

For a safer world

# The Reform of Chinese FCM regulations and the legal compliance

## Part 1

**National reference laboratory for  
Food contact material(NRL-FCM-IQTC)**

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## About IQTC

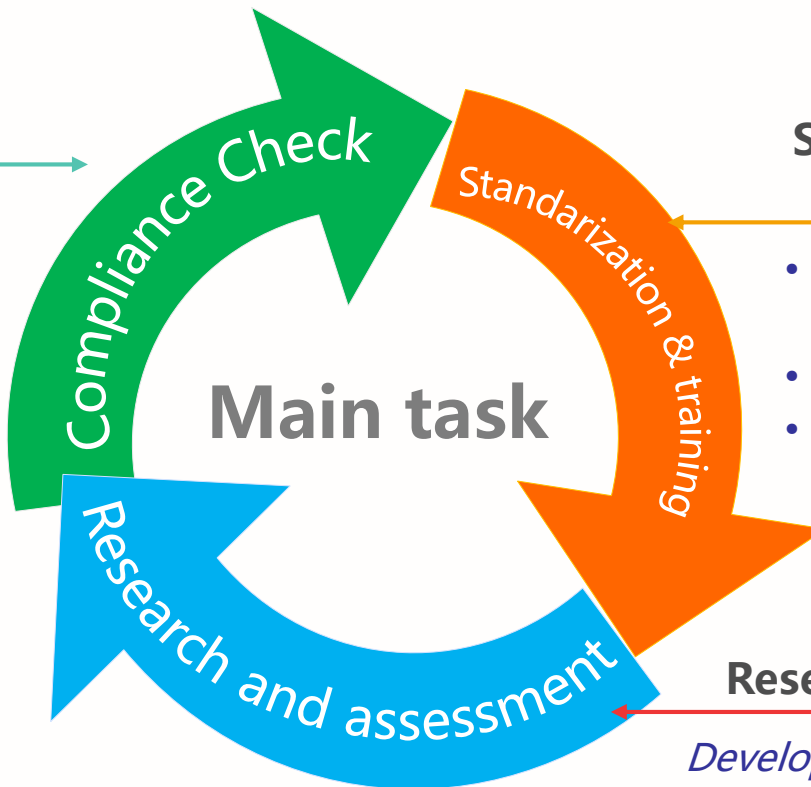
- With a history of more than 30 years
- One of leading technical institute in AQSIQ to offer compliance test and assessment service



# Main Services for FCM

## Compliance test

- Overall migration
- Specific migration
- Sensory check
- QM test



## Standardization & Training

- Regulation & Standards
- Training
- Proficiency program

## Research & Assessment

- Development of new approach
- Application of TTC approach
- Assessment of IAS/NIAS
- Migration modelling



# Organize the Food Contact Safety Symposium in China

- A scientific conference launched on 2012 and taken place on a regular basis
- Addressing the safety issues related to FCM
- [www.foodcontactscience.org](http://www.foodcontactscience.org)-- acquire English version of GB standards



# **Why we shall reform the Chinese FCM regulation?**

## Complex of system in place

### Vary organizations involved in drafting standards for FCM

- *NHFPC: National Health and Family Planning Commission*
- *AQSIQ: General Administration of Quality Supervision, Inspection and Quarantine*
- *Other Administration of the State Council*
- *Local authorities*
- *Industry Association.....*

### Have different position and interest

*Food safety ?*



*Quality of Industry product?*

# >265 standards related to FCM in national level

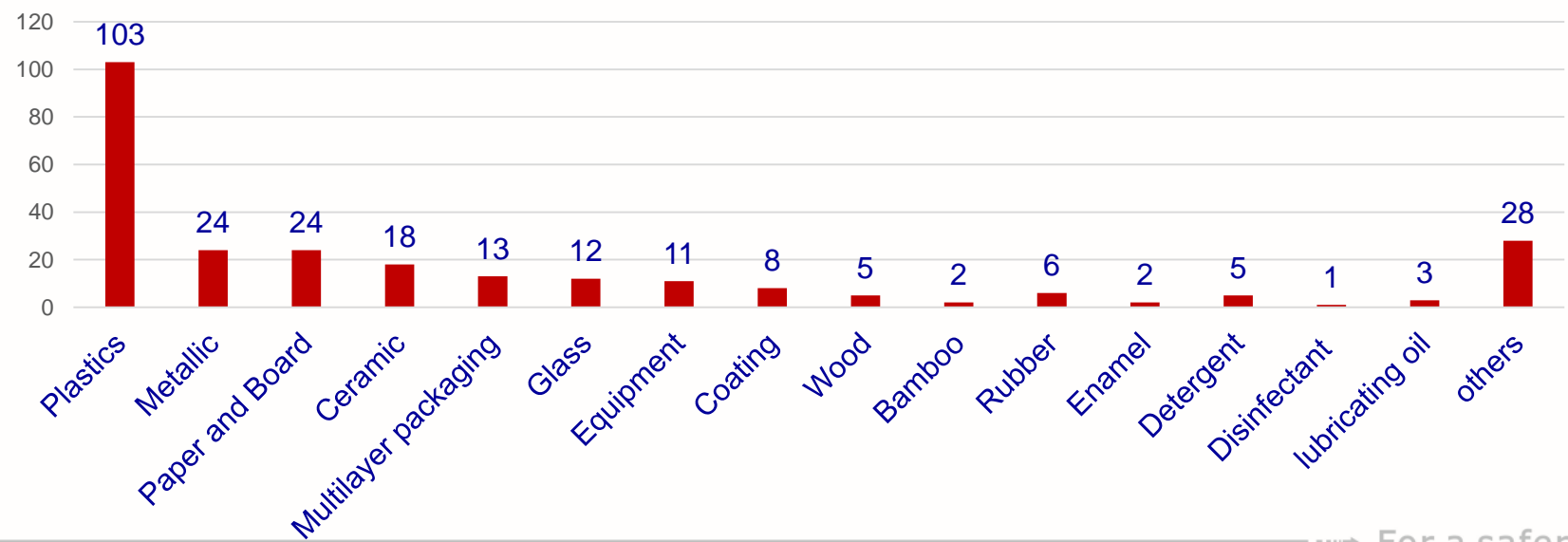
## Most of them no update after enforce in 1980s

- *Product standards*
- *Specific standards*
- *Testing methods*
- *Implementation measures*

*Mandatory: GB*

*Volunteer standards: GB/T,SN,QB.....*

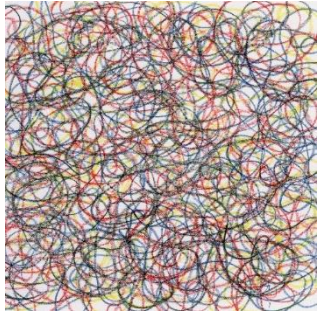
Standards related to FCM



# Gap between existing legislations and compliance' s need

## What we have

- Certain Plastic
- Small amounts of additive
- Stainless steel
- Ceramic
- Glass
- .....



VS

## Demand

- Novel plastics
- More additives are expected to be introduced
- Metallic articles
- Coating
- Rubber
- Adhesive
- Ink
- Wood and bamboo
- ...

## Lack of harmonization and scientific evidence

### Lack of harmonization within various standards implemented

- Different definition or interpretation ,e.g plastic resins
- Different or even conflicts restrictions/limitation for one identical FCM
- Lack of test method /guidance to perform the compliance test

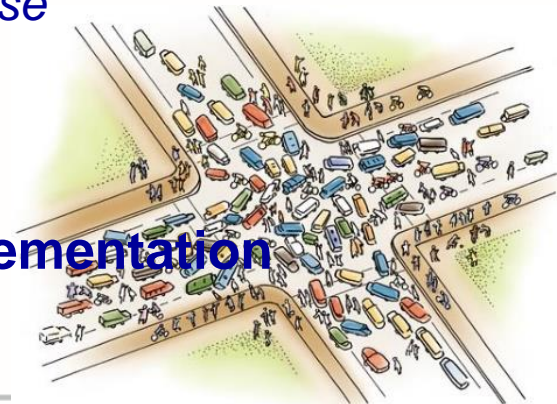
### Some of standards and their provisions have being questioned

*Why the recycled material can not be used in FCM?*

*Does it make sense to adapt a generic or simplified condition to represent most of FCM or their actual/foreseeable condition of use*

- 60°C, 2h,
- 60°C, 0.5h

**Have difficulties on understanding and implementation**



# Migration of Phthalates, PAAs, Photoinitiator, NP, Mineral oil, Heavy metals, PFOA, EDC, etc



巧克力被检出矿物油，你刚过完的情人节“有毒”？  
【原创】2017-03-27 马列生 马上要拜

马上迎接情人节，马上打情骂俏要拜  
近日，多个知名品牌的巧克力检出矿物油，引来消费者对矿物油、增塑剂、邻苯二甲酸盐等食品添加剂是否有害的担心。那么，矿物油究竟是什么？！

巧克力检出矿物油，还能放心吃吗？  
【原创】2017-03-08 阮光锋  
科信食品与营养信息交流中心

近日，有媒体报道称某巧克力检出矿物油，吃了可能导致肝脏损伤。矿物油到底是什么东西？为何会出现在巧克力中？还能放心地吃吗？



The government agency and the industry are being criticized

## Higher protection of consumer 's health is need



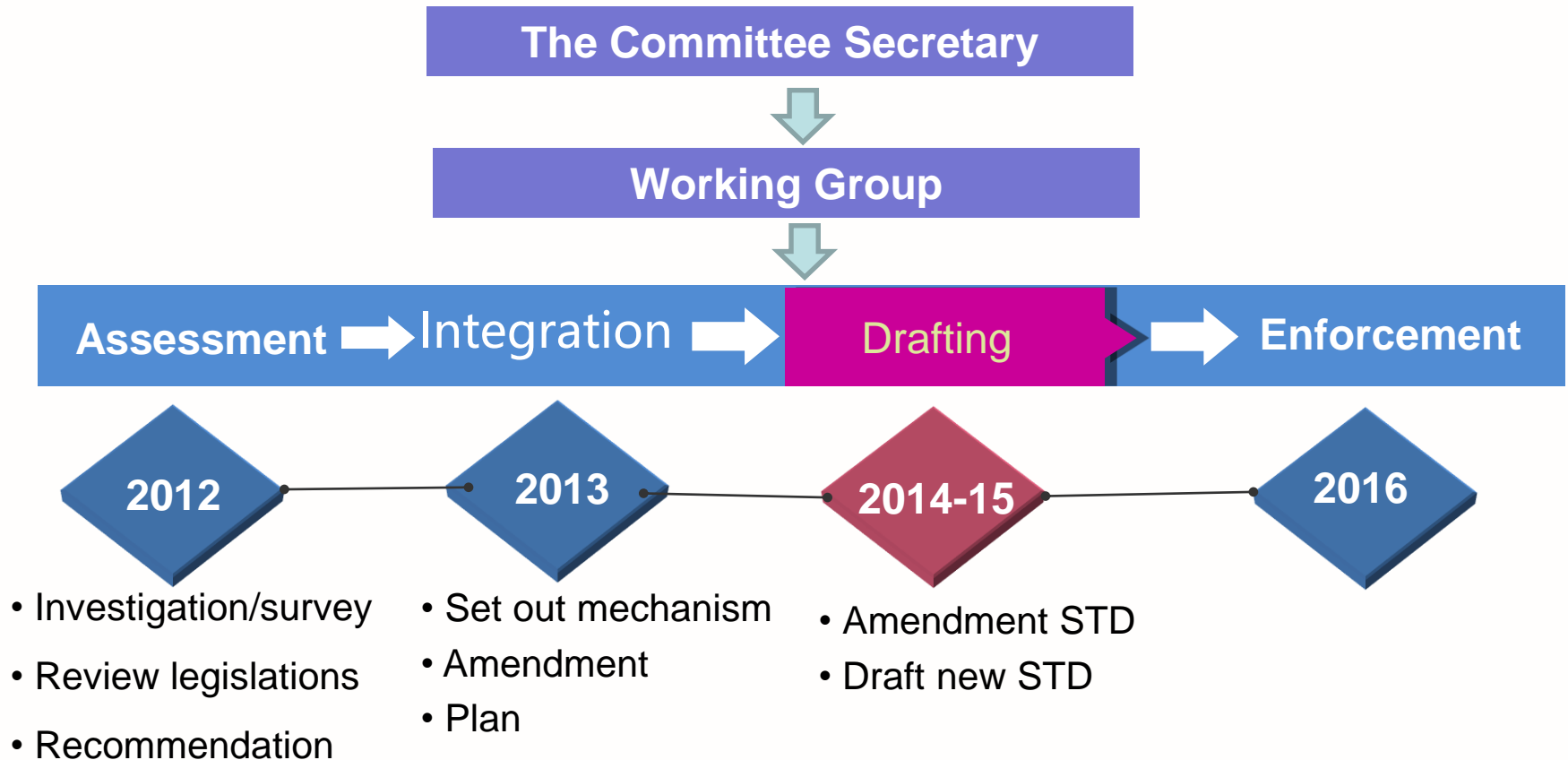
**A new FCM regulation system is needed**

## 《Food safety law》 initiate the reform of food safety control system

- *NHFPC take the full responsibility to draft the regulations concerning the safety of food*
- *Standards for FCM are part of food safety standard*
- *Except for safety standard, it is not allowed to draft mandatory standards applicable to food and food contact materials*

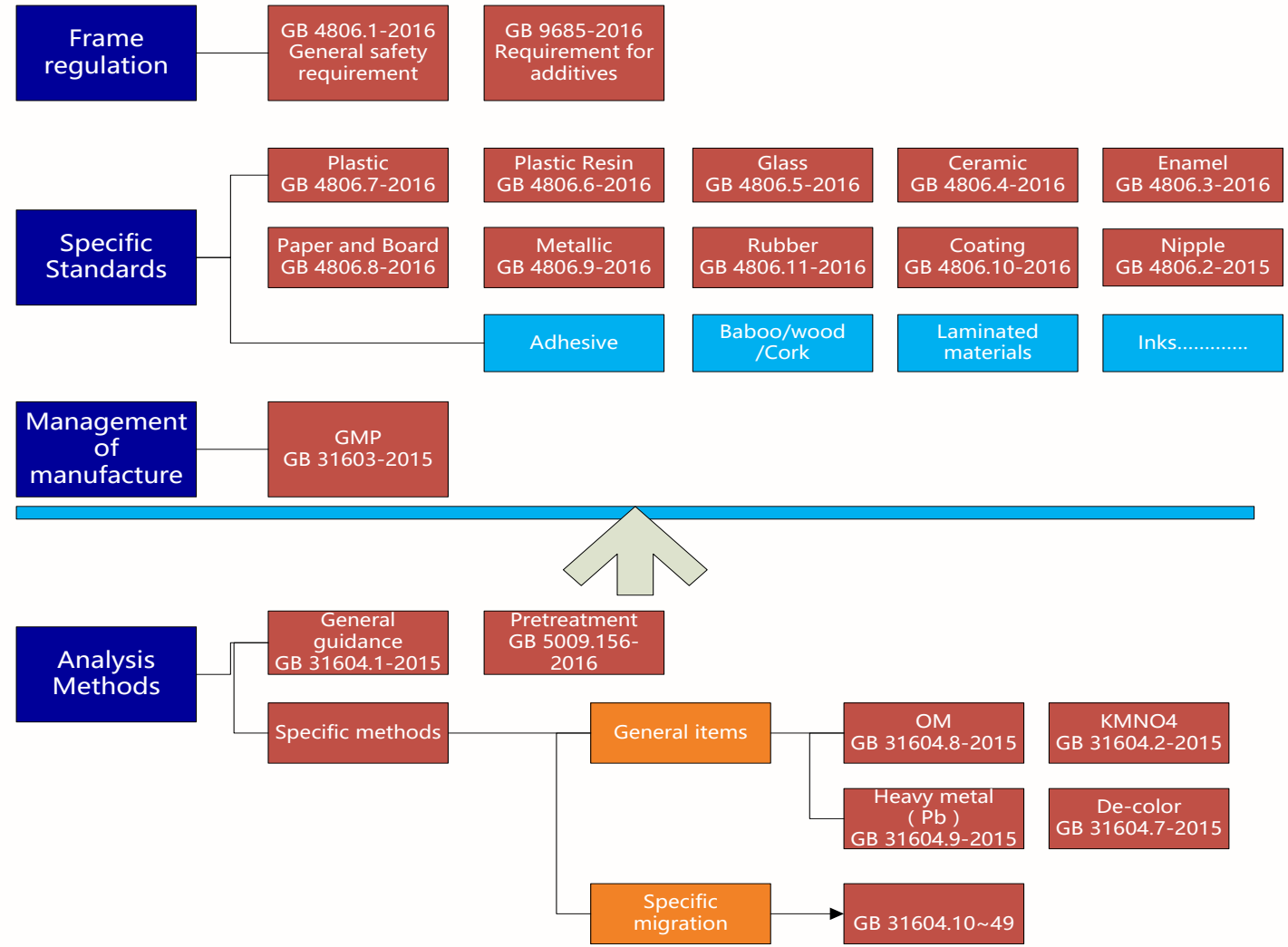


# The process of developing regulations



Source: Dr Zhu lei

# The latest Framework of new FCM regulation



# Fundamental reform for Chinese FCM

## Old system

Hygienic standards  
Negative approach  
mainly refers to products

Focus on general Items

Simplified test condition

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## New system

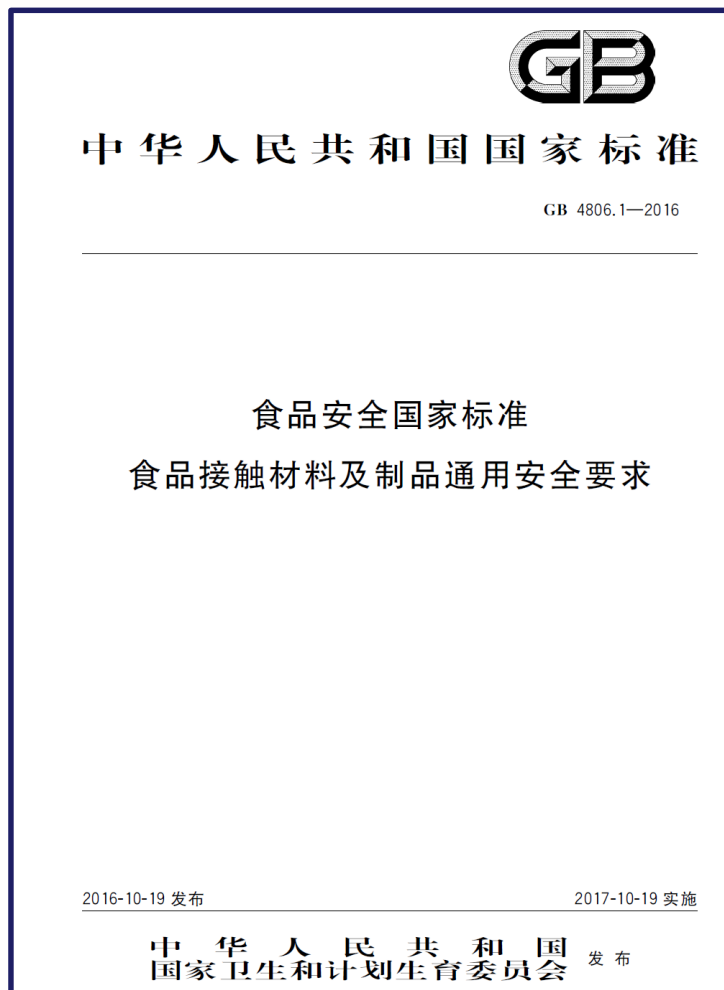
Safety standards  
Positive list approach  
Cover the whole Supply chain: GMP, new substances assessment, finished product

General items + Specific Migration limit+QM+overall migration.....

Corresponding exposure condition(Simulants, contact condition...)

.....

# General requirement for FCM



## GB 4806.1-2016



*2016-10-19 approved*

*2017-10-19 come into enforce*

# **A Comparison of China,EU and USA**

	China	EU	FDA
Structural	Frame regulation+ Specific standards+ GMP Test methods .....	Frame regulation+ Specific standards+ GMP Test methods+ .....	Specific provisions on FCN
Remarks	Uniform system, cover supply Chain		Specific, Fragment
Scope	Plastic, metallic, P&B, Ceramic, Glass, Plastic resins, Rubber, Coating, Teats,	Plastic, Ceramic, regenerated cellulose film	Plastic, Ceramic, paper
Remarks	Aggressive with covering a wide range of FCMS	Limited group of FCMS	Focus on plastic and paper

	China	EU	FDA
Restriction /Limitation	General requirement Positive list Scope of use for each chemical Restrictions of use  <b>limitation:</b> - Sensory - Generic items OML Consumption of $Kmno_4$ Heavy metal(Pb) - SML/SML(T) - QM	General requirement Positive list Restriction on certain application: children  <b>limitation:</b> -OML -SML/SML(T)L -QM	Positive list     <b>limitation:</b> Extractives-
Remarks	Generic items for screening purpose Physical specification Chemical Migration	Chemical Migration Residual	Ending test for clearance purpose Migration test rely on self-determination

	China	EU	FDA
Analysis methods	Test Method is mandatory except for otherwise stated. Several hundred of GB standards are expected	Test method is recommended on EN 13130, EN 1186 serial No update for years	Protocol are provided within provisions of CFR 21 170-189
Simulant	Water 4% acetic acid 10% /20%/50%ethol... Olive/Corn oil .....	Water 3% acetic acid 10% /20%/50%ethol... Vegetable oil MPPO	Water Heptane n-Hexane 8% alcohol 50% alcohol dimethylbenzene
Exposure condition/ calculation	Complex condition( SM,OM test) "Severe" principle is applied -Contact time -Temperature -Surface area: Volume -DRF -FRF <i>Applicable to all kind of FCMS in China, only applicable to plastic in EU</i>		Simplified condition: 120°F 30min 150°F 2h 120°F 24h .....

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**Thank you for your  
attention !**

保护消费者、保护您的业务和您的品牌



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