GLOBAL FOOD CONTACT COMPLIANCE

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White Paper
# CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>4</td>
</tr>
<tr>
<td><strong>Food Contact Compliance in the EU</strong></td>
<td></td>
</tr>
<tr>
<td>The European Framework legislation, a 40-year-old legislation</td>
<td>5</td>
</tr>
<tr>
<td>Good Manufacturing Practice (GMP)</td>
<td>5</td>
</tr>
<tr>
<td>Plastic Food Contact Materials</td>
<td>5</td>
</tr>
<tr>
<td>Non-Harmonized Legislation</td>
<td>7</td>
</tr>
<tr>
<td>Upcoming Legislation</td>
<td>7</td>
</tr>
<tr>
<td>Food Contact Compliance in Switzerland</td>
<td>7</td>
</tr>
<tr>
<td>Approach to Achieving Compliance Within the EU</td>
<td>8</td>
</tr>
<tr>
<td><strong>Food Contact Compliance in the U.S.</strong></td>
<td></td>
</tr>
<tr>
<td>Food and Drug Administration (FDA)</td>
<td>9</td>
</tr>
<tr>
<td>21 CFRs for Indirect Food Additives</td>
<td>9</td>
</tr>
<tr>
<td>Approach to Achieving Compliance Within the U.S.</td>
<td>9</td>
</tr>
<tr>
<td><strong>Food Contact Compliance in China</strong></td>
<td></td>
</tr>
<tr>
<td>National Standards (GB) in China</td>
<td>11</td>
</tr>
<tr>
<td>New Scheme of GB Standards on Food Contact</td>
<td>11</td>
</tr>
<tr>
<td>Approach to Achieving Compliance Within China</td>
<td>12</td>
</tr>
<tr>
<td><strong>Figure 1 - New Scheme of FCM GBS in China</strong></td>
<td>14</td>
</tr>
<tr>
<td><strong>The Intertek Advantage</strong></td>
<td>15</td>
</tr>
</tbody>
</table>
INTRODUCTION

Food contact regulatory requirements around the world are complex with different regions requiring their own notifications (US, EU, China, So. America, etc.) for new food contact substances as well as compliance specifications for food contact materials. It is essential to mitigate the risks associated with migration of chemical substances from food contact materials, or articles, into food, which could pose a health threat. Expedited market entry while ensuring the safe use of your food contact material or article is also desirable.

The dynamic global regulatory landscape and the increasing number of regulations present a real challenge for companies developing and manufacturing food contact substances, materials and articles. Each company involved in the production process of the food contact substance, material or article, is responsible for ensuring the compliance of its end-product. For these stakeholders, it is important to know their obligations and to be able to demonstrate compliance.

The focus of this white paper is to provide the latest information on regulatory requirements in key markets including EU, USA, and China. It will highlight how regulations vary from region to region and what is required for compliance.
FOOD CONTACT COMPLIANCE IN THE EU

In the European Union (EU), there are general obligations and legislations in place for various food contact materials and substances.

To achieve food contact compliance, you are required to:

• Verify which regulations, recommendations or resolutions are in place for your products
• Identify if the substances of your material may be used (check positive lists)
• Perform adequate testing under worst-case intended use conditions
• Prove GMP compliance
• Make sure appropriate documentations are in place

The European Framework Legislation, A 40-Year-Old Legislation

The first version of this legislation, directive 76/893/EEC, was published in 1976. The current version is regulation (EC) No. 1935/2004 which is applicable to all countries within the European Union. The European framework legislation is currently under the scope of the European Commission for eventual modifications. All materials and articles intended to come into contact with food need to comply with the European Framework Regulation (EC) No. 1935/2004. This regulation states that food contact materials must not endanger human health or bring any changes in smell, composition, color or taste to the food. In addition, all food contact materials should be manufactured according to good manufacturing practice (GMP) as regulated by Regulation (EC) No. 2023/2006.

Food contact regulations are mandatory for packaging materials, materials and articles used in the food industry (i.e., machinery, storage tanks, pipes, filters, conveyor belts, etc.), and for kitchen utensils (i.e., cups, dishes, cutlery, food appliances, inner walls of a refrigerator, etc.).

Good Manufacturing Practice (GMP)

GMP principles for food contact materials are covered by the European Regulation (EC) No. 2023/2006. This regulation is applicable at all stages of the production and distribution process of food contact materials excluding the production of raw materials.

The European Regulation (EC) No. 2023/2006 outlines the requirements necessary for quality assurance, quality control systems, and documentation that needs to be retained.

Elements to verify GMP compliance include:

• Risk assessment
• Traceability
• Training
• Documentation
• Internal audits

Plastic Food Contact Materials

Since the 1st of May 2011, plastic materials in contact with food are regulated by (EU) No. 10/2011, which is applicable within the EU. This is also referred to as Plastic Implementation Measures (PIM).
(EU) No. 10/2011 applies to:
- Plastic monolayers
- Plastic multi-layer held together by adhesives
- Plastic materials and articles that are printed or covered by a coating
- Plastic layers or coatings forming gaskets in caps and closure
- Plastic layers in multi-material multi-layer materials

Ion exchange resins, rubbers and silicones are excluded from regulation (EU) 10/2011.

The following sections summarize the main requirements of (EU) 10/2011:

Union List
The positive list (called the Union list) of authorized substances is set out in Annex I of the regulation. Only monomers and additives included in the Union list may be used in the manufacturing process of plastic food contact materials.

If a substance is not listed, a registration process for listing at EFSA can be initiated. Relevant actions may include migration studies and toxicological evaluation amongst others.

Migration Testing
The transfer of substances from food contact materials into food is called migration. Migration limits have been established to restrict the transfer of components from food contact materials into the foodstuff in unacceptable quantities. Two types of migration limits have been established for plastic materials:

Overall Migration
The Overall Migration Limit (OML) of 10 mg/dm² or 60 mg/kg applies to the sum of all substances that can migrate from the food contact material to the food. Migration testing should be performed under standardised test conditions including testing time, temperature and test medium (food simulant). This should represent the worst foreseeable conditions of use of the plastic material or article.

Specific Migration
A Specific Migration Limit (SML) applies to individual substances and is based on toxicological assessment studies conducted by the European Food Safety Authority (EFSA). Analytical techniques are used to measure the limits of these substances. Test conditions for specific migration testing combines contact time and temperature, which are based on the actual condition of use.

Non-intentionally Added Substances (NIAS)
NIAS present in plastic materials are required to be assessed for risk. These substances are chemical compounds that are present in a material but have not been added for a technical reason; they are impurities that have been formed during the production or the decomposition process. The manufacturer must assess any safety risk associated with these compounds in alignment with internationally recognized principles of risk assessment.

Declaration of Compliance (DoC)
Plastic food contact materials that are imported and/or sold in the EU should be accompanied by a DoC, which is a written document stating that the food contact materials/products comply with relevant regulations. The content of the DoC depends on the position of the operator in the supply chain. The evidence to support statements in the DoC called “Supporting Documents” must be available for authorities to review at any time.
Amendments
Since the enactment of the (EU) 10/2011 regulation, seven amendments have been released and implemented. At the date of publishing this white paper, the European Commission (EC) has released the latest amendment, Regulation (EU) 2017/752. This includes adding several new food contact substances to the Union List, establishing a specific migration limit for Nickel in plastic materials (0.02 mg Nickel per kg of food or food simulants), clear assigning of food simulants to demonstrate compliance for overall migration testing, as well as modifying the wording in (EU) 10/2011 Annex IV to “the highest surface area to volume ratio for which compliance has been verified in accordance with Article 17 and 18 or equivalent information”. These requirements are to be applied from May 2018 except the limit for Nickel which shall apply from May 2019.

In the previous amendment 2016/1416 (6th amendment), the migration limit for zinc was lowered to 5 mg/kg food and the migration limit for aluminum was identified as 1 mg/kg food. These specific migration limits are to be applied to plastic materials and articles from September 2018 onwards.

Non-Harmonized Legislation
For several non-plastic materials (i.e., paper and board, printing inks, adhesives, metals, silicon, rubber, etc.), no harmonized European regulation exists outside of the overall Framework regulation EC 1935/2004 and GMP 2023/2006. These materials must comply with applicable national legislation.

In addition to the national regulations, there are guidelines written by the Council of Europe (CoE), which include non-EU countries and guidelines written by industry associations (e.g. for inks, paper, adhesives).

Although these guidelines are not legally binding, they are very useful to assess the safety of materials and articles and to ensure they are compliant with the European Framework regulation. In circumstances where no European regulation exists, national regulations are binding above the guidelines written by the CoE or industry associations.

Upcoming Legislation
The European Commission working group on food contact materials held a meeting on January 30th, 2017, during which the future agenda for the elaboration of a legislation on printed food contact materials was discussed.

The European Commission is currently working on the 8th amendment for plastic materials; no date of release has been planned.

In March 2017, the German Competent Authority released a new draft version of the Consumer Goods Ordinance for the “Mineral Oil Ordinance”. This ordinance provides a specific migration limit (SML) of 0.5 mg/kg food for mineral oil aromatic hydrocarbons (MOAH) and recommends the introduction of functional barriers to reduce the migration of chemicals from recycled paper and board in contact with food. In this version, the SML for mineral oil saturated hydrocarbons (MOSH) has been removed.

Food Contact Compliance in Switzerland
On May 1st, 2017, the New Version of the Swiss Ordinance for “Materials and Articles intended to come into contact with foodstuffs” came into force. The new version is more in alignment with the European Union requirements for food contact materials. The positive list for allowable printing inks to be used for indirect contact with food has been changed from previously Annex 6 to Annex 10. Additionally, some substances that were listed on the non-evaluated list B have been transferred to list A for evaluated substances. Substances recognized as Carcinogenic, Mutagenic and reprotoxic (CMR) have been removed from the list, as well as new substances have been added to Annex 10 and are permitted to be used to manufacture printing inks for food contact materials.
Approach to Achieving Compliance Within the EU

Intertek can support you ensuring the compliance of food contact materials from the substance to the end product based on its intended end use.

Main steps towards achieving compliance:

- Gather a complete list of all materials and substances used in the production of your food contact material/product.
- Verify which regulations (in addition to the (EU) 1935/2004 and GMP 2023/2006) are in place for your products to fulfill compliance for global and/or local markets.
- Verify if industry guidelines or resolutions are available to support you with establishing the safety of your materials (risk management)
- Demonstrate your GMP compliance
- Review the Declaration of Compliance (DoC) from the supplier according to your position in the supply chain
- Identify if the substances of your material may be used (check positive list(s)) and/or if there are any other limitations applicable
- Determine the food contact application of your material (kind of foodstuff, time and temperature conditions)
- Set up a compliance scheme for your product/material. This may include: migration tests, worst case calculation/modelling, screening tests, NIAS studies/toxicological risk assessment
Food and Drug Administration (FDA)
All government branches of the United States of America are included in the Federal Register. The Federal Register is the official journal for the Federal Government of the United States (U.S.) that contains government agency rules, proposed rules, and public notices.

The Food and Drug Administration (FDA) is the governmental agency in the U.S. that regulates food contact substances, materials, and articles. All existing regulations are published in the Code of Federal Regulation (CFR) and all food additives regulations are included in Title 21 CFR parts 170-199.

The U.S. FDA considers three different types of food additives:

- Direct food additives - components added directly to the food for a functional purpose, such as food coloring, not regulated by food contact regulations
- Indirect food additives - substances that may come into contact with food as part of packaging or processing equipment, but are not intended to be added directly to food and do not have a functional purpose; also called Food Contact Substances (FCS)
- Secondary direct food additives - components that are added to the food due to food treatment like treating food with ionic resins, solvent extraction

21 CFRs for Indirect Food Additives (also called Food Contact Substances)
The following parts of 21CFR pertain to “indirect” food additives:

- 21 CFR Part 175 – Adhesives and Components of Coatings
- 21 CFR Part 176 – Paper and Paperboard
- 21 CFR Part 177 – Polymers
- 21 CFR Part 178 – Adjuvants, Production Aids and Sanitizers

Approach to Achieving Compliance Within the U.S.
Intertek can assist with ensuring compliance of food contact materials. We review the compliance status of individual components that comprise the final food contact material to ensure each component is in compliance for its intended end use.

This can be accomplished by:

- Review of Statements of Compliance / Supplier Statements from the supplier of each individual component of the Food Contact Material
- Review of the compliance status of the full composition of the Food Contact Material by each CAS number / chemical name

If all components of the food contact material are in compliance with 21 CFRs for the intended use, the manufacturer or supplier can market the product. Intertek can issue a certification that supports this finding and indicates that the product is in compliance and safe for the intended use.
If any of the components are not in compliance for the intended use, Intertek can offer any of the following services to allow for the new FCS to be regulated for use in food contact applications:

- Food additive petition (FAP), which is no longer used for clearance of new food contact substances, except when FDA deems it necessary
- Food Contact Notification (FCN)
- Generally Recognized as Safe (GRAS)
- Threshold of Regulation (TOR)
- Prior Sanctioned Substances

Intertek offers a wide range of core competencies for the activities required to obtain clearance of a food contact substance, all of which are delivered by our multi-functional team of experts. This includes services such as regulatory reviews, preparation and submission of a new food contact notification, conducting analytical testing, including migration studies, toxicology support and authoring of the safety narrative and environmental assessment required for a new notification.
FOOD CONTACT COMPLIANCE IN CHINA

National Standards (GB) in China

National standards are classified into compulsory standards and voluntary standards in China. The National Food Safety Standards for food contact materials belong to compulsory national standards (abbrev. GB).

According to the Standardization Law, it is mandatory to comply with compulsory standards. It is prohibited to produce, sell or import products that are not in compliance with these standards.

New Scheme of GB Standards on Food Contact

On November 18th, 2016, 53 new GB standards for food contact materials and articles (hereinafter FCM GBs) were published in China.

With the release of these new FCM GBs, a brand new scheme of Chinese FCM GB standards were established. This new scheme includes four major sections: Horizontal Standards, Good Manufacturing Practice (GMP), Product Standards, and Test Methods (Figure 1).

1. Horizontal Standards

GB 4806.1-2016 National Food Safety Standard - General Safety Requirements for Food Contact Materials and Articles

GB 4806.1-2016 is a newly established standard. Within this standard, the definition for food contact materials and articles was mentioned for the first time in China.

Under the normal condition of uses, food materials and articles that are, or are expected to be in contact with food or food Additives (hereinafter food), or their components may transfer into food (i.e., packaging materials, containers, tools and equipment used during the manufacturing, processing, packaging, transportation, storage, retailing and use of food) are all included. Items that may directly or indirectly contact food are also included (i.e., printing inks, adhesive, lubricants, etc.). Detergents, disinfectants and facilities for public plumbing of water are not included.

This standard also stipulates the fundamental requirements, compliance principles, traceability, labelling, Declaration of Compliance, GMP, etc., which are applicable to various food contact materials and articles.

GB 9685-2016 National Food Safety Standard - Standards for Uses of Additives in Food Containers and Packaging Material

In GB 9685-2016, it is required that additives used in plastic, coating, rubber, adhesive, ink, paper, or silicone should be from the Table A of this standard.

If the additives to be used in these kinds materials and articles are not explicitly listed while also does not fit for exemption rules, petition for new additives will be required prior to manufacturing or importing to China.

2. Good Manufacturing Practice (GMP)

GMP standard sets forth basic requirements for the entire manufacturing process for various food contact materials and articles. Manufactures should establish detailed workflow to ensure compliance.
3. Product Standards

GB 4806.3-2016 ~ GB 4806.11-2016 covers nine kinds of materials

This series of GB 4806.3-2016 ~ GB 4806.11-2016 standards combine and supersede many old hygiene standards for materials and articles.

In these revised standards, there are detailed requirements on composition, physical-chemical indicators, specific test conditions, labelling, etc., which are clearly listed with corresponding product standards for food contact materials and articles.

There are strict requirements on how base polymer should be chosen based on the positive lists in these GB standards for plastic, rubber and coating.

For ink, adhesive, wood, bamboo, etc., draft for corresponding standard is in the start-up phase. Relevant manufacturers should follow up with the development of these standards to get prepared as early as possible.

4. Test Methods

For test methods, there are several standards identified, including:

• GB 31604.1-2015 National Food Safety Standard - General Rules for Migration Test of Food Contact Materials and Articles, &
• GB 5009.156-2016 National Food Safety Standard - General Rules of Pre-treatment of the Migration Test of Food Contact Materials and Articles, &
• GB 31604.2-2016 & GB 31604.49-2016 Test methods for different test indicators or for different substances

GB 31604.1-2015 & GB 5009.156-2016 are two basic standards on how test conditions should be selected and how to conduct pre-treatment for test specimen.

GB 31604.2-2016 ~ GB 31604.9-2016 are test or detection methods for different test indicators required in product standards, such as the determination of overall migration, potassium permanganate consumption, loss on drying of resins, etc.

GB 31604.10-2016 ~ GB 31604.49-2016 are test methods for various substances that may have SML or QM restrictions in GB 9685 or GB 4806.xx standards.

With all these new GB standards, many new requirements are being discussed. It is essential for companies to know and understand all the new requirements and take actions for compliance. Food contact compliance in China is no longer equal to simple tests. Comprehensive and systematic effort is needed to ensure compliance with the new Chinese FCM GBs.

Approach to Achieving Compliance Within China

Achieving compliance for food contact materials and articles requires a series of effort in China. Intertek can assist with ensuring compliance step by step. We review the compliance status of individual components that comprise the final food contact material to ensure each component is in compliance for its intended end use.

This can be accomplished by:

• Review of Declaration of Compliance / Supplier Statements from the supplier of each individual component of the Food Contact Material
• Review of the compliance status of the full composition of the Food Contact Material by each CAS number / chemical name

After a components check, if tests are required to confirm compliance, Intertek can arrange tests based on new GB standards including overall migration test, specific migration test and other relevant tests needed. With the components review result and test results, Intertek can issue a report that supports this finding and indicates that the product in compliance is safe for the intended use.

intertek.com/regulatory/food-contact/
If any of the components are not in compliance for the intended use, Intertek can offer services for Chinese food contact petition:

- Chinese Food Contact Petition for new additives or new polymer

Intertek offers a wide range of core competencies for the activities required to obtain clearance of a food contact substance, all of which are delivered by our multi-functional team of experts. This includes services such as regulatory reviews, preparation and submission of a new food contact notification, conducting analytical testing, including migration studies, toxicology support and authoring of the safety narrative assessment required for a new notification.

For a manufacturing plant of food contact materials and articles, Intertek provides GMP validation services to ensure the entire manufacturing process complies with GMP requirements. Intertek also provides GMP training tailored to your requests.

For any issue relevant to food contact materials and articles, Intertek strives to find solutions to it.
FIGURE 1 - NEW SCHEME OF FCM GBS IN CHINA
Our services include food contact regulatory compliance reviews, migration protocol development, third party certifications, migration studies, placement and monitoring of toxicology studies to support a submission, testing for NIAS, as well as guidance for use of recycled content in food contact applications. Our expertise spans the lifecycle of the project, beginning with an initial compliance review through to the notification of the new food contact substance, if necessary, which includes testing, regulatory support and a safety risk assessment until compliance is reached.

Intertek’s strategic and methodical approach to gathering information, to regulatory considerations, and testing requirements and documentation can help you to achieve swift compliance, support notification or provide the analytical data and insight you need for your specific food contact materials or articles - whether they are comprised of plastics, paper and board, glass, metals, ceramics, printed or coated materials or other materials.

We liaise with regulatory agencies on a company’s behalf when required. Our wide-ranging geographic presence and decades of regulatory knowledge have allowed us to create collaborative relationships with agencies around the world, accelerating the regulatory process. We can interpret current regulations as well as design customized food contact compliance programs, each able to demonstrate that your materials and articles are in compliance with the applicable legislations.

We will provide comprehensive regulatory support for fast track and cost-effective approaches to enter new markets, aid with the introduction of new products and assistance to adapt to changes in existing regulations. Our decades of experience guarantees extensive knowledge of all aspects of food law and food contact laws, and our strong communication network with local and regional governmental authorities is a competitive advantage for our clients.
MEET OUR EXPERTS

**DR. SARAH SAMINADIN-PETER, FOOD CONTACT EXPERT**

Sarah Saminadin-Peter is a Regulatory Affairs Expert who started her career as a researcher in Biological Chemistry and System Biology at Harvard Medical School. She developed analytical methods to perform high-throughput 3D imaging on a 2-photon microscope and chromatin immunoprecipitation combined with next generation sequencing to target the impact of changes that occur in the non-coding DNA. She worked there for several years and published scientific articles in a high ranking scientific journal. She changed career paths to become a regulatory affairs expert for food contact materials and materials in contact with drinking water. She is currently assisting clients with worldwide strategic regulatory compliance. Sarah is also supporting clients to register new substances and assist them in discussions with competent authorities. Additionally, she is organizing regulatory training on client sites and seminars. Sarah is currently a Senior Food Contact Regulatory Expert at Intertek Health, Environmental & Regulatory Services in Leinfelden-Echterdingen, Germany.

**NADINE THOMIS, BUSINESS DEVELOPMENT MANAGER, REGULATORY SERVICES**

Mrs. Nadine Thomis holds a Master in Science in Chemistry and Food Technology at the Hasselt University College in Belgium. Within Intertek, she is Business Development Manager for Food Contact Regulatory Services and has many years of experience as Business Consultant for food contact materials. Mrs. Thomis has extensive knowledge on European, national and international food contact regulations and supports clients in setting up an appropriate test program in order to comply with the relevant regulations for their materials and products intended to come into contact with food. This support is not limited to plastic materials but also covers non-plastic materials, like e.g. paper & board, printing inks, coatings, rubbers, silicones and multilayer materials. Mrs. Thomis is playing an important coordinating role in supporting clients worldwide with regulatory projects, setting up compliance programs and notification projects. She has been invited as speaker at national and international regulatory conferences.

**ANGELIQUE DANEK, DIRECTOR, BUSINESS DEVELOPMENT, REGULATORY SERVICES**

As Director of Business Development, Health, Environmental and Regulatory Services (HERS), Angelique Danek is responsible for generating new business and managing projects from start to finish for Intertek’s HERS Group in the U.S. She is also the manager of all regulatory and toxicology experts in the notifications team, which includes both global food contact notifications and global chemical notifications, and manager of food contact compliance and sustainability team. Angelique joined Ciba Expert Services (which became part of Intertek in 2010) at the beginning of 2007. While at Ciba Expert Services (CXS), Angelique helped to grow the food contact and chemicals regulatory business by bringing in new clients and promoting the global network of experts who assisted clients with submissions to the FDA, EPA, and international regulatory authorities. Prior to her work at Ciba Expert Services, Angelique worked for 9 years in the Pharmaceutical Industry with GlaxoSmithKline. At GSK, Angelique started her career as an Analytical Chemist and then Project Manager, leading drug development projects from early stage to market. In her later years at GSK, Angelique became a Regulatory Project Leader focusing on both US and International regulatory submissions, which required numerous interactions with the FDA. Currently, at Intertek, she manages all Food Contact Notifications and Global Chemical Notifications as well as supervises a global network of experts. The essence of the group is to assist clients with entering new markets, introducing new products, and complying with existing regulations. Angelique received her MBA from The University of North Carolina – Chapel Hill and both her BS in Chemistry and MSc. in Chemistry from The University of Virginia.

**CARRIE WANG, REGULATORY SPECIALIST**

Carrie is responsible for food contact regulatory compliance services in China. She focuses on the Chinese food contact regulations and standards to provide regulatory consulting and compliance solutions to clients worldwide. Carrie also has experience in product stewardship work covering chemical registrations (China new chemical notification, K-REACH & TW-REACH), material safety data sheets & label for products, raw materials & formulation management, as well as food contact compliance work. Carrie acquired a masters degree of pharmaceutical chemistry from Fudan University. She is currently a Regulatory Specialist in the Intertek Health, Environmental & Regulatory Services group based in Shanghai, China.
REFERENCES


Swiss Ordinance 817.023.21 Regulation of the EDI on materials and articles intended to come into contact with foodstuffs https://www.admin.ch/opc/de/classified-compilation/2014393/index.html
Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices and over 42,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers’ operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

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