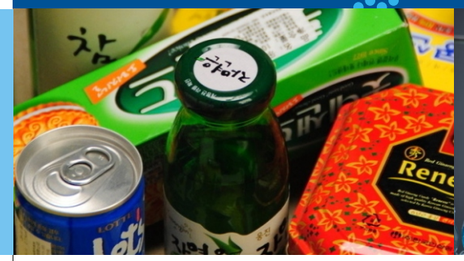

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Food Contact Materials Testing

C&K Testing

Hangzhou C&K Testing Technic Co ., Ltd.

FCM

Food contact materials are materials that are intended to be in contact with food. These can be things that are quite obvious like a glass, a can for soft drinks, but also machinery in a food factory or a coffee machine.

Food contact materials can be constructed from a variety of materials like plastics, rubber, paper, coatings, metal, ink etc. In many cases a combination is used; for example a carton box for juices can include (from the inside to the outside): plastic layer, aluminium, paper, printing and top coating.

During the contact of the food contact materials with the food, molecules can migrate from the food contact material to the food. Because of this, in many countries regulations are made to ensure food safety.

Our Solution

C&K Testing is a leading testing company to render you specialised solutions concerning green and sustainable development of products. Our company is a member of CIRS which is a leading product safety management consulting firm. With our offices in Ireland and the United States as well as our laboratory in China, a global network of testing facilities enables you to meet all the relevant regulatory requirements across different markets more cost-efficiently.

CNAS

CMA

CPSC

CIQ

CNAS: China National Accreditation Service for Conformity Assessment
CMA: China Metrology Accreditation
CPSC: United States Consumer Product Safety Commission Identification
CIQ: Certificate of Qualification for Institution of Import & Export Commodity Inspection and Survey

C&K Testing's analytical laboratories are accredited according to the international standard ISO 17025. We perform new food contact substances testing as well as compliance testing of final food contact materials and articles.

EU Requirements

- (EC) No 1935/2004 Framework Regulation
- (EU) No 10/2011 Plastic Materials
- Directive 84/500/EEC Lead and Cadmium in Ceramic Articles
- Directive 93/11/EEC N-nitrosamines and N-nitrosatable
- EN 14350:2004 Child Use and Care Articles
- EN 14372:2004 Cutlery and Feeding Utensils
- Resolutions of European Commission AP(89)1, AP(2002)1, AP(2004)1, AP(2004)2, AP(2004), AP(2004)5, AP(2005)2
- Germany: LFGB 30&31
- France: DGCCRF Information Announcement
- Italy: D.M.04/04/1985& D.M.21/03/1973
- UK: SI 2011 No.231, SI 2006 No.1179

U.S. Requirements

- Food and Drug Administration (FDA)
- California Proposition 65 (Prop 65)
- State Requirements

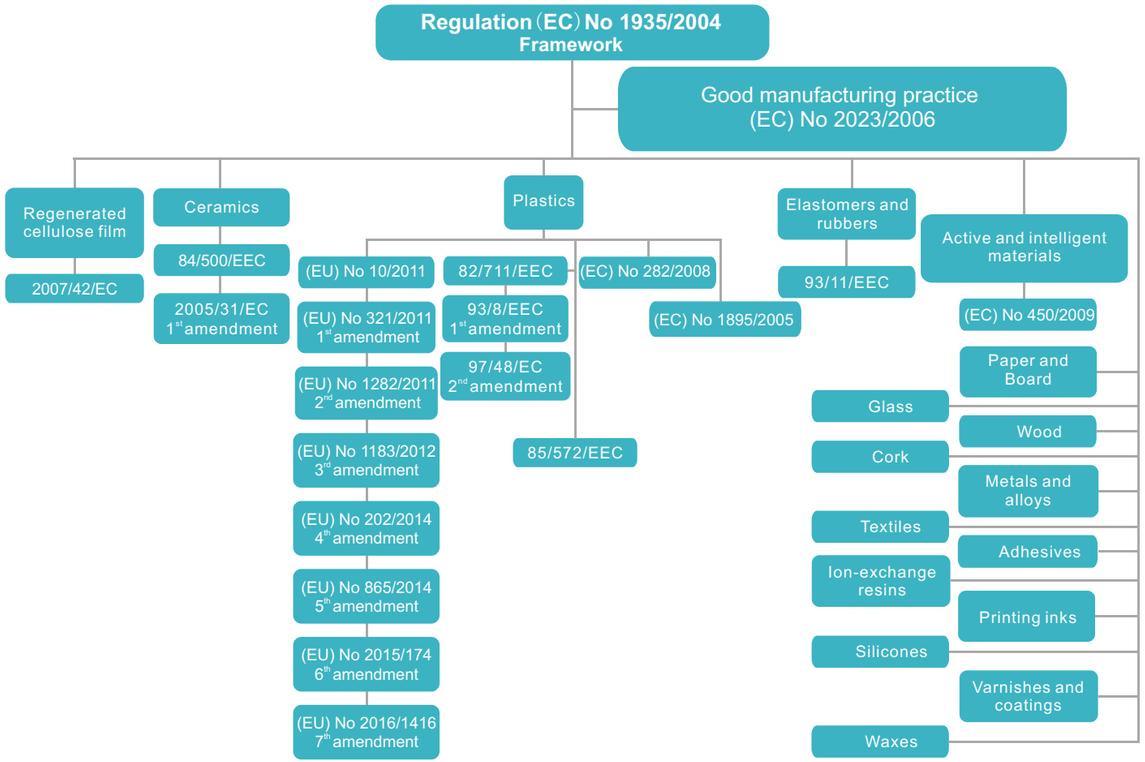
Asia Requirements and Others

- *Food Sanitation Act* in Japan
- *Food Sanitation Act* in South Korea
- Hygienic standards for Food in China
- Canada Hazardous Products Act
- New Zealand Food Regulations
- Requirements for Food Contact Materials in Singapore
- Standards for Food and Drug in Australia

Food Contact Materials Testing

EU Regulations on Food Contact Materials

The safety management and legislation of food contact materials of European Union marked its opening by the directive 76/893/EEC in 1976. Up to now, the regulation has become far more complex that covering many materials. The chart below embodies the regulation framework of EU food contact materials comprehensively.



According to Regulation (EU) No 10/2011, different test conditions shall apply for different foods. General assignment of food stimulants is specified in Table 1. The test conditions for overall and specific migration testing are specified in Table 2 and Table 3 respectively.

Table 1 General Assignment of Food Simulants to Foods

Food simulant	Abbreviation	Foods
Ethanol 10 % (v/v)	Food simulant A	Foods that have a hydrophilic character and are able to extract hydrophilic substances
Acetic acid 3 % (w/v)	Food simulant B	Foods which have a pH below 4.5.
Ethanol 20 % (v/v)	Food simulant C	Alcoholic foods with an alcohol content of up to 20 % and those foods which contain a relevant amount of organic ingredients that render the food more lipophilic
Ethanol 50 % (v/v)	Food simulant D1	Alcoholic foods with an alcohol content of above 20 % and for oil in water emulsions
Any vegetable oil containing less than 1 % unsaponifiable matter	Food simulant D2	Foods which contain free fats at the surface
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E	Dry foods

Table 2 Standardised Test Conditions for Overall Migration Testing

Test number	Test conditions	Intended food contact conditions
OM1	10 d at 20℃	Any food contact at frozen and refrigerated conditions.
OM2	10 d at 40℃	Any long term storage at room temperature or below,including when packaged under hot-fill conditions,and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for a maximum of t = 120/2^((T-70)/10) minutes.
OM3	2 h at 70℃	Any food contact conditions that include hot-fill and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for maximum of t = 120/2^((T-70)/10) minutes, which are not followed by long term room temperature or refrigerated storage.
OM4	1 h at 100℃	High temperature applications for all types of food at temperature up to 100 °C.
OM5	2 h at 100 °C or at reflux or alternatively 1 h at 121 °C	High temperature applications up to 121 °C.
OM6	4 h at 100℃ or at reflux	Any food contact conditions at a temperature exceeding 40 °C, and with foods for which point 4 of Annex III assigns simulants A, B, C or D1. Note: It represents worst case conditions for food simulants A, B and C in contact with non-polyolefins.
OM7	2 h at 175℃	High temperature applications with fatty foods exceeding the conditions of OM5. Note: In case it is technically not feasible to perform OM 7 with food simulant D2 in contact with non-polyolefins.
OM8	Food simulant E for 2 hours at 175 °C and food simulant D2 for 2 hours at 100 °C	High temperature applications only Note: In case it is technically not feasible to perform OM 7 with food simulant D2.
OM9	Food simulant E for 2 hours at 175 °C and food simulant D2 for 10 days at 40 °C	High temperature applications including long term storage at room temperature Note: In case it is technically not feasible to perform OM 7 with food simulant D2.

Table 3 Selection of Test Time and Temperature for Specific Migration Testing

Contact time	Test time	Contact temperature	Test temperature
t≤5min	5 min	T≤5℃	5℃
5min < t≤0.5h	0.5h	5℃ < T≤20℃	20℃
0.5h < t≤1h	1h	20℃ < T≤40℃	40℃
1h < t≤2h	2h	40℃ < T≤70℃	70℃
2h < t≤6h	6h	70℃ < T≤100℃	100℃ or reflux temperature
6h < t≤24h	24h	100℃ < T≤121℃	121℃(*)
1d < t≤3d	3d	121℃ < T≤130℃	130℃(*)
3d < t≤30d	10d	130℃ < T≤150℃	150℃(*)
t≥30d	See specific conditions	150℃ < T≤175℃	175℃(*)
–	–	175 °C < T ≤ 200 °C	200℃(*)
–	–	T > 200 °C	225℃(*)

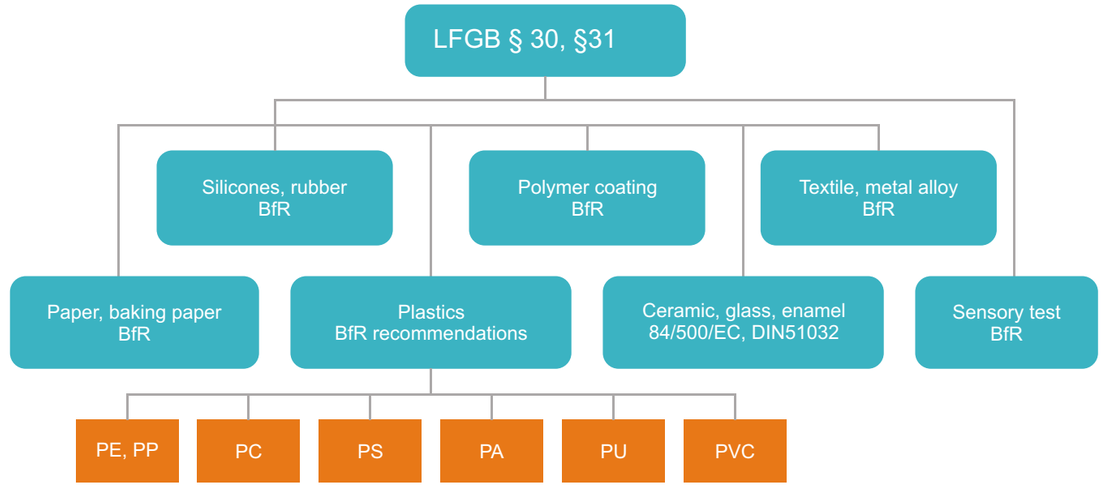
(*) This temperature shall be used only for food simulants D2 and E. For applications heated under pressure migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1 the test may be replaced by a test at 100 °C or at reflux temperature for duration of four times the time selected according to the conditions in the Table.

Food Contact Materials Testing

- German LFGB-Lebensmittel-, Bedarfsgegenstände- undFuttermittelgesetzbuch

In September 2005, Germany reissued “LFGB (German Food, Commodities and Feed Law)”. This document replaces “LMBG (German Food &Commodities Law)” which had been implemented for 30 years. In recent years it has been revised to fulfill European standards. So all the food and food-related commodities ready for sale on Germany market must not only meet the basic requirements of European standards, but also those of LFGB.

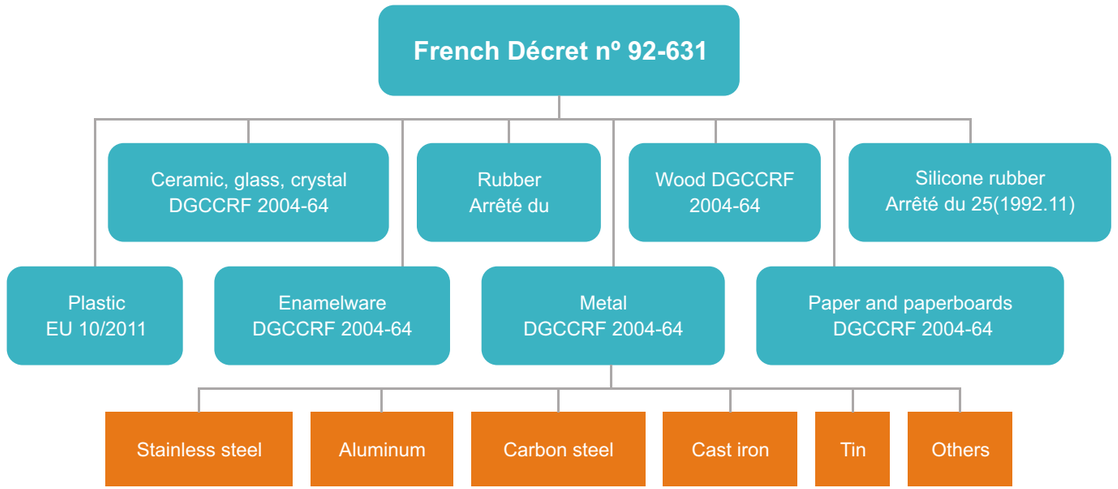
The framework of Germany Regulations about food contact materials is as the following:



- French Décret nº 92-631

In July 1992, France issued “Décret n° 92-631” for the implementation of Regulation (EC) No 1935/2004. The directive is updated as Décret n° 2007-766 in 2007. Like Germany, France also has a relatively complete laws and regulations system. All the food and food-related commodities ready for sale on France market must not only meet the basic requirements of European standards, but also those of Décret n°2007-766.

The framework of France Regulations about food contact materials is as the following:



Other EU Regulations on Food Contact Materials

- **Italy**

On 23 August 1982, Italy issued law DPR 777 in order to implement Directive 76/893/EEC. DPR 777 also specifies the scope of use, punishment against violations and penalties, etc. in addition to the regulations on the safety of food contact materials which are consistent with the basic principle of the EU framework directive.

To implement the framework regulation, a series of MINISTERIAL DECREE (D.M) are derived, like D.M.04/04/1985 on ceramics, D.M. 21/03/1973 on plastics, rubber, regenerated cellulose film, paper and board, glass and stainless steel products.

- **UK**

Different from Germany and France, the UK will not develop special technical regulations about food contact material safety at the level of the country, but rather transfer and implement the EU regulations through release of the Statutory Instrument (SI).

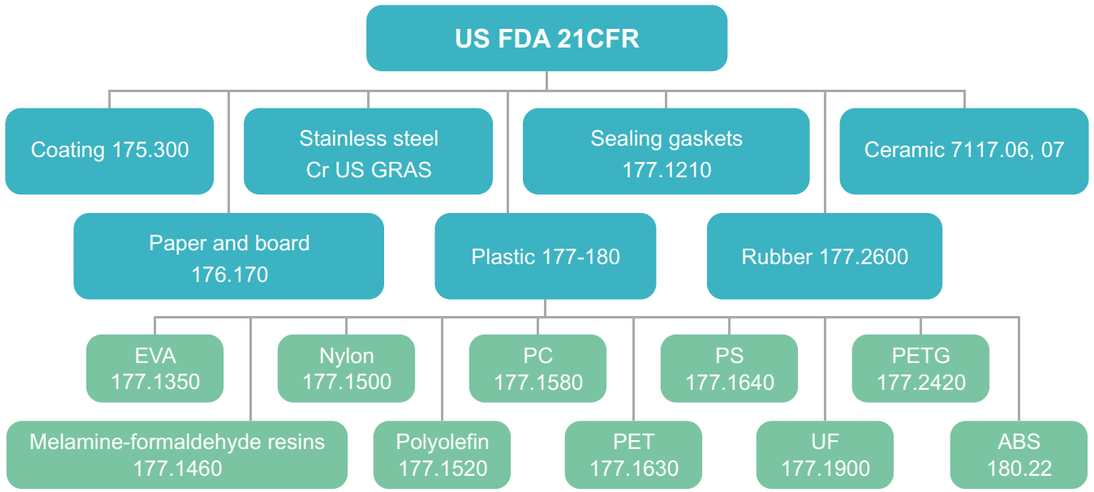
Current SI files include:SI 2011 No. 231 (plastic materials), SI 2006 No. 1179 (ceramics), SI 1995 No. 1012 (nitrosamines materials in pacifiers). SI 2010 No. 2225 released in 2010 is consistent with (EC) No 1935/2004 Framework Regulation and (EC) No 2023/2006 Good Manufacturing Practice Regulation covering Regulation (EC) No 450/2009 on active and intelligent materials and articles and Directive 2007/42/EC on regenerated cellulose membrane.

U.S. Regulations on Food Contact Materials

In the U.S., the materials used for food packaging are regarded as indirect additives, and incorporated in the food additives safety regulation system, involving major regulations and policies as the following:

1. CFR (Code of Federal Regulation) 21 Chart
2. CPG (Compliance Policy Guides) formulated by FDA (U.S. Food and Drug Administration)
3. California Proposition 65 (also known as Safe Drinking Water and Toxic Enforcement Act) was enacted as a ballot initiative in November 1986. Prop 65 aims to protect California citizens and the drinking water from contamination from chemicals to cause cancer or birth defects or other reproductive toxicity.

CFR chart 21 is its main content of the food contact materials, and here is the simple framework .



Asian Regulations on Food Contact Materials

- **China**

Chinese National Health and Family Planning Commission (NHFPC) launched the work for the conformity of national standards as regards food safety in May 2014. The new China regulatory framework of FCMs gradually takes in shape along with the publication of new standards. The newly released standards as regards FCMs can be divided into 3 categories, namely, general standards, product standards and testing standards.

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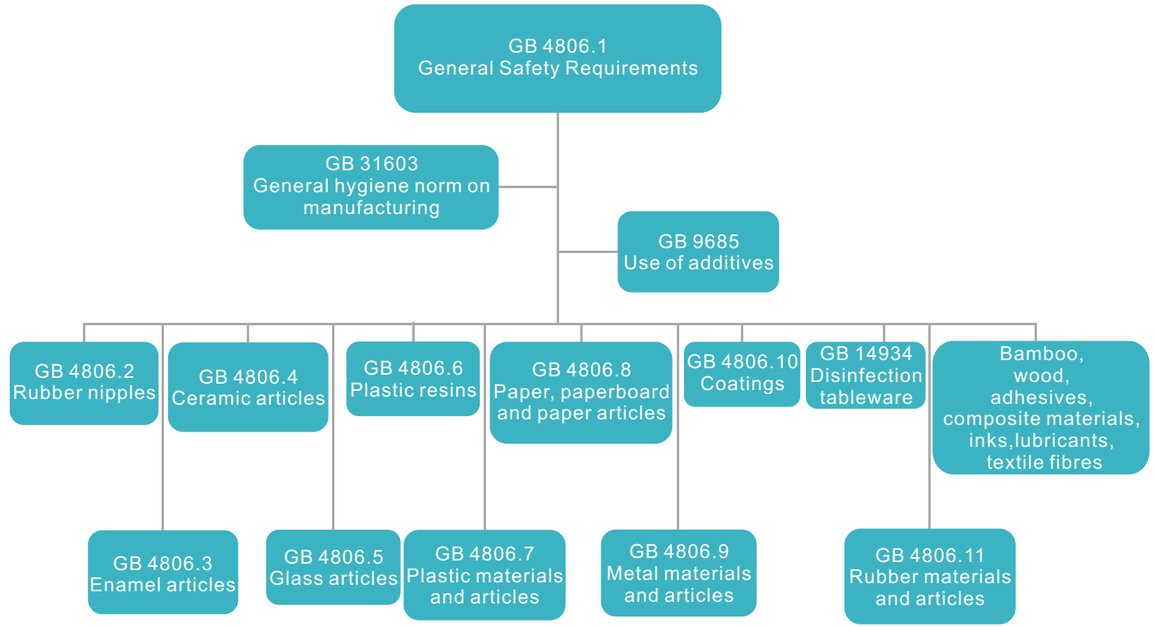
Food Contact Materials Testing

Up to November 2016, NHFPC had issued two general standards GB 4806.1 for general safety requirements and GB 9685 for the use of additives, and 11 product standards covering rubber nipples (applicable on 22 September 2016), enamel articles, ceramics, glass articles, plastic resins, plastic articles, paper and paper board, metal, coatings, rubber and disinfection tableware (GB 14934) . Meanwhile, the requirements for bamboo, wood, adhesives, composite materials, inks, lubricants, textile fires are still under development. Notably, these product standards (excluding GB 4806.2 for rubber nipples) under the new China FCMs regulatory framework come into operation on 19 Apr. 2017.

The chart below is the new China FCMs regulatory framework:



- **Japan**

Japan's regulatory framework for food packaging materials combines government regulations based on the *Food Sanitation Act* of 1947, together with industry standards that have been voluntarily established by trade associations. In terms of the requirements under the *Food Sanitation Act* in Japan, this legislation sets forth a general safety standard that covers not only food, but also food additives, food packaging materials and equipment, detergents for vegetables and fruits, eating utensils, and toys for children.

While Japan does not currently have a "positive list" of substances that are permitted to be used in articles that contact food, or require premarket approval or review of food-contact substances prior to their use in the marketplace. The *Food Sanitation Act* authorises the establishment of specifications for food containers and packaging and the raw materials used to manufacture such articles. The Japanese Ministry of Health, Labour, and Welfare (MHLW)—under the Pharmaceutical and Food Safety Bureau, Department of Food Safety, Standards and Evaluation Division—is responsible for developing such specifications.

- **South Korea**

South Korea's *Food Sanitation Act* establishes the legal basis for food safety-related work conducted by the Ministry of Health and Welfare (MHW) and the Ministry of Food and Drug Safety (MFDS). With respect to food packaging, the Act includes a general requirement that food-contact materials be free of substances harmful to human health. More specific regulations, standards, and specifications impacting food packaging materials are established and enforced by MFDS.