

FOOD | CONTACT MATERIALS Compliance Solutions



About STC

Established in 1963, STC is an independent, not-for-profit testing, inspection and certification organization headquartered in Hong Kong, offering one-stop professional conformity assessment service for customers around the world to get access to the global markets.

As an organization with global network, not only has STC set up testing facilities and customer service offices in China's major cities such as Shanghai, Dongguan, Shenzhen, Zhongshan, Beijing and Changzhou, but also in countries like Germany, Italy, USA, Vietnam and Japan. Our world-class, internationally accredited testing facilities can meet the needs from a wide range of industries.

Dedicated to improving product quality and safety standards, we provide comprehensive support to global supply chain, helping them to build competitive advantage and customer confidence.





Introduction

Food contact materials (FCMs) are anything that can be in contact with food, either directly or indirectly. With FCMs being extensively used in daily life, incidents involving unacceptable quantities of hazardous chemicals found in FCMs, such as plasticizer in sports drinking bottles and manganese in dinnerware, have raised wide public concern.

In light of the potential for hazardous chemicals in FCMs migrating to food which may pose a threat to human health, regions and countries such as the European Union, the United States, China and Japan have imposed rigorous regulations governing the safety and quality of FCMs. Food business operators, from manufacturers and suppliers to retailers, have to comply with respective country's requirements.

Compliance Solutions from STC <

STC has long been assisting businesses to mitigate business risks. Our Chemical, Food and Pharmaceutical Products Division offers a complete range of support to help food business operators achieve compliance with mandatory and voluntary requirements around the world.

Safety and quality assurance service

Equipped with comprehensive testing capabilities and state-of-the-art testing facilities, STC can conduct both chemical and physical testing for a wide range of FCMs. Our one-stop service can support food business operators to validate the safety of FCMs in accordance with national and regional regulatory requirements, and to verify manufacturers' claims on product quality and performance based on well-recognized national and international standards.

Testing program customization

To help you save cost and time, STC can provide customized testing plans that best fit your goal, whether it be multi-market access or new product development.

Technical support

STC can be your resource for technical support. Technical meetings can be set up to guide you through the requirements of the markets where you want to sell your product. After completion of testing, we can offer technical analysis in case of test failure to help you identify the root causes and corrective actions.

Regulatory monitoring

With STC as your testing partner, you are empowered to make prompt response to changing market conditions. We keep a close eye on the ever-changing regulations and standards for FCMs, and keep you informed of any changes in a timely manner.

UZ

European Union

► REGULATORY REQUIREMENTS

Framework Regulation - EC No. 1935/2004

EC No. 1935/2004 lays down the requirements for materials and articles which are intended to come into contact with foodstuffs. These materials must be sufficiently inert to preclude substances from transferring to food in quantities large enough to endanger human health.

EC No. 1935/2004 Ceramic/ Organic **Plasticware** Rubber Wood Metal alloy **Paper** glassware coating 84/500/EC AP(2004)1 93/11/EEC & PCP content; CM/ AP (2002)1 EU No.10/2011 EU No. 284/2011 AP(2004)4 Res(2013)9 PCP content; Leachable Formaldehyde Overall Overall Polyamide & lead and Overall migration release Migration Antimicrobial melamine migration and cadmium migration and of 21 heavy release; specific plastic nitrosamine metals Heavy metal migration kitchenware release; 2005/31/EC **Fluorescent** 1st amendment matter EC No.202/2014 EC No.2016/1416 Amendment EC No. 321/2011 Bisphenol A in plastic infant feeding bottle

EC No. 1935/2004 : General Requirements

- I. Materials and articles shall be manufactured in compliance with Good Manufacturing Practice (GMP)
- II. Shall not transfer constituents which could:
 - endanger human health
 - bring about an unacceptable change in the composition of food
 - bring about a deterioration in the organoleptic characteristics
- III. The labeling, advertising and presentation of a material or article shall not mislead customers

Scope of Application:

- Packing and packaging of foodstuffs
- Tableware and crockery, kitchen utensils and parts of electrical kitchen appliances intended to come into direct contact with foodstuffs
- Feeding bottles and baby bottle teats, cups, etc
- Machinery and equipment used for the production, processing, storage or transport of foodstuffs
- Active materials and intelligent materials
- Miscellaneous articles such as labels, clips, table napkins and kitchen paper towels

NOT applicable to:

- Materials and articles supplied as antiques
- Covering or coating materials which form part of the food and may be consumed together with this food
- Fixed public or private water supply equipment

► REGULATORY REQUIREMENTS

Plasticware – EU No. 10/2011 and amendment



EU No.10/2011 - Overall migration & Specific migration

The recently published regulation EC No. 2016/1416 for food contact materials, amending EU No. 10/2011, will enter into force in September 2018. Products complying with original EU No. 10/2011 could still be placed in the market until September 14, 2017 and may remain until the exhaustion of stocks.

Scope of Application:

- Monolayer plastics
- Multi-layer plastic bound by adhesives which could be printed/coated
- Plastic layers in multi-material multi-layer materials and articles
- Plastic layers or coatings forming gaskets

NOT applicable to:

- Ion exchange resins
- Silicones
- Rubber

Overall migration

Plastic food contact materials and articles

Limit of constituents transferred to food simulants

Not intended for infants & young children	10mg/dm ²
Intended for infants & young children	60mg/kg

Specific migration*

I) Shall not release the following heavy metals in quantities exceeding:

	Barium	Cobalt	Copper	Iron	Lithium	Manganese	Zinc	Aluminum
EU No. 10/2011 EU No. 2016/1416	1 mg/kg	0.05 mg/kg	5 mg/kg	48 mg/kg	0.6 mg/kg	0.6 mg/kg	25 mg/kg 5 mg/kg	Not restricted 1 mg/kg

II) Shall not release primary aromatic amines exceeding:

Sum of Primary Aromatic Amines (PAA) – 0.01 mg/kg

Ceramic ware - 84/500/EC and amendment



Ceramic Articles

Definition: manufactured from mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added. They may be glazed, enameled and/or decorated.

Requirements

Shall not release lead and cadmium in quantities exceeding:

Category	Lead (Pb)	Cadmium (Cd)
Category I (e.g. Plate) Articles cannot be filled; articles can be filled with internal depth < 25mm (from lowest point to horizontal plane passing through upper rim)	0.8 mg/dm ²	0.07 mg/dm ²
Category II (e.g. Cup) All other articles which can be filled	4.0 mg/L	0.3 mg/L
Category III (e.g. Dispenser) Cooking ware; Packaging and storage vessel capacity > 3L	1.5 mg/L	0.1 mg/L

STC has a network of laboratories accredited by LUCIDEON – the most authoritative organization in ceramic product testing and a British Standard Committee Member. Our test reports are widely recognized by retailers in the European Union.

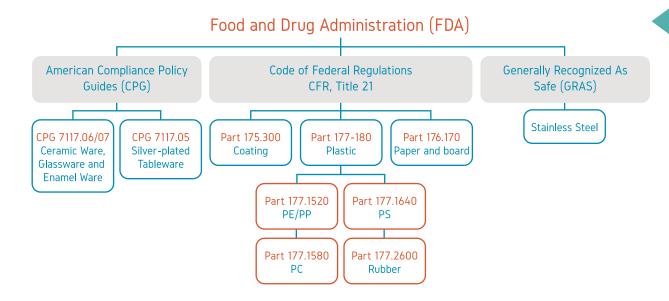


National Regulations in EU Member States

Apart from EU regulations, some member states in EU have their own specific requirements for food contact materials, such as:

- Germany German Food, Commodity and Feed Law
- France DGCCRF
- Italy Ministerial Decree of 21 March of 1973

Food and Drug Administration (FDA), an agency within the U.S. Department of Health and Human Services, is responsible for governing food, drugs, biopharmaceuticals, medical devices, etc.



General Requirements

- I. Food additives shall be safe to consumers
- II. Food contacting articles are regarded as indirect food additives
- III. Should not transfer residues into foodstuff

American Compliance Policy Guides (CPG)

American CPG is a guidance issued by FDA on regulatory actions

- Applicable to: Ceramic ware and silver-plated tableware intended to come into contact with food
- Requirements: ► Ceramic ware Leachable Lead (Pb) and Cadmium (Cd)
 ► Silver-plated tableware Leachable Lead (Pb)

Code of Federal Regulations, CFR, Title 21 – Food and Drugs

CFR is the codification of the general and permanent rules and regulations by Federal Government of U.S. Title 21 is the portion of CFR that collects all federal laws, regulations and implementation rules on food, drugs, cosmetics and medical products administrated and drawn up by FDA

- Applicable to: Plastic, paper and paperboard, polymeric coated materials and articles intended to come into contact with food
- Requirements: > Amount of extractives contained in different food-simulating solvents

Generally Recognized As Safe (GRAS)

Requirements for stainless steel: Total Chromium content not less than 16%

06

Japan

► REGULATORY REQUIREMENTS

Food Sanitation Law is applicable to all food contact materials and articles importing into Japan. Food containers and packages containing harmful substances shall not be manufactured, sold or used in Japan. Under the Food Sanitation Law, the Ministry of Health, Labor and Welfare lays down regulations and standards for food apparatus or containers and packaging or the raw materials which are divided into 4 categories.

07

Food Sanitation Law

General Specifications Specifications by Material Type

Specifications by Application

Standards for Manufacturing

General Specifications:

General standard for metal, polyvinyl chloride, etc.

Specifications by Material Type:

Standards for metal, glass, ceramic, rubber, polymers, etc.

Specifications by Application:

Standards for material with specific purpose, e.g. glass containers for soft drink

Standards for Manufacturing:

Standards for manufacturing apparatus or containers/packages

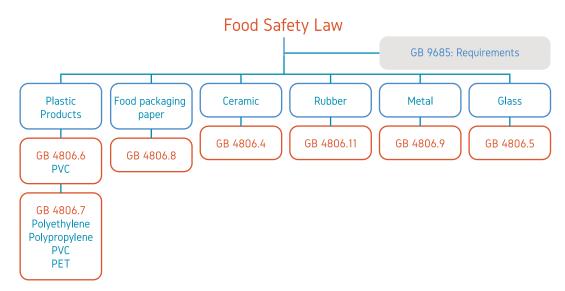


MHLW Foreign Official Laboratory

STC (Hong Kong Standards and Testing Centre) is accredited by Japan's Ministry of Health, Labor and Welfare as its foreign Official Laboratory to test foods, food additives, apparatus, containers, packaging and toys to be imported into Japan. The test reports issued by STC are accepted at Japan quarantine stations. Manufacturers and suppliers of food contact products can get access to the Japanese market without hassle through the unrivalled one-stop testing service offered by STC.

► REGULATORY REQUIREMENTS

Food contact materials in China are regulated by Food Safety Law, under which a series of hygiene standards and method standards have been developed and implemented. The latest version of these standards was released in November 2016.





Other Countries

Country	Standards
UK	BS 6748 : 1986+A1:2011BS 8654 : 2015
Canada	 Canada Consumer Products Safety Act (Glazed Ceramic and Glassware) (Regulation SOR/98-176 with amendments up to SOR/2009-179) Drinking utensil rim area ≤ 20mm (Regulation SOR/98-176 with amendments up to SOR/2007-30)
Australia	 Australia Commonwealth Consolidated Regulation No.289, 1991 AS 4371-2012 Ceramic Tableware
International	ISO 6486-1&2:1999 Ceramic ware, glass-ceramic ware and glass dinnerware

Performance Requirements



Voluntary industry standards for food contact materials have been developed by national and international bodies, which provide well-recognized benchmarks and test methods for evaluating the quality of food contact materials.

09

Claims Verification Tests

Performance Test Test Method		Requirements	
Microwave Safe	ASTM C1607-12 EN 15284 : 2007	No crack / deform / color change should be found	
Oven Safe	EN 13834	Thermal shock - No crack on samples at ≥180°C / T°C difference Heat resistance - No damage after heated for 1 hour at 20°C above claimed heat resistance T°C / 250°C	
Dishwasher Safe	ASTM C676 EN 12875-4 : 2006	ASTM: No observable change after testing / BS: Acceptable = 0 to 1 (0 - No visible change; 1 - First discernible change; 2 - Clearly visible change)	

Performance / Quality Tests

Performance Test	Test Method	Requirements
Resistance to freezing and freezer to oven usage	LUCIDEON PT36	No visible adverse effect
Resistance to freezer to microwave usage	LUCIDEON PT37	No visible adverse effect
Thermal Shock	ASTM C554 EN 1183 : 2007 Method B	No crack on 50% specimens at temperature specified (claimed heat resistance temperature / Buyer's requirement)
Handwashing Safe	LUCIDEON PT35	No observable change after testing
Water Absorption (Stoneware & Earthenware)	BS EN 1217: Method C	Earthenware / Common pottery : no less than 5% Stoneware : 0.5 to 3%
Water Absorption (China & Porcelain)	BS 5416: 1990	Porcelain : No more than 0.5%
Crazing Resistance	BS EN 13258 Method A	Crazing resistance index of ceramicware with water absorption > 0.5% should exceed 10 hours



STC Global **Network**

CHINA

HONG KONG

Hong Kong Standards and Testing Centre (Headquarters)

10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong

**** +852 2666 1888 ⋈ hkstc@stc.group www.stc.group

Hong Kong Inspection Company

Unit B, 10/F, Block 1, Tai Ping Industrial Centre, No.57 Ting Kok Road, Tai Po, N.T., Hong Kong

→ +852 2663 1251

📞 +852 2667 2628 🛮 🖂 hkic@hk-ic.com www.hk-ic.com

Hong Kong Certification Centre

Unit B, 10/F, Block 1, Tai Ping Industrial Centre, No.57 Ting Kok Road, Tai Po, N.T., Hong Kong

**** +852 2661 2083 → +852 2661 3181

www.hk-cc.hk

DONGGUAN

STC (Dongguan)

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China Zip Code: 523770

**** +86 769 8111 9888

→ +86 769 8111 6222 www.dgstc.org

SHENZHEN

STC (Shenzhen)

Room 806, 8/F., Block A, Reith International, 1002 Yanhe North Road, Luohu District, Shenzhen, China Zip Code: 518033

⇒ +86 755 8366 6430 www.dgstc.org

BEIJING

STC (Beijing)

Unit 322, Block E1, Yuan Chenxin Building, 12 Yumin Road, Chaoyang District, Beijing, China

Zip Code: 100029

**** +86 10 8599 6936 → +86 10 8599 6938

 bjo@stc.group www.stc.group

ZHONGSHAN

STC (Zhongshan)

Unit B, 24/F, Block 1, Baijingtai, 383 Fuhua Road, West District, Zhongshan, Guangdong, China Zip Code : 528400

⊕ +86 760 8880 2536

www.stc.aroup

SHANGHAI

STC (Shanghai)

130 Huashen Road, Waigaoqiao Pilot Free Trade Zone, Shanghai, China Zip Code : 200131

**** +86 21 5219 8248

→ +86 21 5219 8249

 shstc@stc.group www.shstc.org

CHANGZHOU

STC (Changzhou)

Changzhou Electronic Product Quality Supervision & Inspection Co., Ltd.

19 Xinke Road, Electronic-Technology Park, Changzhou, Jiangsu, China Zip Code: 213031

\ +86 519 8548 7806 → +86 519 8548 7811

www.stc.group

Microtek Changzhou Laboratories

19 Xinke Road, Electronic-Technology Park, Changzhou, Jiangsu, China Zip Code: 213031

+86 519 8548 7809

→ +86 519 8548 7810

mayteng@thetestlab.cn

www.thetestlab.cn

NORTH AMERICA

STC (USA) Benchmark Laboratories LLC

15 Corporate Drive, #8-9, Wayne, NJ 07470, USA

 +1 862 229 6388
 □ usstc@stc.group www.stc.group

EUROPE

STC (Germany) PKM electronic GmbH

Ohmstrasse 1,84160 Frontenhausen, Germany

+49 8732 6381 info@pkm.eu.com

info@pkm.eu.com www.stc.group

STC (Italy)

Via del Mare, 47, 20142 Milano, Italy

➡ +39 2 4550 3617

www.stc.group

ASIA

STC (Vietnam)

Unit 102, Ground Floor, Lot T2-4, D1 Street, High Tech Park, District 9, Ho Chi Minh City, Vietnam

➡ +84 8 5448 2060 ⊕ www.stc.group

STC (Japan)

1007, 3 Chome-15-2 Higashiikebukuro, Toshima-ku, Tokyo 170-0013, Japan

**** +81 80 4357 1888

www.stc.group





www.stc.group