The Reform of Chinese FCM legislations and the challenges for compliance
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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
Main Services for FCM

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

Main task

Standarization & Training
- Regulation & Standards
- Training
- Proficiency program

Research & Assessment
- Development of new method
- Application of TTC
- Migration modelling
- Assessment of EDC
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Complex and out of date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
Limited legislations for Plastics
Limited additive were authorized
Limited legislations for non-plastic - Stainless steel
- Ceramic
- Glass

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

What we had

Couldn’t response the need
A new FCM regulation system is needed
The process of developing legislations for FCM

The Committee Secretary

Working Group

Assessment → Integration → Drafting → Enforcement

2012
- Investigation/survey
- Review legislations
- Recommendation

2013
- Built up mechanism
- breakdown Plan

2014-15
- Amendment STD
- Draft new STD

2016
The scheme of new FCM legislations

**Framework Legislation**
- GB 4806.1-2016
  - General safety requirement

**Positive list for additives**
- GB 9685-2016

**Specific Standards**
- Plastic: GB 4806.7-2016
- Plastic Resin: GB 4806.6-2016
- Glass: GB 4806.5-2016
- Ceramic: GB 4806.4-2016
- Enamel: GB 4806.3-2016

- Paper and Board: GB 4806.8-2016
- Metallic: GB 4806.9-2016
- Rubber: GB 4806.11-2016
- Coating: GB 4806.10-2016
- Teat: GB 4806.2-2015

- Wood/bamboo/Cork
- Adhesive
- Laminated materials

**GMP**
- GB 31603-2015

**Screening**
- KMNO4: GB 31604.2-2015
- Heavy metal (Pb): GB 31604.9-2015
- De-color: GB 31604.7-2015

**Migration**
- General guidance: GB 31604.1-2015
- OM: GB 31604.2-2015
- SM: GB 31604.10-49
- Pretreatment: GB 5009.156-2016
- QM
Current Status of certain developing legislations

4 legislations are under way:
Wood, bamboo and cork (WBC), Adhesive, Laminated material and articles, Inks

- **2017-10**: Formal meeting for review of legislation for Wood, bamboo and cork (WBC)
- **2017-11**: Public consultation of laminated packaging
- **2018-2**: First draft of legislation for ink
- **2018-05**: Release of legislation for WBC, Laminated packaging and adhesive

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

**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

<table>
<thead>
<tr>
<th>China</th>
<th>EU</th>
<th>FDA</th>
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</table>
| • Single system  
  • covering various FCMs (plastic and non-plastic)  
  • Implemented in whole supply chain (chemicals, raw material, articles, GMP)  
  • corresponding mandatory test methods | • Single system for plastic in EU  
  • non-plastic is regulated in MS  
  • Covering whole supply chain (chemicals, raw material, articles, GMP)  
  • EN 13130, 1186 | • applicable to specific material or resin  
  • Testing methods are not systematic developed |
The authorization of new material

- Only monomer and additives are included 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.

<table>
<thead>
<tr>
<th>China</th>
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<th>FDA</th>
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<tbody>
<tr>
<td>Plastic,P&amp;B,rubber,ink,coating,adhesive</td>
<td>Monomer, additives</td>
<td>Resin, monomer, additives</td>
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<tr>
<td>Resin, monomer, additives</td>
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“Migration limitation” is the main concern of legislations both in China and EU.
China continues to employ some screening items to allow the official control more practical.
FDA focuses on ending the test for clearance purpose, migration test relies on self-determination.

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<th>EU</th>
<th>FDA</th>
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<tbody>
<tr>
<td><strong>Restriction</strong></td>
<td>General requirement</td>
<td>General requirement</td>
<td>General requirement</td>
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<tr>
<td></td>
<td>Positive list</td>
<td>Positive list</td>
<td>apply for food law</td>
</tr>
<tr>
<td></td>
<td>Applicable scope for each</td>
<td>Restriction for use</td>
<td>Restriction for use</td>
</tr>
<tr>
<td></td>
<td>listed chemical</td>
<td>Limitation:</td>
<td>Limitation:</td>
</tr>
<tr>
<td></td>
<td>Restrictions for use</td>
<td></td>
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<td></td>
<td>Limitation:</td>
<td></td>
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<tr>
<td><strong>Limitation</strong></td>
<td>Sensory Screening items</td>
<td>OML</td>
<td>Extractives</td>
</tr>
<tr>
<td></td>
<td>OML</td>
<td>SML/SML(T)QM</td>
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<td></td>
<td>Consumption of KmnO₄</td>
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<td>Heavy metal (Pb)</td>
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<td>SML/SML(T)QM</td>
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<td>QM</td>
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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.

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</thead>
<tbody>
<tr>
<td>Analytical methods</td>
<td>Mandatory</td>
<td>recommended on EN 13130, EN 1186 serials</td>
<td>Protocol are provided within provisions of CFR 21 170-189</td>
</tr>
<tr>
<td>Simulant</td>
<td>Water 4% acetic acid, 10%/20%/50% ethol... Oliver/Corn oil, ...</td>
<td>Water 3% acetic acid, 10%/20%/50% ethol... Vegetable oil MPPO</td>
<td>Water Heptane n-Hexane 8% alcohol, 50% alcohol dimethylbenzene</td>
</tr>
<tr>
<td>Exposure condition/calculation</td>
<td>Complex condition (SM, OM test) “Severe” principle is applied - Contact time - Temperature - Surface area: Volume - DRF - FRF</td>
<td>Simplified condition: 120°F 30min 150°F 2h 120°F 24h ...</td>
<td></td>
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</table>
The challenges for legal compliance
The challenges

- In November, 2016, 53 safety standards published by NHFPC
- The majority of legislations has came 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?
There is no clear criteria and protocol available for checking the compliance of NIAS.

How to perform the NIAS assessment in an affordable way?

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.*

It is hard to collect the information from upper suppliers.

How to deal with those substances which actually be used but not authorized in PL.
Official control

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

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
Thank you for your attention!

National reference laboratory for Food contact material

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