A Road Map
to Food Contact Materials and Articles
Regulations in China

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CIRS Services

Chemical Registration

Global GHS

Food and Food-related Products

Cosmetics

Pesticides and Biocides

Medical Devices
Food Contact Material Services

- New food contact material notification
- FCM testing
- FCM DoC
- FCM consultation and training
- FCM regulation monitoring and alert
**Scope**

- **Production**
- **Manufacturing**
- **Packaging**
- **Transportation**
- **Direct Use**
- **Packing materials**
- **Containers**
- **Tools**
- **Equipment**

**Related**

- **Detergent**
- **Disinfectant**
- **Public Water Supply Facility**

**a.** Already or are to be in direct contact with food or food additives

**b.** Components are likely to migrate into food or food additives
Framework

CHINA

- Built on standards
- Old standards are old...
- Inefficiently revised

But

- Improvement has appeared
- Forming regulation framework
- Still powerful
- Risk assessment catching up
Food Safety Law

General standards
- GB4806.1-2016 General Safety Requirements
- GB9685-2016 Use of Additives

Product standards
- e.g.
  - GB4806.6-2016 Plastic Resins
  - GB4806.7-2016 Plastic
  - GB4806.8-2016 Paper and Paperboard
  - GB4806.9-2016 Metal
  - GB4806.10-2016 Coatings
  - GB4806.11-2016 Rubber

Testing standards
- e.g.
  - GB31604.1-2015 General Rules of Migration Test
  - GB5009.156-2016 General Rules of Migration Test Pretreatment Methods
  - 31604.9-2016 Test Method of Heavy Metals

Manufacturing Practices
- GB31603-2015 General Manufacturing Practices

Framework Overview
The Road Map
New Food Contact Material Notification
Summary

“Standard” based! Have Positive lists
Registry • Service Center of National Health Commission

Technical Evaluation • China National Center for Food Safety Risk Assessment (CFSA)

Decision Maker • National Health Commission (NHC)

Inspection & Supervision (custom) • General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)

Inspection & Supervision (domestic market) • State Administration for Market Regulation (SAMR)
Influence on food industry

• Supervision
  – AQSIQ & SAMR
    • Random inspection
    • Enforcement result
    • Risk alert

• Enforcement
  – Recall or destroy
About Your Products and Yourselves

• Categorizing FCM
  – Raw material
  – Additive
  – Finished product or article

• Identifying yourselves
  – Manufacturer
  – Distributor
3 Steps

- Formula Check
- Testing
- Labelling & Declaration of Compliance
Formula Check

- Positive list - GB 4806.6-2016 Food Contact Plastic Resins

Table A.1 List of Approved Plastic Resins and Usage Requirements (sample)

<table>
<thead>
<tr>
<th>No.</th>
<th>Name</th>
<th>CAS No.</th>
<th>Common category name</th>
<th>SML/QM (mg/kg)</th>
<th>SML(T) (mg/kg)</th>
<th>SML Grouping number</th>
<th>Other requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>NYLON 6/12</td>
<td>26098-55-5</td>
<td>PA</td>
<td>2.4 (1,6-HEXANE DIAMINE :SML)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
• Positive list – GB 9685-2016 Use of Additives in Food Contact Materials.
### Table A.1 List of Approved Additives Used in Food Contact Materials and Usage Requirements

<table>
<thead>
<tr>
<th>FCA number</th>
<th>Name</th>
<th>CAS No.</th>
<th>Application and max usage</th>
<th>SML/QM (mg/kg)</th>
<th>SML(T) (mg/kg)</th>
<th>SML Grouping number</th>
<th>Other requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>FCA0047</td>
<td>Ethylene Glycol</td>
<td>107-21-1</td>
<td>PE, PP, PS, AS, ABS, PA, PET, PC, PVC, PVDC, UP: appropriate amount according to production requirement</td>
<td>30</td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Sometimes **GB 9685 – 2016** is not the only standard applied...

- Mixtures of substances listed in Tables A.1 (no reaction)
- Substances listed in Table A.2 of GB 2760-2014 (no effect to property of food)
- Some salts and crystalline hydrate in Table A.1 of GB 2760-2014
- The approved polymers (molecular weight higher than 1000 Dalton) can be used as food contact additives in the same approved scope.
Testing

WHAT Properties should be tested?
GB 4806.6 *Food Contact Plastic Resins*
GB 4806.7 *Food Contact Plastic*
GB 9685-2016 *Use of Additives in Food Contact Materials*

HOW to carry out testing?
GB 31604.X *Testing Migration Level of XX in XX*
GB 5009.156 *Pretreatment of Food Contact Material for Migration Level Test*
## Testing

Basic required tests in GB 4806.7

<table>
<thead>
<tr>
<th>Required tests</th>
<th>Requirements</th>
<th>Test method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample senses</td>
<td>Normal color, etc.</td>
<td>N/A</td>
</tr>
<tr>
<td>Soaking solution</td>
<td>No odor, etc.</td>
<td>N/A</td>
</tr>
<tr>
<td>Overall migration</td>
<td>&lt;=10mg/dm2</td>
<td>GB 31604.8</td>
</tr>
<tr>
<td>Overall migration for infant FCM</td>
<td>&lt;=60mg/kg</td>
<td>GB 31604.8</td>
</tr>
<tr>
<td>The consumption of Potassium permanganate</td>
<td>&lt;=10mg/kg</td>
<td>GB 31604.2</td>
</tr>
<tr>
<td>Heavy metal (Pb)</td>
<td>&lt;=1mg/kg</td>
<td>GB 31604.9</td>
</tr>
<tr>
<td>Color stability test for FCM with colorant</td>
<td>Negative</td>
<td>GB 31604.7</td>
</tr>
</tbody>
</table>
Imported food contact material Inspection Report in released in 2016

- Inspected by AQSIQ at custom
- Ceramics, plastics, metals, papers and other materials (mostly glass)
- Highest 2.71% (plastics), lowest 0.66% (Ceramics)


Source: Quality of Imported Food Contact Material Product in 2016 by SAMR
The major requirements of GB 4806.1-2016 General Safety Requirements of Food Contact Materials that apply to ALL types of food contact materials are listed as follows:

- Basic Requirements
- Restrictions
- Compliance Principle
- Test Methods
- Traceability
- **Product Information**
What’s required for labelling?

According to GB4806.1:

• Product name;
• Product material;
• Name, address, and contact information of manufacturer and/or distributor;
• Production date;
• Shelf life if applicable;
• Instructions if applicable;
• “food contact use”, or print/past with spoon & chopsticks logo as following:
What about Declaration of Compliance (DoC)?

- A crucial document to acquire clearance at custom
- One of the most neglected documents in dossier
- Section 8 of GB 4806.1-2016
- Industrial Guidance by China National Food Industry Association (CNFIA)
Declaration of Compliance & Labelling

Declaration of Compliance (DoC) is a part of label which is MANDATORY in the supply chain in China.
As a finished plastic product, the DoC is suggested to issue like below:

Title: Declaration of Compliance (Product A)

<table>
<thead>
<tr>
<th>Disclosed information</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td></td>
</tr>
<tr>
<td>Material Information</td>
<td>Supplier vs importer vs distributor</td>
</tr>
<tr>
<td>Manufacturer</td>
<td></td>
</tr>
<tr>
<td>Contact Info of Manufacturer</td>
<td></td>
</tr>
<tr>
<td>Declarant</td>
<td></td>
</tr>
<tr>
<td>Contact Info of Declarant</td>
<td></td>
</tr>
<tr>
<td>Condition of Use</td>
<td></td>
</tr>
<tr>
<td>Regulatory Compliance</td>
<td></td>
</tr>
<tr>
<td>Proof of Compliance</td>
<td></td>
</tr>
<tr>
<td>Disclaimer</td>
<td></td>
</tr>
</tbody>
</table>

Confidentiality?
What if you have something new?
Scope

In accordance with Food Safety Law of the People's Republic of China, company which plan to:

1. *Use new substances (including new food contact resins and new food contact additives),*

2. *Apply existing food contact resins or additives in a larger scope,*

shall submit the related safety assessment to NHC.

Legislative

Food Safety Law

<GB 4806.1-2016>

<Administrative Measure on New Food Related Products>, Notice 25, 2011, NHFPC
Required Documents

1. Application form
2. Physicochemical property
3. Technical necessity, application & use condition
4. Manufacturing technique
5. Qualification specification requirements, test methods and test report
6. Toxicology safety assessment documents
7. Migration test or residual test, dietary exposure, and analytical methods
8. Other document to support the use at overseas
9. Other supplementary documents
10. Power of attorney (when the registration application run by entrusted agencies)
11. Certifying documents issued by government authorities or industry associations in the exporting country (region) of origin, proving that the new food contact substance is allowed to manufacture or sell in the country (region)
12. Certifying documents issued by government authorities or industry associations in the producing country (region) of origin, proving that the new food contact substance manufacturer has been examined or certificated
## Time Frame

<table>
<thead>
<tr>
<th>Notification Procedure</th>
<th>Time line</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feasibility analysis</td>
<td>5-7 workdays</td>
</tr>
<tr>
<td>Available documents integration by client</td>
<td>Case-by-case</td>
</tr>
<tr>
<td>Document gap analysis</td>
<td>Usually within 1 month</td>
</tr>
<tr>
<td>Qualification specification test</td>
<td>14 workdays</td>
</tr>
<tr>
<td>Migration test</td>
<td>15-60 workdays</td>
</tr>
<tr>
<td>Toxicity tests (if necessary)</td>
<td>5-10 workdays</td>
</tr>
<tr>
<td>Dossier preparation and submission</td>
<td>1 month</td>
</tr>
<tr>
<td>Application acceptance</td>
<td>5 workdays</td>
</tr>
<tr>
<td>Technical review</td>
<td>60 workdays</td>
</tr>
<tr>
<td>Re-evaluation if necessary (supplement dossiers)</td>
<td>1 year</td>
</tr>
<tr>
<td>(Usually can be completed within 4 months)</td>
<td></td>
</tr>
<tr>
<td>CFSA issues the draft comments for approval</td>
<td>1 month</td>
</tr>
<tr>
<td>NHC makes the final approval decision</td>
<td>Within 20 workdays</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>11-25 months</strong></td>
</tr>
</tbody>
</table>
More standards to be developed
General supervision and enforcement levels are likely to go up in the near future
Importance of DoC
Unnecessary disclosure of confidential business information can be avoided
Check if it’s necessary to notify NHC about your FCM
Q&A