

For a safer world

# The Reform of Chinese FCM legislations and the challenges for compliance

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

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## About IQTC-FCM

- A national reference lab affiliated to AQSIQ with a history of more than 30 years
- Based in Guangzhou, the capital of Guangdong province who is the largest economic in China

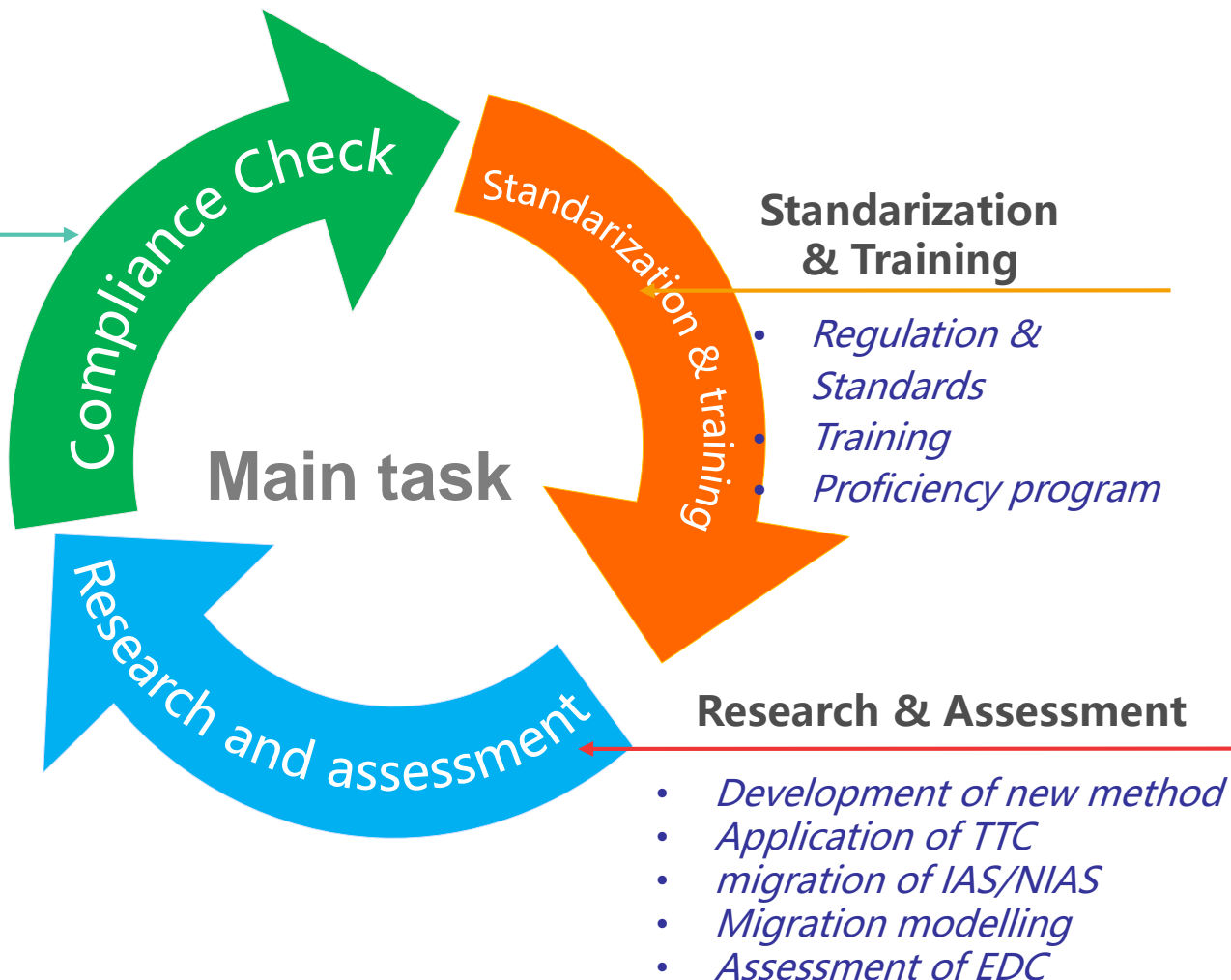
**IQTC-FCM**



# Main Services for FCM

## Compliance test

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





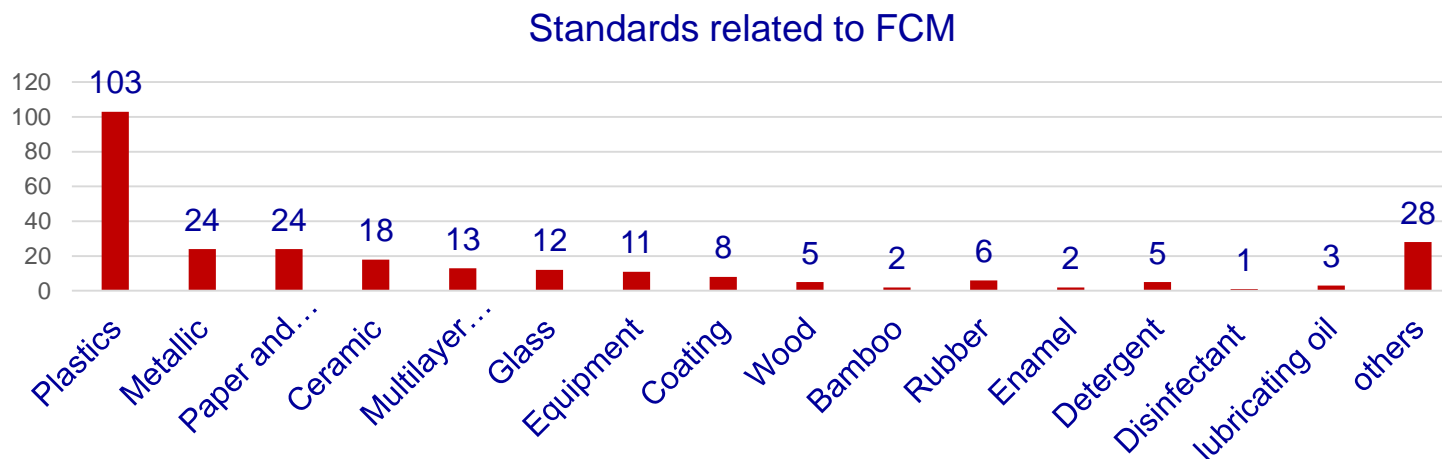
# Food Contact Safety Symposium

- A scientific conference launched on 2012 and take place on a regular basis
- Addressing the safety issues related to FCM



## **Why China shall reform the FCM legislations?**

## Complex and out of date



- *A large number of standards employed*
  - 265 standards
  - non harmonize
- *Various of agencies and institutions getting involved in different level*
  - National Level(NHFPC,AQSIQ)
  - Local authority
  - Industry Association.....
- *80% legislations implemented in 80s and not update for 20 years*

## Lack of harmonization

*Food safety ?*



*Quality of Industry product?*

- *No harmonization on certain key aspects*
  - *Scope, definition, requirement*
  - *The approach to regulate the use of chemicals and raw material*
- *Different or even conflicts restrictions/limitation for similar FCMs*



## Couldn't response the need

### What we had

Limited legislations for Plastics

Limited additive were authorized

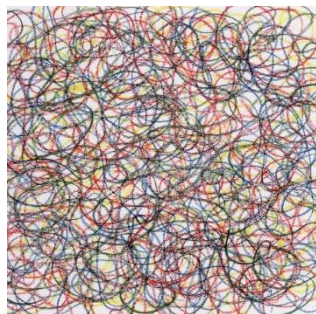
Limited legislations for non-

plastic -Stainless steel

-Ceramic

-Glass

.....



VS

### Demand

Novel plastics need to be regulated

More additives need to be introduced

More legislations need for non-plastic

-Metallic articles

-Coating

-Rubber

-Adhesive

-Ink

-Wood and bamboo

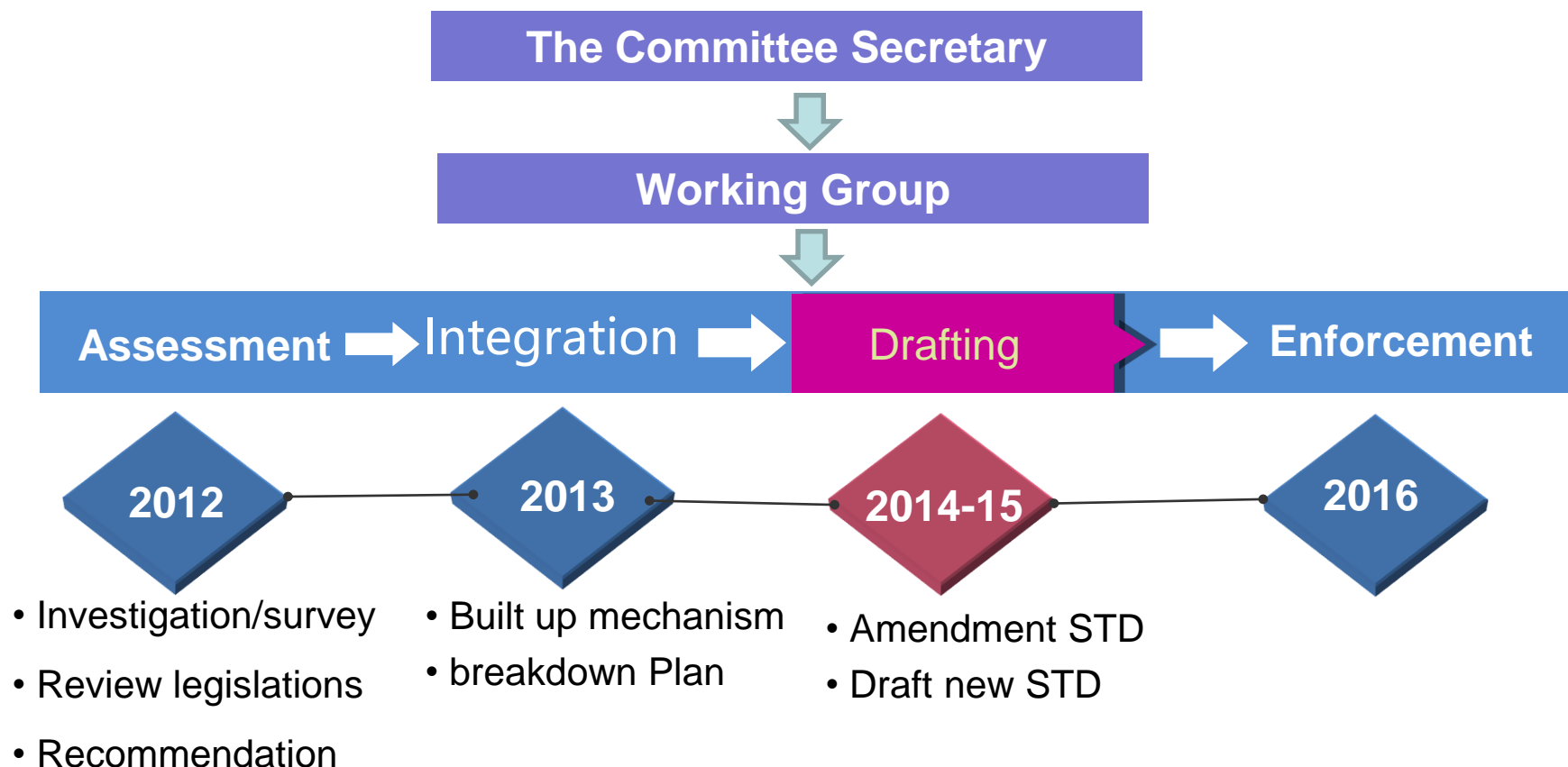
-Paper and paperboard

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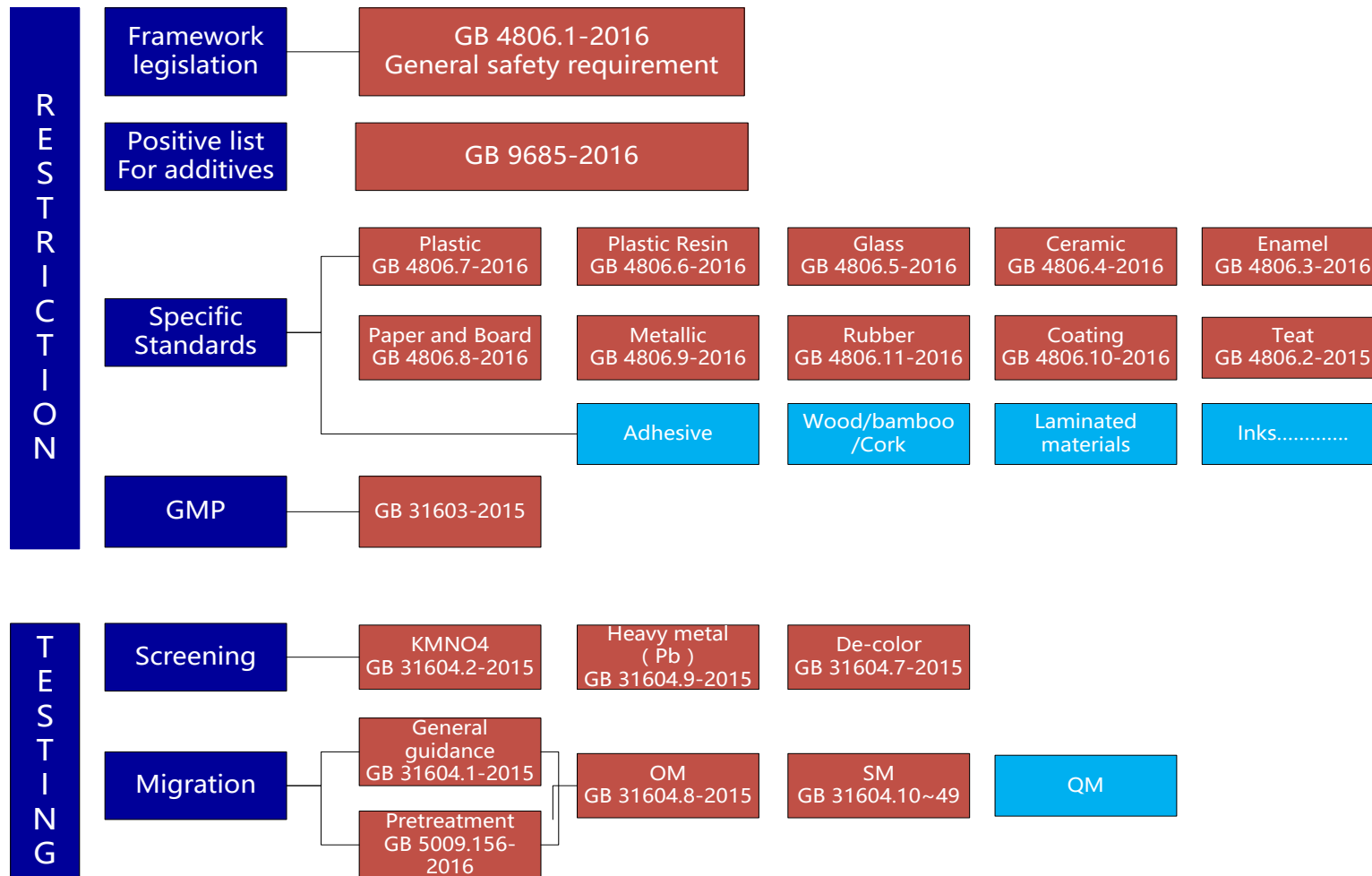


**A new FCM regulation system is needed**

# The process of developing legislations for FCM



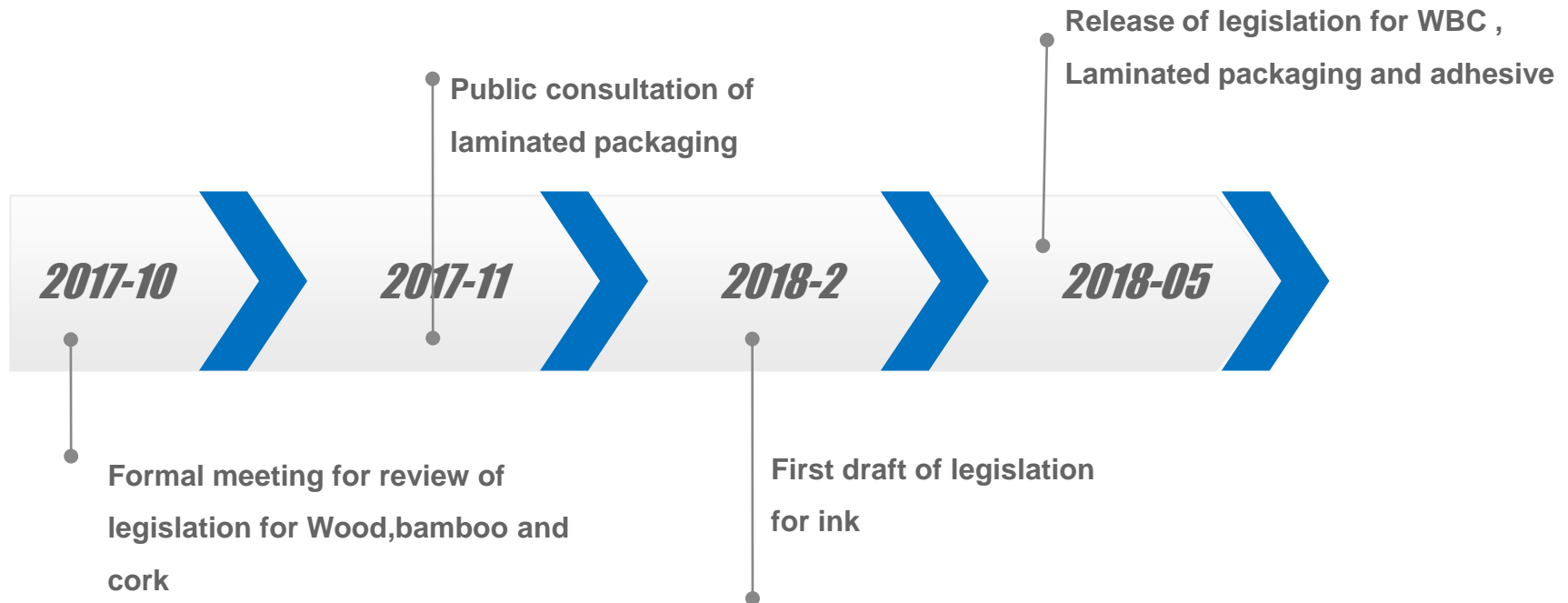
# The scheme of new FCM legislations



# Current Status of certain developing legislations

4 legislations are under way :

**Wood, bamboo and cork(WBC), Adhesive,  
Laminated material and articles, Inks**



**New parameters for FCM assessment is under evaluating**

- More accurate exposure assessment: probability assessment  

$$\text{Exposure (mg/person/day)} = \text{migration (mg/dm}^2\text{)} \times \text{contact area (dm}^2\text{/person/day)}$$

# Fundamental reform for Chinese FCM

## Old system

Hygienic standards

**Negative approach**

mainly refers to finished products

Focus on general Items

Simplified test condition

.....

VS

## 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.....

Severe condition (Simulants, contact condition,S/V...) to reflect the intend use

.....



## **A comparison with EU,FDA and China**

# The main features of system in place

**China:** Aims to establish a uniform and mandatory legislation system covering various FCMs before 2018

**EU:** legislation for plastic is harmonized, non-plastic are being regulated in MS

**FDA:** Focus on specific material or articles: Plastic and paper

## China

- Single system
- covering various FCMs (plastic and non-plastic)
- Implemented in whole supply chain (chemicals, raw material, articles, GMP)
- corresponding mandatory test methods

## EU

- Single system for plastic in EU
- non-plastic is regulated in MS
- Covering whole supply chain (chemicals, raw material, articles, GMP)
- EN 13130, 1186

## FDA

- applicable to specific material or resin
- Testing methods are not systematic developed

# The authorization of new material

- Only monomer and additives are include in EU 's list, resin,monomer and additive are all regulated both in FDA and China
- In USA, FCN is only effective for the manufacturer in the notification, in China and EC, the substance or material listed in Notification is accessible for the public

## China

- PL:GB 9685
- Plastic,P&B,rubber,ink,coating,adhesive,
- Resin,monomer,additives

## EU

- PL:EC 10-2011
- Monomer ,additives

## FDA

- PL:21 CFR 170-189
- Resin,monomer,additives

# The Restriction/limitation

- “Migration limitation” is the main concern of legislations both in China and EU
- China continues employ some screening items to allow the official control more practical
- FDA focus on ending test for clearance purpose, migration test rely on self-determination

	China	EU	FDA
Restriction	General requirement Positive list Applicable scope for each listed chemical Restrictions for use Limitation:	General requirement Positive list  Restriction for use Limitation:	General requirement apply for food law  Restriction for use Limitation:
Limitation	Sensory Screening items OML Consumption of $\text{KmnO}_4$ Heavy metal(Pb) SML/SML(T) QM	OML  SML/SML(T)L QM	Extractives

# The supporting test methods

- The principle of **severe test** is applicable to most type of FCMS in China, which only refer to plastic in EU, a simplified condition is applied in FDA
- some slight differences exist , e.g. simulants

	China	EU	FDA
Analytical methods	<b>Mandatory</b>	recommended on EN 13130, EN 1186 serials No update for years	Protocol are provided within provisions of CFR 21 170-189
Simulant	Water <b>4% acetic acid</b> 10% /20%/50%ethol... Olive/Corn oil .....	Water <b>3% acetic acid</b> 10% /20%/50%ethol... Vegetable oil <b>MPPO</b>	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		Simplified condition: 120°F 30min 150°F 2h 120°F 24h .....

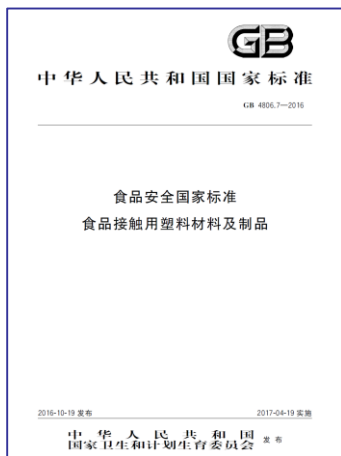
# **The challenges for legal compliance**



# The challenges

- In november,2016, 53 safety standards published by NHFPC
- The majority of legislations has come into enforce : 19/4,2017
- The framework legislation GB 4806.1 will be effective in 19/10,2017

**It is a tight schedule to fulfil the requirements of new legislations !!**



## Use of chemicals

- Only authorized substance/material listed in GB 9685 and relevant Notifications can be used
- > 1400 additives has been authorized but it is not sufficient
- *Example: for ink, 189 authorized VS 3000 industry needed*



## Assessment of FB

- **Non-authorized substances can be used only if :**
  - Not directly contact with food, blocked by functional barrier, Not exceed 0.01mg/kg of food, Not Carcinogenic, mutagenic, teratogenic and Nano-material
- *How to run the test to demonstrate the compliance of functional barrier*



## Compliance of GMP

- For raw material ,e.g. Ink, resin, adhesive, it is not possible to meet GB 31603
- How to deal with the compliance for SME?

## NIAS

- There is No clear criteria and protocol available for checking the compliance of NIAS
- How to perform the NIAS assessment in a affordable way?

## Labeling & identification

- Lack of guidance for how to prepare the labelling and to present the product information
- *the symbol or wording*
- *production date, type of material, use condition, etc.*

## Declaration of compliance

- It is hard to collect the information from upper suppliers
- How to deal with those substance which actually be used but not authorized in PL



图 A.1 调羹筷子标志图

A large, dark blue arrow pointing downwards, containing the text 'Official control' in white.

## Official control

- How to harmonize the official control in such big country since a clear protocol is not available
- Difficulties to fulfil the positive list due to lack of analytical method

A large, dark blue arrow pointing downwards, containing the text 'compliance test' in white.

## compliance test

- How to obtain a comparable result within different laboratories due to
- the technical issues( S/V, contact condition, Tenax, detection limit)
- Lack of experience and knowledge for number of labs in China

## Conclusions

- *A remarkable progress made in China regarding the FCM legislation*
- *The legal compliance shall be fulfilled in the whole supply chain*
- *There is a urgent need for the transfer of information from upper supplier to the end user(DOC)*
- *Further revision are needed for certain legislations, PL*
- *More training and new tools for the compliance test and assessment are needed, particular on assessment of NIAS, Functional barrier*

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*Thank you for your attention !*

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