

Chinese Food Contact Regulation and Its Requirements for EU Converters

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Rachida Semail, Partner
Keller and Heckman LLP
Brussels, Belgium Office
+32 (0) 2 645 5094
semail@khlaw.com



Presentation Overview



China	EU
Food Safety Law of 2009 (overarching law)	EU General Food Law (Reg. 178/2002)
General Safety Requirements for FCM&A – GB 4806-1-2016 (GSS)	Framework FC Regulation (1935/2004)
General Hygienic Norms for Manufacture of FCM&A – GB 31603-2015 (GMP standard)	GMP Regulation (2023/2006)
Plastics Standards: GB 4806.6-2016: Plastic Resins GB 4806.7-2016: Plastic Articles	Plastics Regulation (10/2011)
Additives Standard: GB 9685-2016 (Table A.1. refers to additives permitted in plastics)	Plastics Regulation
Migration Testing Standards: GB 31604.1-2015: General Standard for Migration testing for FCM&A GB 5009.156-2016: General Standard for Migration Testing Pretreatment for FCM&A	

Overarching Law: Food Safety Law

Adopted on June 1, 2009

- Replaced 1995 Food Hygiene Law
- Last revised: **October 1, 2015**
- Implementing Regulation (draft for approval): **August, 2017**
- Mandates regulation of “food-related products” (e.g., **food packaging**, equipment, etc.)



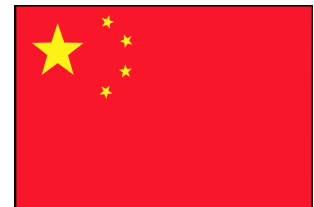
全国人民代表大会

The National People's Congress of the People's Republic of China

Food Safety Law



- FSL requires the Chinese authorities to promulgate Food Safety Standards (FSS) for food-related products
- Products not complying with an applicable Food Safety Standard are unlawful!
- Prior to manufacturing or importing “new varieties” of food-related products, companies are required to obtain premarket approval from the authorities
 - *Management Rules for the Administrative Approval of New Varieties of Food Related Products* (“Management Rules”)

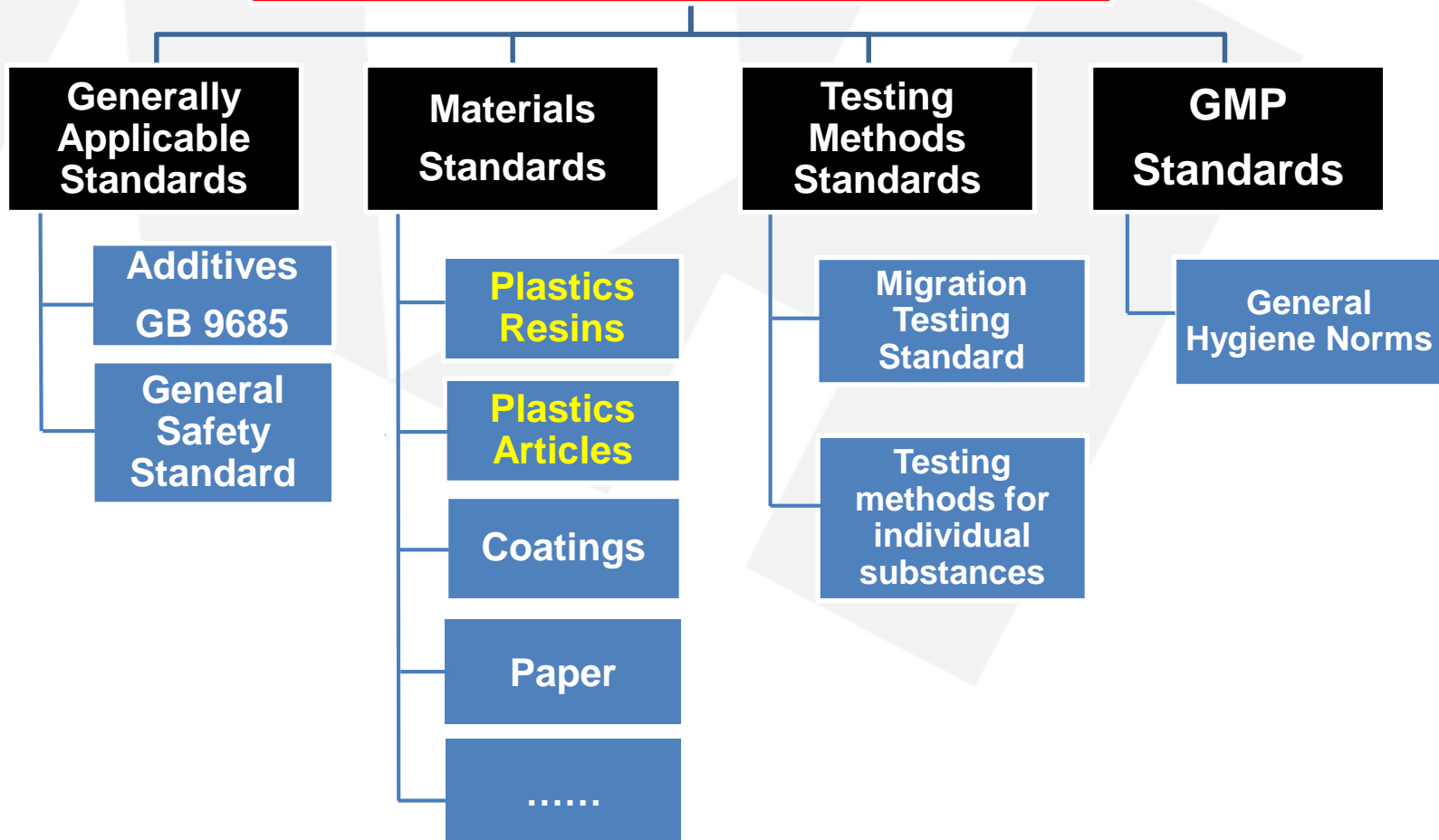


Food Safety Law & Implementing Acts



Chinese Food Safety Law

Relevant regulations on manufacture, pre-market approval, inspection, etc.



GB Food Contact Standards



- The Chinese authorities have been working diligently over the last couple of years to consolidate varied requirements in a more organized manner.
- On November 18, 2016, various long-awaited GB food FCM&A standards were published

GB Food Contact Standards



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

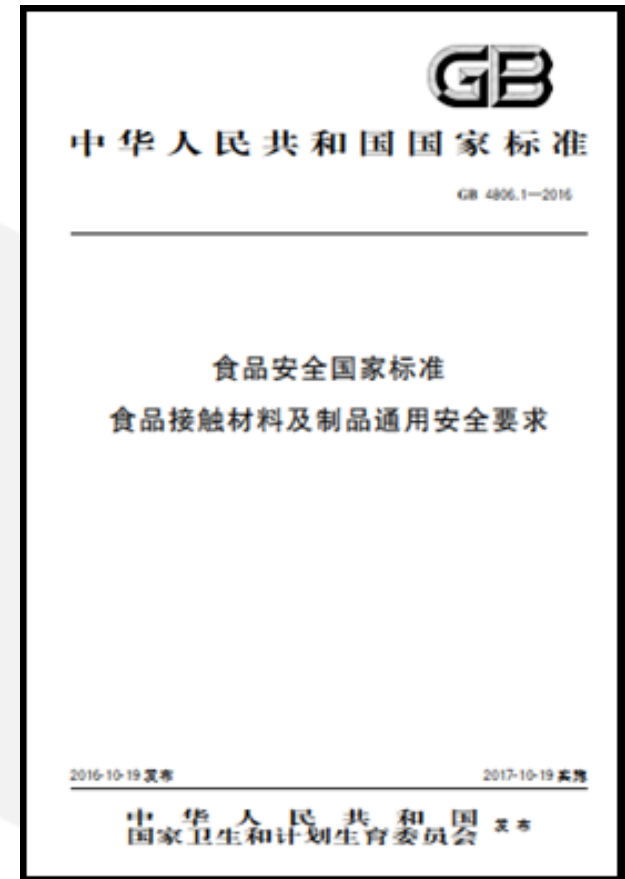
Being Developed

- Adhesives Standard
- Printing Inks Standard
- Composite Material Standard

General Rules Applicable to All FCMs



- **GB 4806.1-2016 General Safety Requirements for Food Contact Materials and Articles (“GSS” Standard)**
 - ✓ Took effect on **October 19, 2017**
 - ✓ Applies to **ALL types of FCM&A**



- **Contains definitions, including the following:**
 - **“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 during the manufacturing, processing, packaging, transportation, storage and use of food
 - **Includes:** Packaging materials, containers, tools, equipment for food uses, printing inks, adhesives, lubricants oils which may come into contact with foods
 - **Does not include:** Detergents, disinfectants, public water facilities
 - **OML, SML, SML(T), QM**
 - **NIAS**
 - **Functional barrier**

**SAFETY
FIRST!**



NIAS

- Impurities in FCMs that are not intentionally added, including impurities derived from raw and auxiliary materials, decomposition products, contaminants and residual reaction intermediates resulting from production and use.
- GSS does not require that NIAS be explicitly approved on GB 9685 or elsewhere
- Manufacturer must control NIAS to ensure the general safety and inertness requirements are met



Unlisted substances may be used in food packaging provided they are used behind a **functional barrier**

■ Definition

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

■ 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

➤ Use of functional barrier NOT limited to plastics



- **Basic requirements** relating to FCM&A (Section 3.1 & 3.2)
 - ✓ 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
- **Manufacture of FCM&A** must comply with the GMP standard (3.7)
- **Use of FCM&A** must comply with the provisions of the **national food safety standards** for the corresponding products
- **Use of additives** in FCM&A must comply with the provisions of GB9685-2016

- Requires that migration testing be performed in compliance with GB 31604.1 and GB 5009.156, unless specific provisions apply

Labeling

- Finished food-contact materials and articles 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)**
- Other requirements are set but not really clear
- Where?
 - To be provided on product or label
 - If information cannot be displayed on product or label due to technical reasons, the information may be displayed in the instruction manual or accompanying document



Traceability

- Producers must establish product traceability system

DoC

- FCM&A operators must supply customers with a DoC in Chinese covering:
 - ✓ Applicable regulations and standards
 - ✓ List of restricted substances and their restrictions (e.g., SMLs)
 - ✓ Compliance with overall migration limit



- **GB 31603-2015 General Hygienic Norms for Manufacture of Food Contact Materials and Articles**



中华人民共和国国家标准

GB 31603—2015

食品安全国家标准

食品接触材料及制品生产通用卫生规范

2015-09-21 发布

2016-09-21 实施

中华人民共和国
国家卫生和计划生育委员会 发布

- Sharing similar principles and certain similar requirements (e.g., those on printing inks), GB 31603 contains more detailed requirements than the EU GMP Regulation
 - Plant environment, facilities and equipment, personnel, requirements for raw materials, product traceability system, product recall system, document management and record...

- GB 31603 generally applies to **ALL** food contact materials and articles
 - Technically speaking, applies to FCMs imported into China as well
 - Practically, related enforcement risks may be negligible so long as product safety can be established
 - Demonstration of compliance with applicable GMP regulation in the jurisdiction of production, as well as product safety, would be helpful

- **GB 4806.6-2016 Plastic Resin Standard**
- **GB 4806.7-2016 Plastic Articles 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, which did not only cover plastics)

附录 A

允许使用的塑料树脂及使用要求

A.1 表 A.1 规定了允许使用的塑料树脂及使用要求。

A.2 GB 9685—2016 附录 B 中特定迁移总量限量[SML(T)]及 SML(T)分组编号适用于本标准。

表 A.1 允许使用的塑料树脂及使用要求

编号	中文名称	CAS号	通用类别名	SML/QM mg/kg	SML(T) mg/kg	SML(T) 分组编号	其他要求
1	(3R)-3-羟基丁酸与4-羟基丁酸共聚物	125495-90-1	Poly (3HB-co-4HB); P (3,4HB)		5(以1,4-丁二醇计)	30	生产的塑料材料或制品不得用于接触含乙醇食品;使用温度不得高于100℃
2	1,1,1,2,2,3,3-七氟-3-[三氟乙氧基]丙烷与四氟乙烯的聚合物	26655-00-5	PFA	0.05(四氟乙烯; SML)			

▪ Scope

- Resins and resin blends used to produce food-contact use plastic materials and articles
- All components of the blend must be 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**

- Plastic resins must comply with **GB 4806.1**
- Must be **listed** in Appendix A

- Sensory Requirements

Item	Requirements
Appearance	With normal color, no abnormal odor or unclean objects, etc.
Soak	The soaking solution from the migration test shall be free from sensory deterioration, such as obvious coloring, turbidity, precipitation, abnormal odor

- SML, SML(T), QM, and other applicable restrictions for monomers and other starting materials are set in Appendix A
 - No OML
- Additives must comply with GB 9685-2016
- Migration testing must be done in accordance with GB 31604.1 and GB 5009.156

- Labeling

- Must comply with GSS 4806.1-2016

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- Must label the **name of resin** in accordance with Appendix A

- In case of polymer blends, the **names of all resins** must be labeled

- To be provided on label, instruction manual or accompanying documents



Scope

- ✓ Food-contact plastic materials and articles
- ✓ Also captures non-vulcanized thermoplastic elastomer materials and articles



- Definitions
 - Plastic materials include plastic pellets (slices), masterbatch, and sheets
 - Plastic articles: articles using plastic resins or plastic materials as raw materials and which are molded/processed into certain shapes
 - Masterbatch: plastic additives (e.g., colorants, fillers, stabilizers) in one or more resins which are then processed into other plastic M&A

GB 4806.7-2016: Plastic Articles Standard

- Must comply with:
 - GSS 4806.1
 - Plastic resin Standard 4806.6-2016
- Same sensory requirements as for plastic resins
- Same labeling requirements as for plastic resins



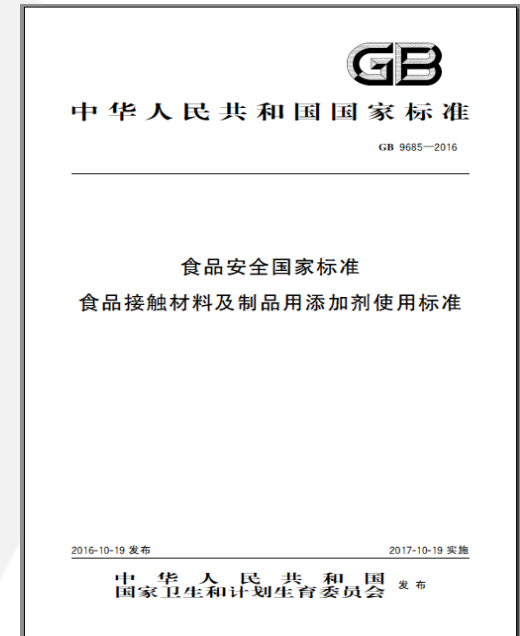
GB 4806.7-2016: Plastic Articles Standard



- Physicochemical Specifications

Item	Specification
Overall migration limit /(mg/dm ²)	≤10
Potassium permanganate consumption /(mg/kg) Water, 60°C, 2h	≤10
Heavy metals (as lead)/(mg/kg) 4% (v/v) acetic acid, 60°C, 2h	≤1
Decoloration test	Negative

- ❑ *Additives in food contact materials and articles”*
 - Substances added during the manufacturing process of FCMs; also include *processing aids* added to promote smooth production rather than improve the quality or properties of the final product
- Took effect on **October 19, 2017**



Positive List of Additives

- **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:

FCA No.	Chinese Name	CASRN	Use Scope & Max. Use Level	SML/QM (mg/kg)	SML(T) (mg/kg)	SML(T) No.	Other Requirements

GB Migration Testing Standards



- *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

GB Migration Testing Standards

- GB 31604.1 generally adopts testing requirements set out in EU's Plastics Regulation
- Introduces new concepts in China (e.g., OML, FRF, etc.)
- Notable changes vs EU:
 - 4% acetic acid as simulant of food with pH < 5
 - No simulant for dry food
 - Minimum SML testing time is 30 minutes



- Compliance of FCM in EU does **not automatically** mean compliance with Chinese standards
- **Similar rules** in EU and China **BUT not identical**
- Determining whether compliance with EU is sufficient is a **case-by-case determination**

- **Converters must obtain from suppliers complete and accurate DoCs with Chinese Standards stating:**
 - Compliance with the GSS
 - with the Plastic Resins Standard
 - with the Additives Standard
 - If FB availed of, this must be stated
- **Difficult in practice to obtain**

- In ideal situations where upstream compliance well done, then converters would have to:
 - comply with the Plastic Articles Standard, including sensory requirements
 - issue DoC
 - ensure labeling in accordance with GSS and Plastic Articles Standard

- **But since compliance with Chinese requirements is rarely confirmed by EU companies, EU converters are often obliged to do the entire compliance work**

- Testing done in accordance with EU requirements should be accepted in China
 - Verification case-by-case still needed
- No need to use Chinese lab
- Worst-case calculations could be, in principle, used in China to demonstrate compliance with SMLs
 - Also in petitions
- Mathematic modelling can be used but not in petitions

- Compliance work with Chinese standards stirs similar challenges as for EU compliance work
 - E.g., obtaining full formulation (confidentiality)
- But additional challenges as legislation not available in English and rules even translated are not clear





THANK YOU

Rachida Semail, Partner

Keller and Heckman LLP

Brussels, Belgium Office

+32 (0) 2 645 5094

semail@khlaw.com

Washington, DC • Brussels • San Francisco • Shanghai • Paris

Keller and Heckman LLP