All Wrapped Up: An Analysis of China’s Newly Finalized GB Food Packaging Standards

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  - Paris office opened in 2015

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K&H Shanghai Office

- Virtually all of our practice in China (and Asia generally) is regulatory in nature, with a special emphasis on food and food packaging.
With specific regard to China, K&H has prepared many applications for product approval and represented clients before the following Chinese agencies:

- China Food and Drug Administration (CFDA)
- National Health and Family Planning Commission (NHFPC)
- General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)
- Ministry of Environmental Protection (MEP), and
- Ministry of Agriculture (MOA)
• Existing CRMs are available on the K&H website here: http://www.khlaw.com/newsletter.aspx?Area=96

• We also distribute alerts on other countries in the region, referred to as “Asia Regulatory Matters!”
Agenda

- Part I
  - Overview of Food Safety Law and GB Food Packaging Standards
  - Additives Standard
  - General Safety Standard
- Part II
  - Paper, metal, rubber, plastic resin/articles, and coatings standards
- Part III
  - Testing Methods Standards
  - China Petition Process
  - Q & A
All Wrapped Up: Part I

- Overview of Food Safety Law and GB Food Packaging Standards
- Additives Standard
- General Safety Standard
Food Safety Law

On June 1, 2009, China adopted a new overarching Food Safety Law (FSL)

→ Replaced 1995 Food Hygiene Law
→ Revisions Effective: October 1, 2015
→ Implementing Regulation (draft for approval): October 19, 2016

- Mandates regulation of “food-related products” (e.g., food packaging, disinfectants, detergents, etc.)
Food Safety Law

Promulgation of Food Safety Standards (FSS)

- FSL requires the Chinese authorities to promulgate Food Safety Standards for food-related products (FSL Article 26)

- Products not complying with an applicable Food Safety Standard are unlawful!

- No local Food Safety Standards may be formulated for food-related products (Article 25 of the latest draft Implementation Regulations for the FSL)
Food Safety Law

 Premarket approval by NHFPC

- Prior to manufacturing or importing “new varieties” of food-related products (i.e., unapproved substances used in food packaging), companies are required to obtain premarket approval from NHFPC (FSL Article 37)

- The petition procedures will be discussed in greater detail later in our presentation
Food Safety Law

Packaging Materials Imported into China

- Must comply with national Food Safety Standards (FSL Article 92)
Food Safety Law

- Violation of Food Safety Law can result in heavy fines

E.g.:

- Production or importation of new varieties of food-related products without NHFPC approval → Up to 20 times the commodity value

- A food producer/operator purchases or uses substandard food-related products → Up to 10 times the commodity value
Recap

• Products not complying with an applicable Food Safety Standard are unlawful

• Packaging materials imported into China must comply with national Food Safety Standards
GB Food Packaging Standards

Chinese Food Safety Law

- Generally Applicable Standards
  - Additives
    - GB 9685
  - General Safety Standard

- Materials Standards
  - Paper
  - Plastic
  - Coatings
  - Rubber
  - Metal

- Testing Methods Standards
  - Migration Testing Standard
  - Testing methods for individual substances

- GMP Standards
  - General Hygiene Norms
GB Food Packaging Standards

- The Chinese authorities have been working diligently over the last couple of years to consolidate varied requirements in a more organized manner.
GB Food Packaging Standards

- The finishing strokes

On November 18, 2016, NHFPC published various long-awaited GB food packaging standards
GB Food Packaging Standards

- The finishing strokes

Effective from October 19, 2017
- GB 9685-2016 Uses of Additives
- GB 4806.1-2016 General Safety Standard

Effective from April 19, 2017
- GB 4806.6-2016 Plastic Resins
- GB 4806.7-2016 Plastic Materials and Articles
- GB 4806.8-2016 Paper and Paperboard Materials and Articles
- GB 4806.9-2016 Metal Materials and Articles
- GB 4806.10-2016 Coatings and Coating Layers
- GB 4806.11-2016 Rubber Materials and Articles
- GB 5009.156-2016 Pre-treatment Methods for Migration Testing
GB 9685-2016

- Applies to additives used in food-contact materials
- Will take effect on October 19, 2017

Compared to the old standard
- Revised title and scope
- Revised terms and definitions

Compared to the draft
- Further revised positive list of additives
- Other changes
GB 9685-2016

Revised Title

Standards for Uses of Additives in Food Contact Materials and Articles

(Old title: Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials)

Revised Scope of Standard

Captures monomers for certain base polymers or other starting materials of polymerization used during the manufacture of food contact materials and articles
Terms and Definitions

- Removed definition for “food contact materials and articles” in the draft (defined in the GSS)

- “Additives in food contact materials and articles”
  
  Substances added during the manufacturing process of food contact materials and articles that assist in improving the quality and properties or aid to improve the quality and properties; also include processing aids added to promote smooth production rather than improve the quality or properties of the final product.
**GB 9685-2016: Appendix A**

Positive List of Additives

*MANY* new clearances added to the positive list

- Additives in Appendix A increased from 958 to 1294

Like the draft version, the new Standard permits certain substances that are not explicitly listed

- Mixtures of cleared additives, provided that no chemical reaction occurs
- Food additives listed in Table A.2 of GB 2760, provided that they perform no technical function on food
- Hydrous forms of permitted substances
- Sodium, potassium and calcium salts (including acidic salts and double salts) of listed acids, alcohols, and phenols
- Separately approved food-contact resins having a molecular weight greater than 1,000 Daltons
GB 9685-2016: Appendix A

Positive List of Additives

Certain Substances Restricted or Removed

- Removed 4 phthalates and adjusted the permitted use scope and restrictions on food types to be contacted for other phthalates (same as the draft)

- Removed additives with use scopes covering glass, metal, ceramics and enamel (same as the draft)

- Approvals for certain phthalates have been narrowed to cover only their use in PVC polymers (same as the draft)

- Removed 3 perfluourinated compounds that were recently banned by the U.S. FDA
GB 9685-2016: Appendix A

- **Table A Includes 7 Tables**
  - Table A.1 Additives permitted for use in plastic materials and articles
  - Table A.2 Coatings
  - Table A.3 Rubber
  - Table A.4 Printing inks
  - Table A.5 Adhesives
  - Table A.6 Paper
  - Table A.7 Silicone rubber and others

Substance listings contain the following contents:

<table>
<thead>
<tr>
<th>FCA No.</th>
<th>Chinese Name</th>
<th>CASRN</th>
<th>Use Scope &amp; Max. Use Level</th>
<th>SML/QM (mg/kg)</th>
<th>SML(T) (mg/kg)</th>
<th>SML(T) No.</th>
<th>Other Requirements</th>
</tr>
</thead>
</table>

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GB 9685-2016: Appendix B

Total specific migration limit (SML(T))

- The maximum permitted sum of two/more substances released from packaging into food or food simulants

- Expressed in terms of a designated substance or category of substances
### GB 9685-2016: Appendix B

**Examples of SML(T)s for restricted substances**

<table>
<thead>
<tr>
<th>SML(T) Group No.</th>
<th>CAS Reg. No.</th>
<th>Name of Restricted Substance</th>
<th>SML (T) (mg/kg)</th>
<th>Restriction Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>75-07-0</td>
<td>Acetaldehyde</td>
<td>6</td>
<td>As acetaldehyde</td>
</tr>
<tr>
<td></td>
<td>105-38-4</td>
<td>Propionic acid, vinyl ester</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>Stearic acid, esters with ethyleneglycol</td>
<td>30</td>
<td>As 1,2-Ethanediol</td>
</tr>
<tr>
<td></td>
<td>107-21-1</td>
<td>1,2-Ethanediol</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>111-46-6</td>
<td>Ethanol, 2,2'-oxybis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>...</td>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>
SMLs for certain metal elements *(same as the draft)*

<table>
<thead>
<tr>
<th>Metal Element</th>
<th>SML (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barium</td>
<td>1</td>
</tr>
<tr>
<td>Cobalt</td>
<td>0.05</td>
</tr>
<tr>
<td>Copper</td>
<td>5</td>
</tr>
<tr>
<td>Iron</td>
<td>48</td>
</tr>
<tr>
<td>Lithium</td>
<td>0.6</td>
</tr>
<tr>
<td>Manganese</td>
<td>0.6</td>
</tr>
<tr>
<td>Zinc</td>
<td>25</td>
</tr>
</tbody>
</table>
### GB 9685-2016: Appendix D

☑ Meanings of abbreviations of plastic materials

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>English Name</th>
<th>Chinese Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS</td>
<td>Acrylonitrile styrene</td>
<td>丙烯腈-苯乙烯共聚物</td>
</tr>
<tr>
<td>ABS</td>
<td>Acrylonitrile butadiene styrene</td>
<td>丙烯腈-丁二烯-苯乙烯共聚物</td>
</tr>
<tr>
<td>BDR</td>
<td>Polybutadiene rubber</td>
<td>聚丁二烯橡胶</td>
</tr>
<tr>
<td>E/NB</td>
<td>Ethylene-2-norbornene copolymer</td>
<td>乙烯与二环[2,2,1]庚-2-烯共聚物</td>
</tr>
<tr>
<td>EVA</td>
<td>Ethylene-vinyl acetate resin</td>
<td>乙烯-乙酸乙烯酯共聚物</td>
</tr>
<tr>
<td>EVOH</td>
<td>Ethylene-vinyl alcohol copolymer,</td>
<td>乙烯-乙烯醇共聚物</td>
</tr>
<tr>
<td>LCP</td>
<td>Liquid-crystal polymer</td>
<td>液晶聚合物</td>
</tr>
<tr>
<td>PA</td>
<td>Polyamide</td>
<td>聚酰胺</td>
</tr>
<tr>
<td>... Etc.</td>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>
GB 9685-2016: Appendix E

- List of All Approved Additives Sorted by CAS Number and Chinese Name

Table E.1 - CAS Number List

<table>
<thead>
<tr>
<th>CAS号</th>
<th>中文名称</th>
<th>FCA号</th>
<th>页码</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-00-0</td>
<td>甲胶</td>
<td>FCA0895</td>
<td>127;209;258</td>
</tr>
<tr>
<td>50-79-4</td>
<td>钙型精醇</td>
<td>FCA0517</td>
<td>106;191;240</td>
</tr>
<tr>
<td>50-99-7</td>
<td>钼酸盐</td>
<td>FCA1847</td>
<td>253</td>
</tr>
<tr>
<td>52-51-7</td>
<td>2,3-二磷酸-1,3-丙二醇</td>
<td>FCA0301</td>
<td>96;188;234</td>
</tr>
<tr>
<td>56-35-9</td>
<td>二(三丁基锡)氧化物</td>
<td>FCA0722</td>
<td>201</td>
</tr>
<tr>
<td>56-81-5</td>
<td>丙三醇</td>
<td>FCA0608</td>
<td>52;120;193;244</td>
</tr>
<tr>
<td>57-09-0</td>
<td>十六烷基三甲基氧化铵</td>
<td>FCA1124</td>
<td>85</td>
</tr>
<tr>
<td>57-11-4</td>
<td>硝酸十八烷基酯</td>
<td>FCA1291</td>
<td>93;139;154;221;273</td>
</tr>
<tr>
<td>57-13-8</td>
<td>丙醇</td>
<td>FCA1036</td>
<td>79;265</td>
</tr>
<tr>
<td>57-50-1</td>
<td>蔗糖</td>
<td>FCA0106</td>
<td>273</td>
</tr>
<tr>
<td>57-55-6</td>
<td>1-2-丙二醇</td>
<td>FCA0042</td>
<td>7;97;111;155;176;223</td>
</tr>
</tbody>
</table>

Table E.2 – Chinese Name List

<table>
<thead>
<tr>
<th>中文名称</th>
<th>CAS号</th>
<th>FCA号</th>
<th>页码</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1,1-二甲基乙基)-4-甲氧基苯氧基-丁基羟基香草醛（BHA）</td>
<td>25015-16-5</td>
<td>FCA0001</td>
<td>4;95;140;174;222</td>
</tr>
<tr>
<td>(1,1-甲基苯基)-4-甲氧基苯氧基-丁基羟基香草醛（BHA）</td>
<td>25608-64-4</td>
<td>FCA0003</td>
<td>4</td>
</tr>
<tr>
<td>(1,3-二甲基苯基)-4-甲氧基苯氧基-丁基羟基香草醛（BHA）</td>
<td>351870-33-2</td>
<td>FCA0004</td>
<td>4</td>
</tr>
<tr>
<td>(1,1-甲基苯基)-4-甲氧基苯氧基-丁基羟基香草醛（BHA）</td>
<td>491580-22-1</td>
<td>FCA0005</td>
<td>4</td>
</tr>
<tr>
<td>(2E)-2-丁烯二酸与1,3-丁烯二酸,苯乙烯,2,2-丙烯酸和乙酸酯的聚合物</td>
<td>85600-91-5</td>
<td>FCA0006</td>
<td>174;222</td>
</tr>
<tr>
<td>(2E)-2-丁烯二酸与1,3-丁烯二酸,苯乙烯,2,2-丙烯酸和乙酸酯的聚合物</td>
<td>131-53-3</td>
<td>FCA0007</td>
<td>4</td>
</tr>
<tr>
<td>(2E)-2-丁烯二酸与1,3-丁烯二酸,苯乙烯,2,2-丙烯酸和乙酸酯的聚合物</td>
<td>131-57-7</td>
<td>FCA0008</td>
<td>4</td>
</tr>
</tbody>
</table>
GB 4806.1-2016: GSS

- **General Safety Requirements for Food Contact Materials and Articles**
  - Applies generally to **all** food-contact materials and articles
  - Takes effect on **October 19, 2017**
GB 4806.1-2016: GSS

“Food contact materials and articles”

Materials and articles that have been/will be in contact with food or food additives (collectively “food” in this definition) or the components of which may migrate to food, including:

1) Packaging materials, containers, tools and equipment for food uses; and
2) inks, adhesives, lubricating oil, etc. that may directly or indirectly contact food
3) during the manufacturing, processing, packaging, transportation, storage and use of food
4) Does not include:
   – Detergents
   – Disinfectants
   – Public water facilities
GB 4806.1-2016: GSS

Basic requirements relating to FCMs and articles

- Must not migrate to food at levels that endanger human health
- Must not impart changes to ingredients, structure, or properties of food (e.g., color, taste, aroma) when in contact with food
- Must not have technical effects on food
GB 4806.1-2016: GSS

NIAS

- Revised definition in the final Standard:
  Impurities in FCMs that are not intentionally added, including impurities derived from raw and auxiliary materials, decomposition products, pollutants and residual reaction intermediates resulting from production and use.

- The GSS does not require that NIAS be explicitly approved on GB 9685 or elsewhere.

- The draft version required that food packaging producers “perform safety assessments” on NIAS.
  - Language removed in the final Standard but manufacturer still must control their use to ensure the general safety requirements are met.

**Impact:** NIAS need *not* be cleared in China provided that safety can be established.
Compound/composite materials/articles

- Where different migration limits are in place for the same restricted item

  • **Draft**: The lowest limit applies for the material and/or article as a whole
  
  • **Final**: The material and article as a whole must comply with the weighted average value (权重加和值) of the corresponding restrictive limits. If the weighted average value cannot be calculated, the lowest restriction for the substance will apply.
GB 4806.1-2016: GSS

Functional barrier

Adopted in the draft but defined in the final:

1) A barrier composed of one / more materials used to prevent migration to food of substances behind it

2) Migration of an unlisted substance must be \( \leq 0.01 \text{ mg/kg} \) (or 10 ppb)

Requirements

- Manufacturer must perform safety assessment on and control unlisted substances behind the functional barrier to ensure migration \( \leq 0.01 \text{mg/kg} \)

- Unlisted substance is not a carcinogen, mutagen, or reproductive toxin (CMR) or nanomaterials

➢ Unlisted substances may be used in food packaging provided that the above criteria are met
GB 4806.1-2016: GSS

Traceability & Documents

- Producers must establish product traceability system
  - Raw material suppliers
  - Customers
- Must ensure that information regarding the origin and destination of FCMs as well as relevant compliance information can be obtained
GB 4806.1-2016: GSS

Declaration of Compliance (DoC)

Packaging producers must supply customers with a DoC covering:

✓ Applicable regulations and standards

✓ Restricted substances and their limits (e.g., SMLs)

✓ Compliance regarding overall migration limit
GB 4806.1-2016: GSS

Labeling

- Food packaging materials must be labeled to state “for food contact,” “for food packaging” or similar language, or contain the “spoon and chopsticks” graphic, except those clearly for food-contact uses (e.g., chopsticks, frying pans)

- Where to apply?
  - Shipping container?
  - Shipping documents?

Note: Section 8.5 of the GSS suggests that information be provided on labels, but it may also be included via instruction documents or other enclosed documents
All Wrapped Up: Part II

- Paper Standard
- Metal Standard
- Rubber Standard
- Plastic Resin Standard
- Plastic Articles Standard
- Coatings Standard
GB 4806.8-2016: Paper Standard

- **Scope**
  Captures paper, paperboard, paper articles, including pulp molded articles

  → Paper coatings covered?
  → Finalized Coatings Standard (GB 4806.10-2016) explicitly excludes “paper coatings and paper coating layers”
GB 4806.8-2016: Paper Standard

- Raw material requirements
  - Not harmful to human health
  - Fiber raw materials must be composed mainly of plant fibers, and synthetic fibers must comply with the Resin Standard
  - Wax coated on the food-contact surface must meet relevant GB standards (*must be “food-grade” in the draft*)
### GB 4806.8-2016: Paper Standard

- **Sensory requirements**

<table>
<thead>
<tr>
<th></th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Normal color; no abnormal odor, mildew or dirt</td>
</tr>
<tr>
<td>Soak</td>
<td>No coloring, abnormal odors or other sensory deterioration</td>
</tr>
</tbody>
</table>
Residue and migration specifications

- Mostly same as the draft, except that **decoloration test** was removed from the migration specifications

<table>
<thead>
<tr>
<th>Item</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pb and As specifications</strong></td>
<td></td>
</tr>
<tr>
<td>Pb / (mg/kg)</td>
<td>≤ 3.0</td>
</tr>
<tr>
<td>As / (mg/kg)</td>
<td>≤ 1.0</td>
</tr>
<tr>
<td><strong>Residue specifications</strong></td>
<td></td>
</tr>
<tr>
<td>Formaldehyde / (mg/dm²)</td>
<td>≤ 1.0</td>
</tr>
<tr>
<td>Fluorescent substances</td>
<td>Negative</td>
</tr>
<tr>
<td>Wavelength 254nm and 365nm</td>
<td></td>
</tr>
<tr>
<td><strong>Migration specifications</strong></td>
<td></td>
</tr>
<tr>
<td>Overall migration limit / (mg/dm²)</td>
<td>≤ 10</td>
</tr>
<tr>
<td>KMnO4 consumption / (mg/kg)</td>
<td>≤ 40</td>
</tr>
<tr>
<td>Water (60°C, 2h)</td>
<td></td>
</tr>
<tr>
<td>Heavy metal (as Pb) / (mg/kg)</td>
<td>≤ 1</td>
</tr>
<tr>
<td>4% (v/v) acetic acid, 60°C, 2h</td>
<td></td>
</tr>
</tbody>
</table>
GB 4806.8-2016: Paper Standard

- Microbial specifications

<table>
<thead>
<tr>
<th>Item</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coliforms / (/50 cm²)</td>
<td>Not detectable</td>
</tr>
<tr>
<td>Salmonella / (/50 cm²)</td>
<td>Not detectable</td>
</tr>
<tr>
<td>Mold /(CFU/g)</td>
<td>≤ 50</td>
</tr>
</tbody>
</table>
GB 4806.8-2016: Paper Standard

- Migration testing
  Unique requirements for performing migration testing on paper filters

- Screening

- Labeling
  → Must comply with GSS
GB 4806.9-2016: Metal Standard

- Provide definitions for:
  - Food-contact metal materials/articles, metal plating, base materials
    - Base materials do not include surface coating and metal plating

- But removed definitions in the draft for alloy, alloying elements, and impurity elements
# GB 4806.9-2016: Metal Standard

- **Migration limits for stainless steel**

<table>
<thead>
<tr>
<th>Items (mg/kg)</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>As</td>
<td>≤ 0.04</td>
</tr>
<tr>
<td>Cd</td>
<td>≤ 0.02</td>
</tr>
<tr>
<td>Pb</td>
<td>≤ 0.05</td>
</tr>
<tr>
<td>Cr &lt;sup&gt;a&lt;/sup&gt;</td>
<td>≤ 2.0</td>
</tr>
<tr>
<td>Ni</td>
<td>≤ 0.5</td>
</tr>
</tbody>
</table>

<sup>a</sup> Not for martensitic stainless steel
### GB 4806.9-2016: Metal Standard

- **Migration limits for other metal materials and articles**

<table>
<thead>
<tr>
<th>Items (mg/kg)</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>As</td>
<td>≤ 0.04</td>
</tr>
<tr>
<td>Cd</td>
<td>≤ 0.02</td>
</tr>
<tr>
<td>Pb</td>
<td>≤ 0.2</td>
</tr>
</tbody>
</table>
GB 4806.9-2016: Metal Standard

- Special requirements for use
  - Articles of aluminum and aluminum alloys, copper and copper alloys with the food contact surface not applied with organic coatings are NOT allowed in contact with acidic foods

- Labeling
  - Must comply with GSS
  - Plating or coating materials must be labeled if the food contact surface is applied with metal coating or organic coating
GB 4806.11-2016: Rubber Standard

- **Scope**
  - FCMs and articles composed primarily from natural rubber, synthetic rubber *and silicon rubber*

- **Sensory requirements**

<table>
<thead>
<tr>
<th>Item</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Normal color; no abnormal odor, dirt</td>
</tr>
<tr>
<td>Soak</td>
<td>Shall have no coloring, turbidity, precipitation, abnormal odors or other sensory deteriorations</td>
</tr>
</tbody>
</table>
GB 4806.11-2016: Rubber Standard

- **Physicochemical specifications**

<table>
<thead>
<tr>
<th>Items</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall migration limit (OML) (mg/dm²)</td>
<td>≤ 10</td>
</tr>
<tr>
<td>KMnO₄ consumption/(mg/kg) Water, 60°C, 0.5h</td>
<td>≤ 10</td>
</tr>
<tr>
<td>Heavy metal (As Pb)/(mg/kg) in 4% (v/v) acetic acid, 60°C, 0.5h</td>
<td>≤ 1</td>
</tr>
</tbody>
</table>

- **Labeling**
  - Must comply with GSS
  - Must identify natural emulsion if it is contained in the product
GB 4806.11-2016: Rubber Standard

- Positive list of polymers for use in synthetic rubber in Table A.1 of Appendix A
  - 24 polymers
  - SML/QM, SML(T) and use requirements

- Positive list of polymers for use in silicon rubber in Table A.2 of Appendix A

- Thermoplastic elastomers included in GB 4806.6-2016, when vulcanized
GB 4806.6-2016: Plastic Resin Standard

- **Scope**
  - Resins and resin blends used to produce food-contact use plastic materials and articles
  - Captures polymer blends
    - Must ensure that all components of the blend are individually permitted
  - Captures non-vulcanized thermoplastic elastomers (TPE)
Definition of “Resins”

Macromolecular substances generated by means of addition polymerization, condensation polymerization, microbial fermentation polymerization, etc., and chemically modified natural macromolecular substances; also known as polymers.
GB 4806.6-2016: Plastic Resin Standard

- Sensory requirements

<table>
<thead>
<tr>
<th>Item</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>With normal color, no abnormal odor or unclean objects, etc.</td>
</tr>
<tr>
<td>Soak</td>
<td>The soaking solution from the migration test shall be free from sensory deterioration, such as obvious coloring, turbidity, precipitation, abnormal odor</td>
</tr>
</tbody>
</table>

- Physicochemical specifications
  - SML, SML(T), QM, and other applicable restrictions are set in Appendix A
  - OML, KMnO4 consumption, heavy metals, and decoloration specifications included in the draft version are removed
    - Plastic pellets (slices), masterbatch, and sheets are still subject to these requirements per GB 4806.7-2016
GB 4806.6-2016: Plastic Resin Standard

- Positive list of 102 resins derived from
  - Prior GBs for various resins (PE, PET, PS, etc.)
  - List of 107 resins (per 2010 “Clean-up” procedures)

### 表 A.1 允许使用的塑料树脂及使用要求

<table>
<thead>
<tr>
<th>编号</th>
<th>中文名称</th>
<th>CAS号</th>
<th>通用类别名</th>
<th>SML/QM mg/kg</th>
<th>SML(T) mg/kg</th>
<th>分组编号</th>
<th>其他要求</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>(3R)-3-羟基丁酸与4-羟基丁酸共聚物</td>
<td>125495-90-1</td>
<td>Poly (4HB co-4HB)</td>
<td>P (3.4HB)</td>
<td>5 (1,4-丁二醇酯)</td>
<td>30</td>
<td>生产的塑料材料或制品不得用于接触含乙醇食品；使用温度不得超过100℃</td>
</tr>
<tr>
<td>2</td>
<td>1,1,1,2,2,3,3-七氟-3-[三氟丙烯基]氧]丙烯与四氟乙烯的聚合物</td>
<td>26655-00-5</td>
<td>PFA</td>
<td>0.05 SML</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
GB 4806.6-2016: Plastic Resin Standard

- Labeling
  - Must comply with GSS
  - Must label the name of resin in accordance with Appendix A
  - In case of polymer blends, the names of all resins must be labeled
GB 4806.7-2016: Plastic Articles Standard

- **Scope**

  ✓ Food-contact use plastic materials and articles

  ✓ Also captures **non-vulcanized** thermoplastic elastomer materials and articles
The definition of “plastic materials” includes plastic pellets (slices), masterbatch, and sheets.

Masterbatch should be mixed with resins or pellets in accordance with formulation, and processed to final food-contact articles for testing of physiochemical specifications.
### GB 4806.7-2016: Plastic Articles Standard

- **Physicochemical specifications**

<table>
<thead>
<tr>
<th>Item</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall migration limit /(mg/dm²)</td>
<td>≤ 10</td>
</tr>
<tr>
<td>KMnO₄ consumption /(mg/kg)</td>
<td>≤ 10</td>
</tr>
<tr>
<td>Water, 60°C, 2h</td>
<td></td>
</tr>
<tr>
<td>Heavy metals (as lead)/(mg/kg)</td>
<td>≤ 1</td>
</tr>
<tr>
<td>4% (v/v) acetic acid, 60°C, 2h</td>
<td></td>
</tr>
<tr>
<td>Decoloration test</td>
<td>Negative</td>
</tr>
</tbody>
</table>
GB 4806.7-2016: Plastic Articles Standard

- Labeling
  - Must comply with GSS
  - Must label resin names in accordance with Appendix A of the Plastic Resin Standard (GB 4806.6-2016)
  - Polymer blends must label names of all resins
GB 4806.10-2016: Coatings Standard

- **Scope**
  - Coatings applied to *direct food contact surface* of FCMs and articles as well as the resulting coating layers (films)
  - Does not apply to paper coatings and coating layers
### GB 4806.10-2016: Coatings Standard

- **Physicochemical specifications**

<table>
<thead>
<tr>
<th>Item</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall migration limit/(mg/dm²)</td>
<td>≤ 10</td>
</tr>
<tr>
<td>KMnO₄ consumption/(mg/kg)</td>
<td>≤ 10</td>
</tr>
<tr>
<td>Water, 60°C, 2h</td>
<td></td>
</tr>
<tr>
<td>Heavy metals (as lead)/(mg/kg)</td>
<td>≤ 1</td>
</tr>
<tr>
<td>4% (v/v) acetic acid, 60°C, 2h</td>
<td></td>
</tr>
</tbody>
</table>

- Restrictions applicable to individual materials from existing 8 coating standards are kept.
Positive list of 105 base resins derived from
• 8 existing GB standards for various coatings (epoxy, phenolic, etc.)
• List of 107 resins (2010 “Clean-up” procedures)

Labeling
→ Must comply with GSS
→ Coating layer materials and articles must label both base materials and coating layers
All Wrapped Up: Part III

- Testing Methods Standards
- China Petition Process
- Q & A
Migration Testing Standard

- **General Standard for Migration Testing for Food Contact Materials and Articles** (GB 31604.1-2015)
  - Effective date: September 22, 2016
  - Imposes general requirements

- **General Standard for Migration Testing Pretreatment for Food Contact Materials and Articles** (GB 5009.156-2016)
  - Effective date: April 19, 2017
  - Details the manner in which to prepare testing samples, etc. for migration testing
Migration Testing Standard

- GB 31604.1 generally adopts protocols in EU’s Plastics Regulation (No. 10/2011)
- Introduces new concepts (e.g., OML, FRF, etc.)
- Notable changes:
  - 4% acetic acid as simulant of food with pH < 5
  - No simulant for dry food
  - Minimum SML testing time is 30 minutes
## Migration Testing Standard

### Food Categories and Food Simulants

<table>
<thead>
<tr>
<th>Food category</th>
<th>Food simulant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aqueous foods (alcohol ≤ 10 % v/v)</td>
<td></td>
</tr>
<tr>
<td>• Non acidic foods (pH ≥ 5)</td>
<td>10% v/v alcohol or water</td>
</tr>
<tr>
<td>• Acidic foods (pH &lt; 5)</td>
<td>4% v/v acetic acid</td>
</tr>
<tr>
<td>Alcoholic beverages (alcohol &gt;10% v/v alcohol)</td>
<td></td>
</tr>
<tr>
<td>• Alcohol content ≤ 20% v/v</td>
<td>20% v/v alcohol</td>
</tr>
<tr>
<td>• 20% v/v &lt; alcohol content ≤ 50% v/v</td>
<td>50% v/v alcohol</td>
</tr>
<tr>
<td>• Alcohol content &gt;50% v/v</td>
<td>Actual alcohol concentration or 95% v/v of alcohol</td>
</tr>
<tr>
<td>Fatty foods &amp; foods with surface fats</td>
<td>Vegetable oil</td>
</tr>
</tbody>
</table>
Other Testing Method Standards

Testing methods on determination of impurities (residue and/or migration) (GB 31604 series):

- GB 31604.2 to GB 31604.10 (effective March 1, 2017)
  - Potassium permanganate consumption
  - Decoloration
  - OML
  .......

- GB 31604.11 to GB 31604.49 (effective April 19, 2017)
  - Sulfur dioxide content in wooden material
  - 1,3-xylylenediamine
  - Terephthalic acid migration
  - Ethylene oxide and propylene oxide content
  - Free phenols content and migration
  - Vinyl acetate migration
  .......


Reminder: Pre-market approval by NHFPC is required under the Food Safety Law

- New varieties (i.e., unapproved) of food-related products are subject to premarket approval by NHFPC (FSL Article 37)
New Approval Procedures

- MOH’s *Management Rules for the Administrative Approval of New Varieties of Food Related Products* ("Management Rules")

- Became effective June 1, 2011 and apply to “food related products,” which include:
  - New food packaging materials
  - Expanded use of approved additives and packaging materials
  - Food use disinfectants
  - Detergents
  - Food contact materials and additives in tools and equipment
New Approval Procedures

Transfer

- In July 2016, the administrative review and approval of new varieties of food-related products was taken over by CFSA ("China National Center for Food Safety Risk Assessment") from the Center of Inspection and Supervision under NHFPC
Two Steps

- **Step 1: Submission to Reception Desk**
  - Petition dossier is filed here, and reviewed by administrators who carry out a formality check (box checking)
    - (1) Acceptance
    - (2) Rejection
    - (3) Filed but with notice of deficiency

- **Step 2: Review by Expert Panel**
  - After passing the formality review, the petition dossier will be passed to the experts for review
Submission Process Overview

Initial Filing

Reception Desk

Formality Check

Expert Panel Review

Draft Approval

NHFPC Approval

Supplements
Petition Materials and Key Considerations

**Petition Materials:**

1. Application form
2. Physicochemical properties
3. Technical necessity, use, and conditions of use
4. Manufacturing process
5. Quality specifications, test method, and test report
6. Toxicological assessment
7. Migration values, estimated dietary exposure and the method of determination
8. Approvals in other countries and relevant documentation
Manufacturing Process Details

- Chinese manufacturing process flow chart must be provided
- Include times and temperature, etc., for each step in the process → Ranges may be provided rather than precise values
- Specifications for raw materials are often requested
Enterprise Quality Standard

- Should include specifications on purity and relevant impurities (e.g., heavy metals, other substances of potential concern)

  **Example:** Colorants must comply with the purity requirements set forth in GB 9685 (identical to Council of Europe Resolution AP(89)1)

- Test methods must be precise and verified
  - Ideally want to cite to a Chinese GB testing method standard, ASTM, ISO, etc.
# Migration and Toxicity Data Requirements

<table>
<thead>
<tr>
<th>Migration value</th>
<th>Required Toxicology Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 0.01 mg/kg (&lt; 10 ppb)</td>
<td>Structural analysis and other safety data or literature</td>
</tr>
</tbody>
</table>
| 0.01 - 0.05 mg/kg (10 - 50 ppb) | Three mutagenicity studies  
(1) Ames test,  
(2) In vitro mammalian chromosome aberration test, and  
(3) In vivo bone marrow cell micronucleus test |
| 0.05 – 5.0 mg/kg (50 ppb – 5 ppm) | Three mutagenicity studies and a 90-day oral feeding study in a rodent species |
| 5.0 – 60 mg/kg (5 ppm – 60 ppm) | Three mutagenicity studies, a 90-day oral feeding study in a rodent species, a teratogenicity study, a two-generation reproductive toxicity study, chronic toxicity and carcinogenicity |
Migration and Toxicity Data Requirements

- Toxicity data should satisfy the testing requirements in MOH’s Guidance

- **Example:** If calculations or testing show migration between 10 ppb – 50 ppb, the petition should include the required mutagenicity tests:
  - Ames Test
  - *in vitro* mammalian chromosome aberration test
  - bone marrow cell micronucleus test
International Clearances

- Although not explicitly stated in the Chinese regulations, the reviewers generally require that the petitioned substance be explicitly cleared in at least two international jurisdictions (e.g., U.S., Canada, EU, Japan)

- The experts want to see an explicit clearance covering the petitioned use
Something to Watch

“The safety assessment materials concerning ..new varieties of food-related products that applicants submit …shall include the essential supporting materials in technology from relevant industry organization, safety assessment opinion from specialized technical institutions, the development of relevant standards and the standards’ text, etc.” (Proposed Article 37 in draft Implementing Regulation of FSL)

- It is unclear how this would be implemented if adopted. Stay tuned.
## Management Rules Petition Summary

### As of December, 2016

<table>
<thead>
<tr>
<th>Year</th>
<th>Petitions Filed</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>5 petitions</td>
<td>→ 5 final approvals</td>
</tr>
</tbody>
</table>
| 2012 | 21 petitions    | → 16 final approvals  
            |                   | → 2 discontinued  
            |                   | → Rest under review |
| 2013 | 26 petitions    | → 25 final approvals  
            |                   | → Rest under review |
| 2014 | 38 petitions    | → 26 final approvals  
            |                   | → 2 draft approvals  
            |                   | → Rest under review |
| 2015 | 21 petitions    | → 6 final approvals  
            |                   | → Rest under review |
| 2016 | 23 petitions    | → 3 draft approval  
            |                   | → Rest under review |
| Total| 134 petitions   | → 78 final approvals  
            |                   | → 5 draft approvals  
            |                   | → Rest under review |
GB Food Packaging
THANK YOU

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