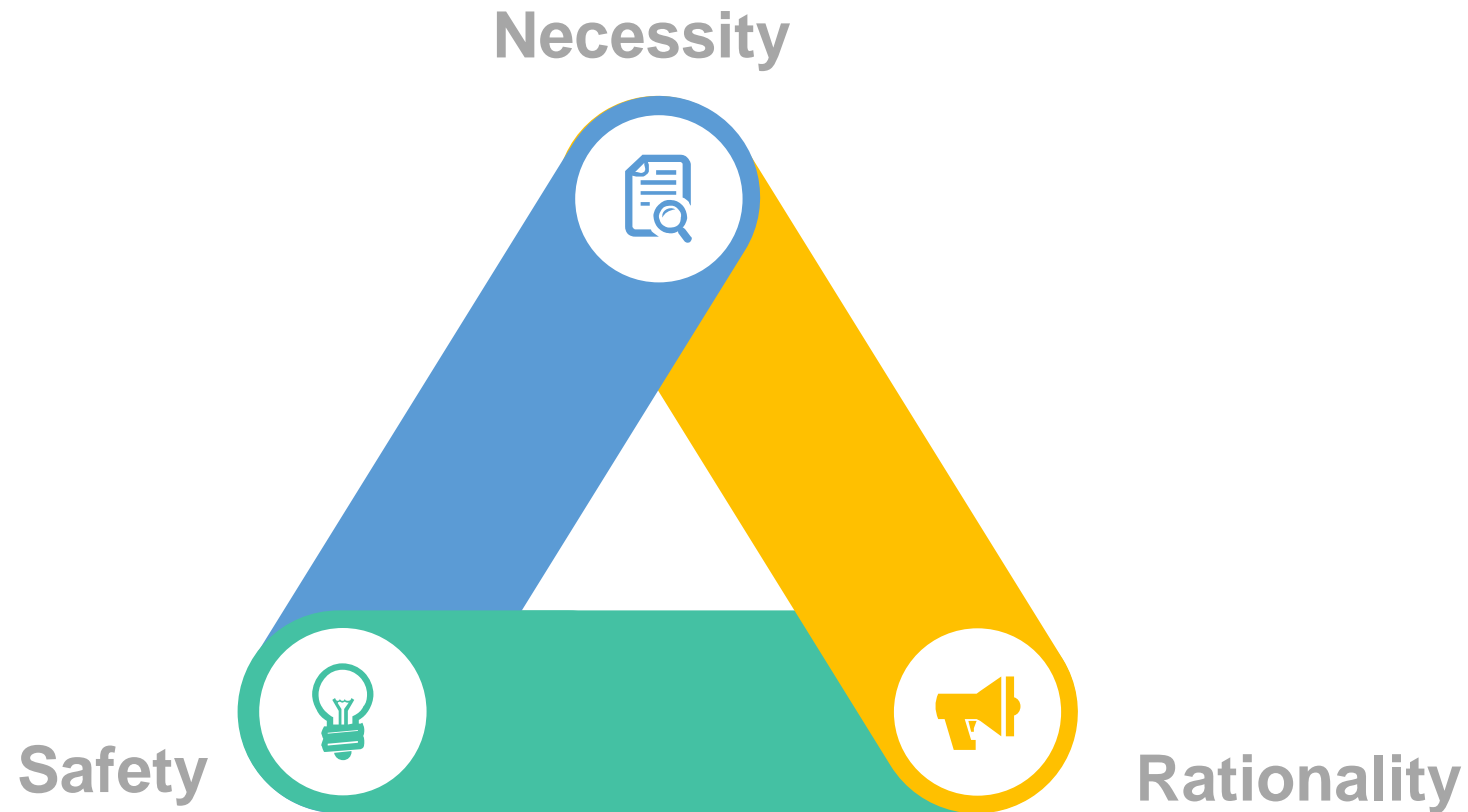
— health food for registration

Probiotic allowed in health food

中文名	外文名
两岐双岐杆菌	Bifidobacterium bifidum
婴儿双岐杆菌	B. infantis
长双岐杆菌	B. longum
短双岐杆菌	B. breve
青春双岐杆菌	B. adolescentis
保加利亚乳杆菌	Lactobacillus. Bulgaricus
嗜酸乳杆菌	L. acidophilus
干酪乳杆菌干酪亚种	L. Casei subsp. Casei
嗜热链球菌	Streptococcus thermophilus
罗伊氏乳杆菌	Lactobacillus reuteri

Requirements for Health Food Ingredients — health food for registration

Principles of using health food ingredients



Raw materials 69

Calcium : 12	Vitamin A : 3
Magnesium : 5	Vitamin D : 2
Potassium : 5	Vitamin B ₁ : 2
Manganese : 2	Vitamin B ₂ : 2
Ferrum : 5	Vitamin B ₆ : 1
Zinc : 6	Vitamin B ₁₂ : 1
Selenium : 3	niacin : 2
Copper : 2	folic acid : 1
	biotin : 1
	choline : 1
	Vitamin C : 4
	Vitamin K : 2
	pantothenic acid : 1
	Vitamin E : 6

Auxiliary materials 179

- No harm to health;
- Not for covering food spoilage;
- Not for covering flaws, fakeness, or impurity;
- Not denting the function and nutrition of products ;
- Lower usage level as soon as possible ;
- Processing agent shall be used in line with GB2760 and relevant provisions.

Requirements for Health Food Ingredients —health food for filing

Case study

Raw material		auxiliary material	
Vitamin C		Starch etc.	
[主要原料] 维生素C、木糖醇、K30、甜菊糖苷、甜橙油、姜黄素、硬脂酸镁			
功效成分及含量/每片含		维生素C 213mg	
[保健功能] 补充维生素C			
[适宜人群] 需要补充维生素C的成人			
[不适宜人群] 孕妇、乳母			
[食用方法及食用量] 每日1次，每次1片，嚼食			
[规格] 1.2g/片			
[包装规格] 1.2g/片×100片			
[保质期] 24个月			
[生产日期] 见瓶底 [生产批号] 见瓶底			
[贮藏方法] 密封、置阴凉干燥处			

Raw materials

主要原料：针叶樱桃浓缩物、山梨糖醇、预胶化淀粉、硬脂酸镁、樱桃香精
Sorbitol etc.

保健功能：增强免疫力

功效成分：每100克含维生素C6.21克

适宜人群：免疫力低下者

不适宜人群：3岁以下人群

产品规格：850mg/片

保质期：24个月

贮存方法：密封、避光、置阴凉干燥处

食用方法及食用量：每日2次，每次1片，嚼食

Functional Claims

1. Enhancing immune function ▲	2. Aiding blood lipids reduction	3. Aiding blood sugar reduction	4. Increasing antioxidants
5. Improving memory	6. Relieving body fatigue ▲	7. Relieving eye fatigue●	8. Facilitating lead excretion
9. Clearing throat	10. Aiding blood pressure reduction	11. Improving sleep ▲	12. Increasing milk secretion and anti-mutation
13. Improving endurance during anoxia ▲	14. Aiding protection against irradiation ▲	15. Aiding weight loss	16. Improving growth and development
17. Increasing bone density ▲	18. Improving nutritional anemia	19. Aiding protection against chemical liver injury ▲	20. Removing acne●
21. Removing chloasma●	22. Improving skin moisture●	23. Improving skin oil ●	24. Regulating enteric bacteria flora
25. Facilitating digestion	26. Improving constipation	27. Aiding protection against gastric mucosa	

● human experiment only; ▲ animal experiment only; the rest need both experiments.

04 Regulatory requirements for ingredients used in FSMP

FSMP intended for infants

- Lactose free formula or low lactose formula food
- Partially hydrolyzed milk protein formula food
- Extensively hydrolyzed milk protein formula or amino acid-based formula food
- Premature or low birth weight infant formula food
- Breast milk nutrition food
- Amino acid metabolism disorder formula food

Other FSMP

➤ **Nutritionally complete formula food**

- For people aged 1~10;
- For people aged above 10.

➤ **Special full nutritional formula food**

➤ **Nutritionally incomplete formula food**

- Nutrient module
- Electrolyte formula
- Thickener module
- Liquid formula
- Formula for amino acid metabolic patients

- For diabetics;
- For respiratory system disease patients;
- For kidney disease patients;
- For cancer patients;
- For hepatopathies;
- For muscle attenuation syndrome patients;
- For patients with trauma, infection, surgery or other stress condition;
- For patients with inflammatory bowel disease;
- For food protein allergy sufferers;
- For patients with intractable epilepsy;
- For patients with gastrointestinal disorders, pancreatitis;
- For patients with fatty acid metabolism;
- For patients with obesity, fat reducing surgery.

Requirements for FSMP Ingredients

— FSMP intended for infants

Raw materials

- Cause no damage to infants' health.
- Gluten-free.
- No hydrogenated oils or fats.
- No irradiated ingredients.
- Lactose and glucose polymers should be the preferred carbohydrates in FSMP intended for infants if no special occasion such as lactose intolerance. Gelatinized starched only. No fructose.
- According to special requirements arising from the disease(s), disorder(s), or medical condition(s), L-type monomer amino acids, their minerals and ones compiled in GB 14880 could be added to formula.
- No bovine colostrum or its products;

Food additives & nutrition fortification substances

- In accordance with relevant standards and provisions.
- GB 2760 & GB 14880.

Requirements for FSMP Ingredients

— FSMP intended for infants

Case study

ingredients **配料:** Lactose, maltodextrin, plant oil

Hydrolyzed whey

乳糖、麦芽糊精、植物油、二十二碳六烯酸油脂(DHA)、花生四烯酸油脂(ARA)、水解乳清蛋白(添加量21.5g/100g)、牛磺酸、L-组氨酸、左旋肉碱、矿物质(磷酸二氢钾、氯化镁、磷酸三钙、氯化钙、硫酸亚铁、硫酸锌、氯化钠、氯化钾、硫酸铜、碘化钾、磷酸二氢钠、柠檬酸钾)、维生素(维生素A(醋酸视黄酯)、维生素D(胆钙化醇)、维生素E(dl-α-醋酸生育酚)、维生素K(植物甲萘醌)、维生素B1(硝酸硫胺素)、维生素B2(核黄素)、维生素B6(盐酸吡哆醇)、维生素B12(氰钴胺)、烟酸、叶酸、泛酸(D-泛酸钙)、维生素C(L-抗坏血酸钠)、D-生物素、胆碱(酒石酸氢胆碱)、肌醇)、食品添加剂(柠檬酸脂肪酸甘油酯)。

ingredients **配料:**

玉米糖浆, 植物油, 中链甘油三酯/MCT(不少于5%), 淀粉, L-赖氨酸醋酸盐, L-亮氨酸, L-脯氨酸, L-谷氨酰胺, L-精氨酸, L-缬氨酸, L-异亮氨酸, 甘氨酸, L-天冬氨酸, L-苏氨酸, L-丝氨酸, L-苯丙氨酸, L-酪氨酸, L-组氨酸, L-丙氨酸, L-胱氨酸, L-色氨酸, L-天冬氨酸镁, L-蛋氨酸, 二十二碳六烯酸油脂(DHA), 花生四烯酸油脂(ARA), 甘油磷酸钙, 氯化钾, 柠檬酸钙, 柠檬酸钠, 柠檬酸钾, 磷酸二氢钠, 氧化镁, 硫酸亚铁, 硫酸锌, 硫酸铜, 碘化钾, 硫酸锰, 硒酸钠, 维生素C(L-抗坏血酸钠), 牛磺酸, 胆碱(酒石酸氢胆碱), 肌醇, 维生素E(dl-α-醋酸生育酚), 左旋肉碱(L-肉碱), 烟酸, 泛酸(D-泛酸钙), 维生素B2(核黄素), 维生素A(醋酸视黄酯), 维生素B1(硝酸硫胺素), 维生素B6(盐酸吡哆醇), 叶酸, 维生素D(胆钙化醇), 维生素K(植物甲萘醌), 维生素B12(氰钴胺), D-生物素, 麦芽糊精, 食品添加剂(柠檬酸脂肪酸甘油酯, 柠檬酸)乳糖含量不大于0.2g/100g, 淀粉经预糊化处理。

L- proline etc.

Requirements for FSMP Ingredients — other FSMP

Raw materials

- GB 25596, GB 29922 etc.
- Food ingredients only (no unknown substances)
- Substances that are both drug and food, health food, drugs are prohibited.

Food additives & nutrition fortification substances

- For people aged 1~10: refer to GB 2760 varieties and amounts of food additives allowed in infant formula.
- For people aged over 10: refer to GB 2760 varieties and amounts of food additives allowed in same or similar products.
- Specifications shall be in line with relevant standards and provisions.
- According to special demands, one or more amino acids are allowed to be added (GB 29922 appendix B and/or GB 14880).
- Other components shall be in line with relevant regulations.

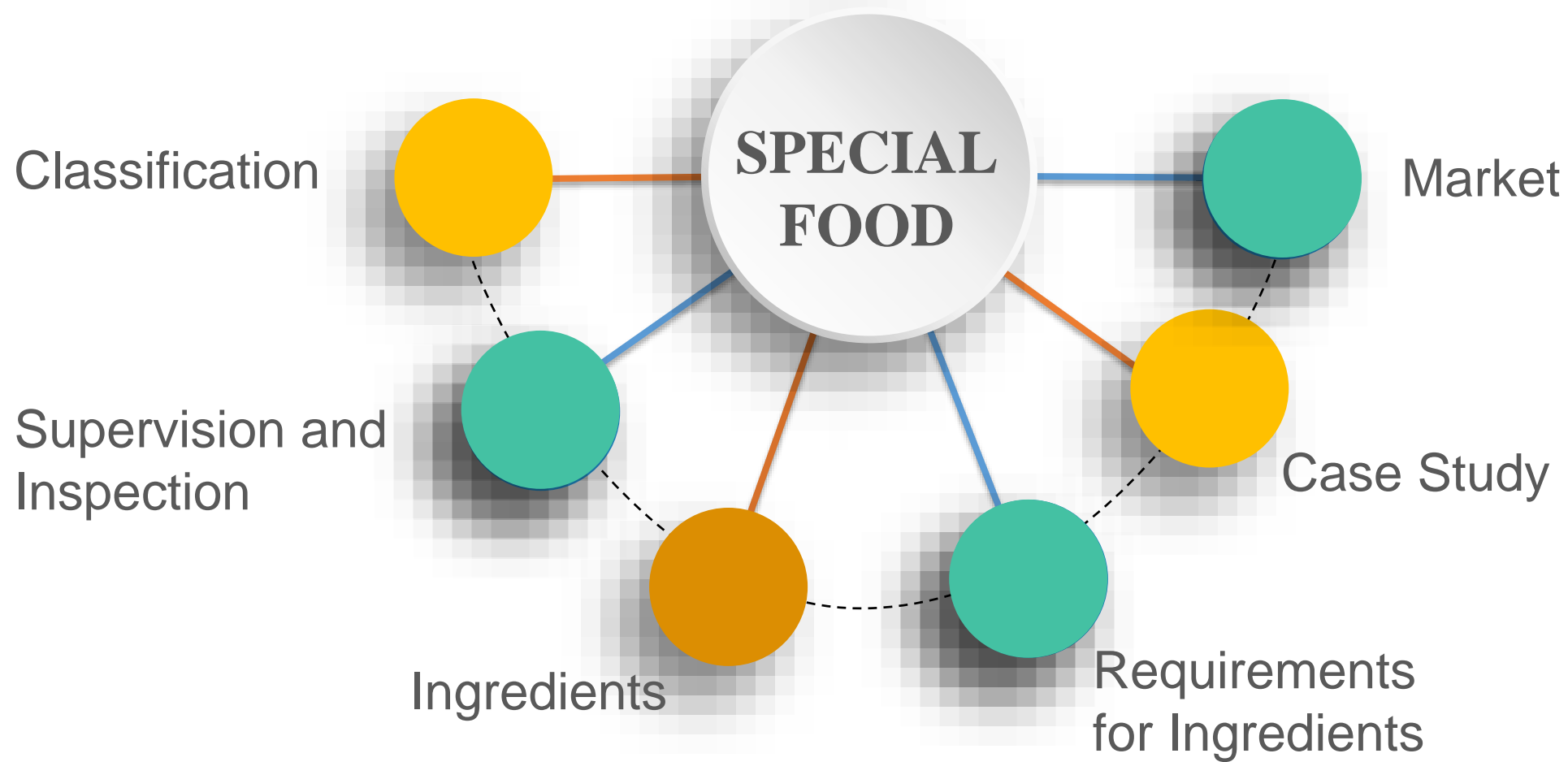
Requirements for FSMP Ingredients — other FSMP

Case study

固体玉米糖浆，白砂糖，植物油（葵花籽油，大豆油，中链甘油三酯（MCT添加量：不低于2%）），浓缩牛奶蛋白粉，低聚果糖（FOS），浓缩乳清蛋白粉，矿物质（柠檬酸钾，磷酸三钙，氯化钾，磷酸氢镁，氯化钠，碳酸钙，硫酸亚铁，硫酸锌，硫酸铜，硫酸锰，碘化钾，亚硒酸钠），大豆分离蛋白粉，食用香料（香荚兰豆浸膏，香兰素，乙基香兰素），维生素（氯化胆碱，L-抗坏血酸，抗坏血酸棕榈酸酯，混合生育酚浓缩物，dl- α -醋酸生育酚，D-泛酸钙，烟酰胺，核黄素，盐酸硫胺素，棕榈酸维生素A，盐酸吡哆醇，叶酸，植物甲萘甙，D-生物素，维生素D3，氰钴胺），二十二碳六烯酸油脂（DHA，寇氏隐甲藻来源），花生四烯酸油脂（AA，高山被孢霉来源），牛磺酸，乳双歧杆菌（不少于 10^6 CFU/g），肌醇，嗜酸乳杆菌（不少于 10^6 CFU/g），左旋肉碱。

Translated version:

Solid corn syrup, sugar, plant oil(sunflower oil, soybean oil, MCT (>2%)), concentrate milk protein powder, FOS, concentrate whey protein powder, minerals(potassium citrate...), soybean protein isolate powder, edible flavoring (vanilla bean concrete, vanillin, ethyl vanillin), vitamins (Choline chloride, L-ascorbic acid...), DHA (source: cryptocodinium cohnii), AA (source: mortierella alpina), taurine, Bifidobacterium (> 10^6 CFU/g), Inositol, Lactobacillus acidophilus (> 10^6 CFU/g), L-carnitine



Regulatory analysis

- [Probiotics in Infant Formula](#)

E-book

- [Health Food Raw Materials Directory \(1st Batch\)](#)
- [List of Auxiliary Materials for Health Food Filing and Terms of Use \(Trial\)](#)
- [Administrative Measures on Health Food Raw Material Directory and Health Function Directory \(Consultation Draft\)](#)
- [Regulation for Application and Acceptance of New Food Raw Materials](#)
- [Administrative Measures for Registration and Filing of Health Foods](#)

Flist

- [Bacterial Cultures that Can Be Used in Baby Foods in China](#)
- [Essential and Optional Ingredients in Formula for Infants and Young Children in China](#)

THANK YOU

Visit food.chemlinked.com for more information

Contact Us

ChemLinked by
REACH24H Consulting Group

Add: 14th Floor, Building 3, Haichuang Technology Center, Hangzhou, China (311121)

Email: food@chemlinked.com | Skype: ChemLinked Official
Tel: +86 571 8710 3822 | Fax: +86 571 8700 7566

China Food Contact Materials and Articles Regulation Trends & Compliance Challenges

Lily Li

liliyi@reach24h.cn

+86 0571-87006627

REACH24H Consulting Group China

Jul 2018

Content

- 1. FCM Regulation System & Latest Updates**
- 2. Supervision Dynamics in FCM**
- 3. Compliance Challenges Under New National Standards**
- 4. Our Services**



1. FCM Regulation System & Latest Updates

1.1 FCM Regulation System

1.2 Overview of Regulation Status

1.3 Regulation Updating

1.1 FCM Regulation System

1.2 Overview of Regulation Status

1.3 Regulation Updating

1.1 FCM Regulation System

Nov 18, 2016

53

GB 4806.1-2016



1.1 FCM Regulation System

General Standard	Product Standard	Testing Standard	GMP
GB 4806.1-2016 General Safety Requirements	GB 4806 collection of product standards	GB 31604 collection of testing standards	
	GB 4806.3-2016 Enamel	GB31604.1-2015 General Rules for Migration Test	
	GB 4806.4-2016 Ceramic		
GB 9685-2016 Standard for Uses of Additives in FCM	GB 4806.5-2016 Glass	GB 5009.156-2016 General Rules for Pre- Treatment of Migration Test	GB 31603-2015 General Hygienic Code for Production
	GB 4806.6-2016 Plastic Resin		
	GB 4806.7-2016 Plastic Materials & Articles	
		

1.1 FCM Regulation System

1.2 Overview of Regulation Status

1.3 Regulation Updating

1.2 Overview of Regulation Status

Category	Name
General Standard (2 items)	GB4806.1-2016 General Safety Requirements on FCM GB 9685-2016 Standard for the Use of Additives in FCM
Product Standard (10 items)	GB 4806.2-GB4806.11 Nipples, enamelware, ceramic ware, glass products, plastic resin, plastic materials & products, paper and board materials & products, metal materials & articles, paints and coatings, rubber materials & articles
GMP (1 items)	GB31603-2015 General Hygienic Code for Production of FCM
Testing Method (51 items)	GB 31604.1-2015 General Rules for Migration Test of FCM GB 5009.156-2016 General Principles for Pre-Treatment Method of Migration Test of FCM GB 31604.2-GB31604.49 、 GB4789.15 → 49 corresponding testing methods

1.2 Overview of Regulation Status

Category	Item Name	Condition
Product Standard (9 items)	Food contact metal materials and articles	Being revised
	Food contact paper and paperboard materials and articles	Being revised
	Food contact plastic resin and plastic materials and articles	Being integrated & revised
	Food contact bamboo, wood and cork products	Consultation draft
	Composite food contact materials and articles	Consultation draft
	Food contact adhesive	Being developed
	Food contact cellophane	Being developed
	Food contact ink	Being developed
	Food contact starch-based plastic materials and articles	Consultation draft
Testing Standard (3 items)	General Rules for Migration Test of Food Contact Materials and Articles	Being revised
	The Detection Method of Migration Amount 5-Ethylidene-2-norbornene	Being developed
	The detection method of FCM residual solvent	Being developed

1.1 FCM Regulation System

1.2 Overview of Regulation Status

1.3 Regulation Updating

1.3 Regulation Updating

Food contact adhesive

2014: project establishment & drafting

2016: seminar held in Beijing

- Positive list
- Research on substance necessity
- Migration test



1.3 Regulation Updating

Food contact ink

2016 : project establishment
At present: investigation and research

- Direct & indirect contact ink
- Condition of migration test
- Detection & evaluation of harmful substances in ink
- Study on the barrier effect of base material
- Study on risk prevention & control





2. Supervision Dynamics in FCM

2.1 Summary of Product Quality Sampling 2017

2.2 Key Points of Product Quality Sampling in 2018

2.3 National Product Quality Sampling Plan 2018

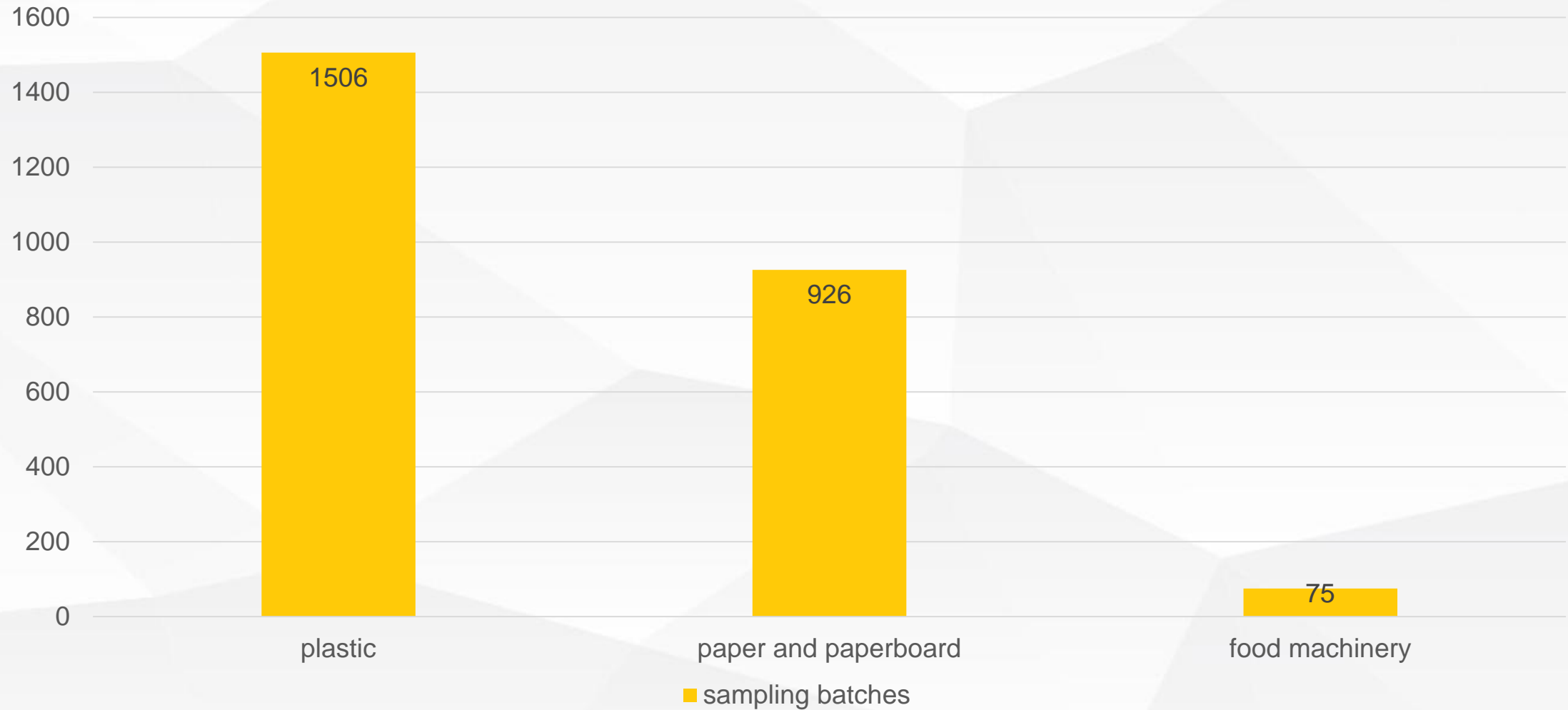
2.1 Summary of Product Quality Sampling 2017

2.2 Key Points of Product Quality Sampling in 2018

2.3 National Product Quality Sampling Plan 2018

2.1 Product Quality Sampling 2017

Food-Related Products Sampling Data in 2017

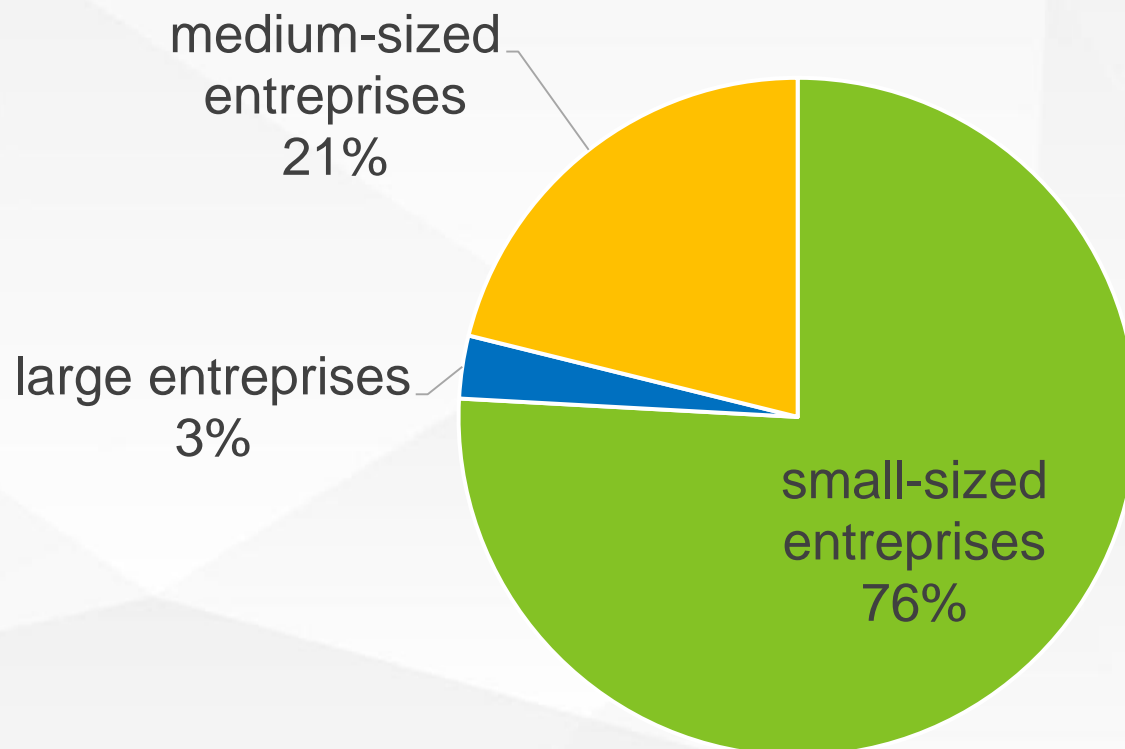


2.1 Product Quality Sampling 2017

Product category	Product	Defect rate	Problems
plastics	RCPP, retort pouch, box	0.5%	Stain resistance
	Melamine tableware		Barrier function
paper & board	Food wrap paper	4.1%	Sensory indexes Cup stiffness Fluorescent substance Anti-seepage (oil) Anti-seepage (water)
	Food packaging board		
	Paper bag		
	Paper can		
	Paper cup		
	Paper tableware		
	Paper box		
		
food machinery	Slicing machine	53.3%	Aluminum physical and chemical index- cadmium Internal wiring
	Dough mixer		

2.1 Product Quality Sampling 2017

Sampling Data of Food Related Products Enterprise Scale in 2017



2.1 Product Quality Sampling 2017

Features of Product Quality Sampling 2017

1. Tracking and sampling licensed products;
2. Selecting technical laboratories ;
3. Expanding the range of products for inspection ;
4. Giving priority to physiochemical indexes.



2.1 Summary of Product Quality Sampling 2017

2.2 Key Points of Product Quality Sampling in 2018

2.3 National Product Quality Sampling Plan 2018

2.2 Key Points of Sampling 2018

Highlighting the supervision over quality and safety of food related products

Stringent Supervision

1. licensing
2. Inspection & Sampling
3. Risk control

Key Materials for Strict Inspection

Plastics, paper, metal, glass



2.1 Summary of Product Quality Sampling 2017

2.2 Key Points of Product Quality Sampling in 2018

2.3 National Product Quality Sampling Plan 2018

2.3 National Sampling Plan 2018

National Product Quality Sampling Plan 2018

1. Food contact materials :

plastics ; paper & board ; metal ; glass
products ;

2. Household electronics :

electric oven ; pressure cooker ; kitchen
machinery ; heating kettle ; auto rice
cooker ;

category	product
Plastics	Thin plastic bag or film
	Plastic container
	Plastic tool
Composite materials	polymer-aluminum packaging material
Paper	Food packaging paper & board
	Food contact paper container
Metal	Food contact metal utensils and tools
	Pressure cooker
	Food contact metal lid
	Food contact metal can
Glass	Glass wine bottle
	Food container
	Food contact utensils
Food machinery	Household processing equipment



3. Compliance Challenges Under New National Standards System

3.1 How to Deliver Declaration of Compliance (DoC)

3.2 Data Requirements for New Substance Registration

3.3 Good Manufacturing Practice (GMP)

3.1 How to Deliver Declaration of Compliance (DoC)

3.2 Data Requirements for New Substance Registration

3.3 Good Manufacturing Practice (GMP)

3.1 How to Deliver DoC



**Substances
manufacturer**

**Intermediate
materials
manufacturer**

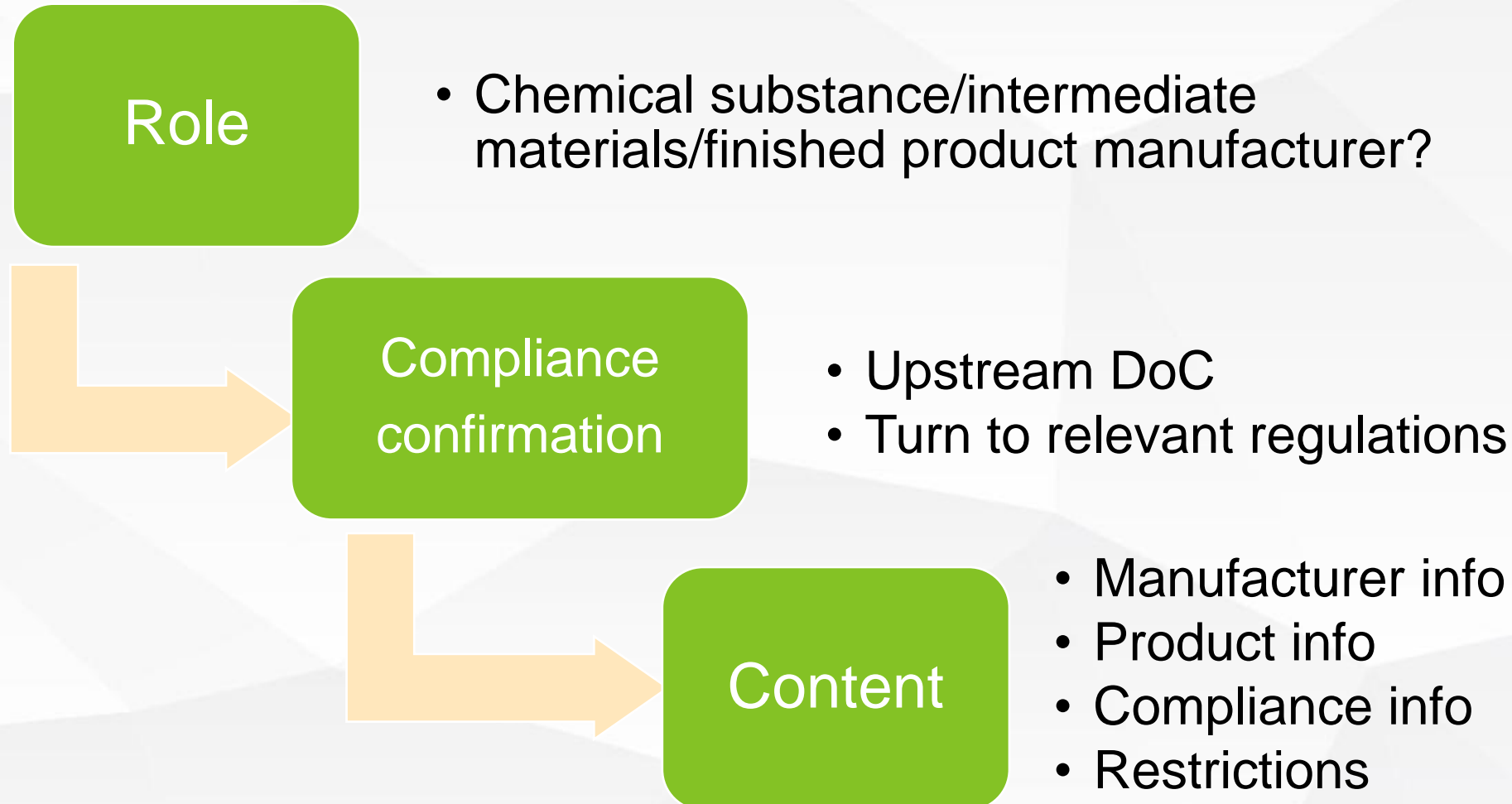
**Finished
product
manufacturer**

**Finished
product user**

Consumer



3.1 How to Deliver DoC



3.1 How to Deliver DoC

Declaration of Compliance (Chemical substance)

Product name:

Substance info

Chemical name (if applicable):

Manufacturer (if applicable):

Contact information (if applicable):

Manufacturer info

Declarant:

Contact information:

Usage condition (applies to final product):

Regulatory compliance:

Compliance info & restrictions

Usage notice:

Responsibility statement:

Signature:

Date:

3.1 How to Deliver DoC

Appendix: List of Restricted Substances and Their Limits

FCA No./ Name	CAS No. (if applicable)	Standard/ Announcement	Limits
FCA1089/ Tris(nonylphenyl) phosphite	26523-78-4	GB 9685-2016	Application scope & maximum level / %: PE, PP, PS, ABS, PA, PET, PC; appropriate dose; ND (nonylphenyl, SML (T), group No. 21)
FCA0065	552-30-7	GB 9685-2016	Application scope & maximum level / %: PET:2%; 5 (SML (T), group No. 21)
Methylmethacrylate- ethylacrylate- trimethylolpropane trimethacrylate copolymer	59779-17-8	Announcement No.10 - 2016	Application scope & maximum level / %: 6.0 (expressed as methacrylic acid, SML) ; 6.0 (expressed as acrylic acid, SML) ; 0.05 (expressed as trimethylol propyl triacrylate, SML).
Code A218	—	GB 9685-2016	30 (SML (T), group No. 21) ND (Acrylonitrile, SML, DL=0.01mg/kg)

3.1 How to Make Compliant Claims

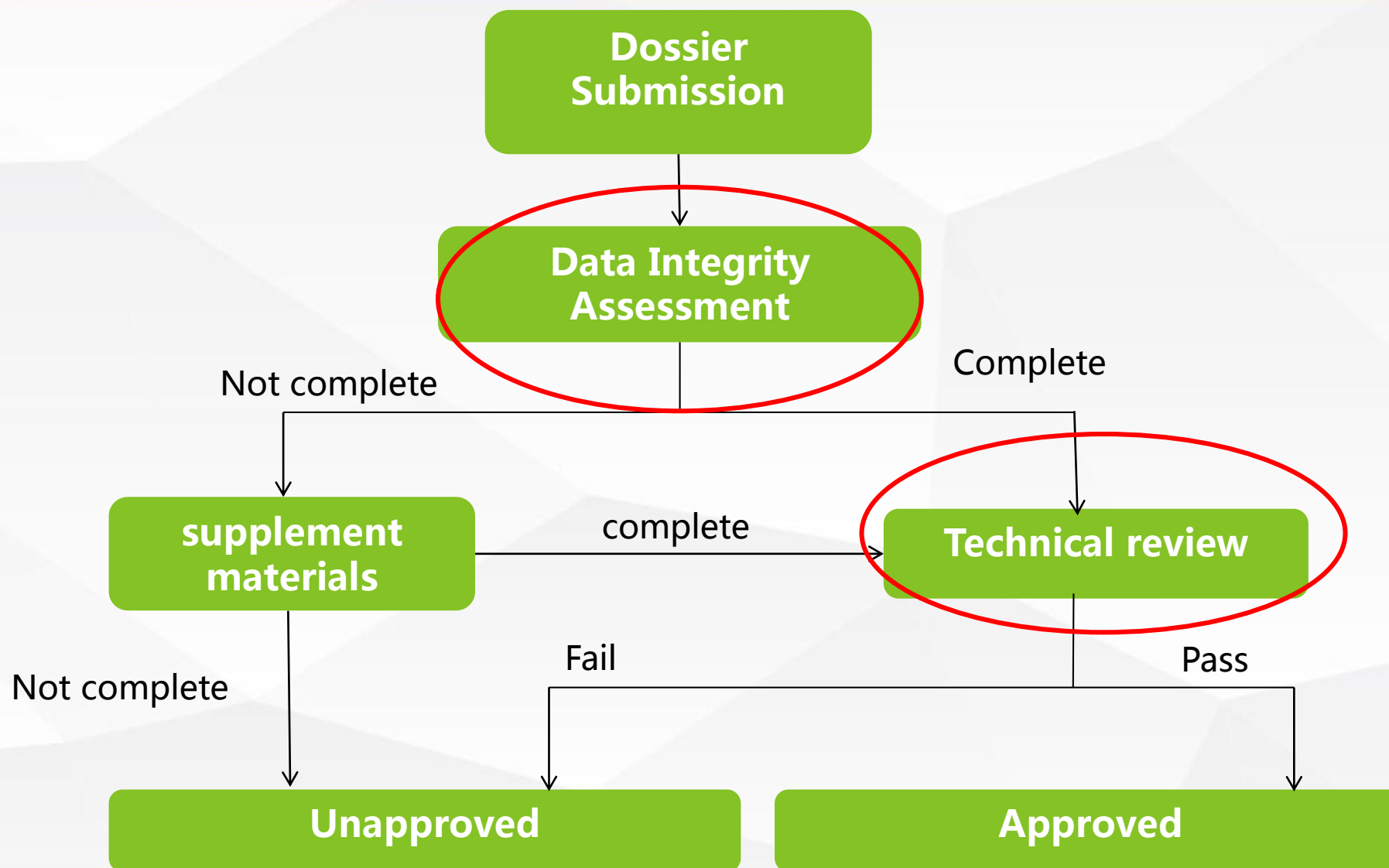
3.2 Data Requirements for New Substance Registration

3.3 Good Manufacturing Practice (GMP)

3.2 Data Requirements for New Substance Registration

Data Requirements
Application form
Physicochemical data
Migration data
Toxicology data
Authorization in other countries

3.2 Data Requirements for New Substance Registration



3.1 How to Make Compliant Claims

3.2 Data Requirements for New Substance Registration

3.3 Good Manufacturing Practice (GMP)

3.3 Good Manufacturing Practice (GMP)

GB 4806.1-2016 Provision 3.7:

“The manufacture of food contact materials and articles
shall **comply with GB 31603**”

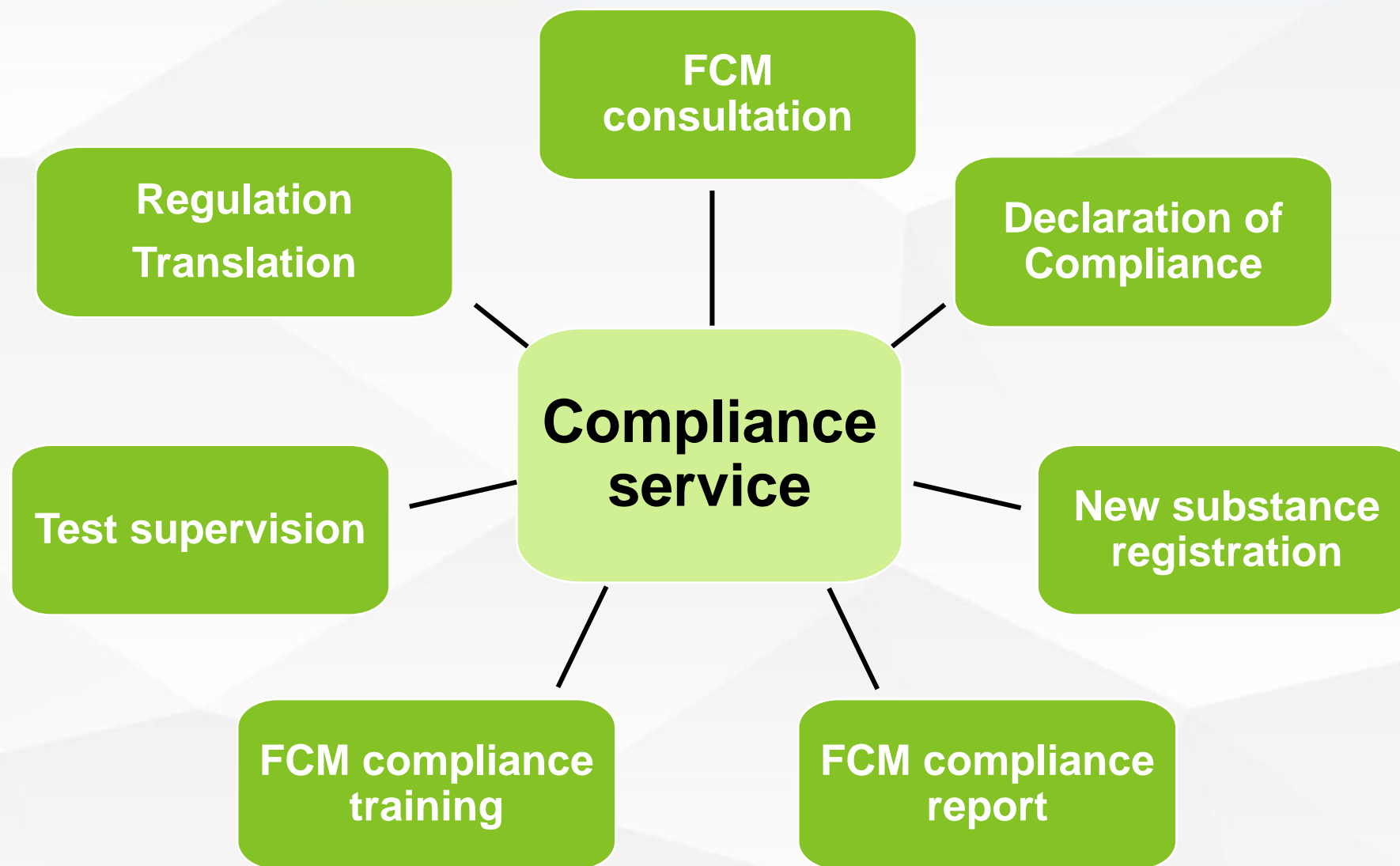


3.3 Good Manufacturing Practice (GMP)





4. REACH24H Services



Recommended Reading

Foodpedia

- [Food Contact Materials Regulation](#)

Regulatory analysis

- [An Analysis of China New Food Contact Material Substances in 2017](#)
- [Chinese New Food Contact Material Standard System and the Impact on Industry](#)

Report

- [Interpretation of Guideline on Identification of Food Contact Materials Used in Household Appliances in China](#)
- [Checklists of National Sampling of Food Contact Materials and Articles in China](#)

Webinar

- [Regulatory Requirements for Thermoplastic Elastomer in China, USA and EU](#)
- [Supply Chain Responsibilities and Declaration of Compliance for Food Contact Materials & Articles in China](#)
- [China Regulatory System for Food Contact Materials and Interpretation of GB9685 New Version](#)

Thank You for Your Attention !

Lily Li

liliyi@reach24h.cn

+86 0571 8700 6627

Reach24H Consulting Group

Jul, 2018

SAVE THE DATE

ChemLinked Food Regulatory Conference **- Connect Oceania with China**

Date: November 8, 2018

Venue : Marriot Hotel, Melbourne, Australia

120

SAVE THE DATE





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