OCI sharing:
FCM regulations in China and the US - a comparison

Translated by Kelly

Dr J. Brian Xu and Dr Scott J. Burya of The Acta Group examine the changing regulations for food contact materials in China in the context of existing regulations in the US.
ACTA 公司的 J. Brian Xu 博士和 Scott J. Burya 博士在美国现行法规的背景下，考察了中国食品接触材料的法规变化，全文如下：

While the intention of food contact regulations in both China and the US is to protect public health, the approaches taken, the obligations for industry and other facets of the regulations differ in notable ways. This article overviews the two regulatory systems, highlighting key similarities and differences between the emerging regulatory regime in China and the established US Food and Drug Administration (FDA) food contact regulations.
虽然中国和美国的食品接触条例都旨在保护公众健康，但采取的方法，行业的义务和其他方面的规定也各不相同。本文概述了这两个法规体系，突出了发展初期的中国法规制度与美国确立的食品与药品管理局（FDA）食品接触法规之间的关键相似点和不同点。

China overview
中国概况
Under China's Food Safety Law (FSL), food contact materials (FCMs) are regulated under the term'food-related products'. These include packaging materials, containers, utensils, equipment, detergents, disinfectants, etc. that may come into contact with food. The FSL prohibits the importation, use or sale of food-related products that do not comply with applicable National Food Safety Standards (NFSS).
根据中国《食品安全法》（FSL），食品接触材料（FCMS）作为食品相关产品进行监管。这些包括包装材料、容器、器具、设备、洗涤剂、消毒剂等，它们可能与食物接触。食品安全法禁止进口、使用或销售不适用于国家食品安全标准（NFSS）的食品相关产品。

FCMs are one category of food-related products in the Chinese regulatory system. The majority of the NFSSs for FCMs, including GB 4806.1-2016 and GB 9685-2016, as well as 50 material and testing standards, were revised in 2016. GB 4806.1-2016 and GB 9685-2016 both became effective on 19 October 2017 and form the new regulatory system for FCMs.
在中国法规体系中食品接触材料是食品相关产品中的一个分类。在 2016 年修订了大多数食品接触材料的国家食品安全标准，包括 GB 4806.1-2016 和 GB 9685-2016，以及 50 中原料和测试标准。GB 48061-2016 和 GB 9685-2016 均于 2017 年 10 月 19 日生效，形成了新的标准体系。

The definition of FCMs from GB 4806.1-2016 translates as "any materials and

products that, under normal use conditions, contact with or are expected to contact with food or food additives (foodstuff), or whose components may migrate into foodstuff, including packaging materials, containers, utensils, tools and equipment used in manufacturing, processing, packaging, transporting, holding or marketing foodstuff, as well as printing inks, adhesives, lubricating oils, etc. that possibly contact with foodstuff directly or indirectly; excluding detergents, disinfectants and public water-transporting facilities".
国标 GB 4806.1-2016 中定义了食品接触材料，是指"在正常的使用条件下，各种已经或预期可能与食品或食品添加剂（以下简称食品）接触、或其成分可能转移到食品中的材料和制品，包括在生产，加工，包装，运输，存储、销售中所使用的包装材料，容器，器具，工具和设备，及可能直接或间接接触到食品的液体，如印刷油墨、胶粘剂、润滑油等。不包括清洁剂，消毒剂和公共输水设施"。

Three ministries regulate FCMs in China. The National Health Commission (NHC) is responsible for pre-market approval of new FCMs and existing FCMs with new use or expanding use limits, carrying out risk assessments of food related-products and formulating and updating the NFSS. New FCMs are substances and additives that are neither listed in the GB 9685 nor approved by NHC in its official announcement. The State Administration for Market Regulation (SAMR) is tasked with supervision and enforcement activities for the manufacture and processing of FCMs. Finally, the General Administration of Customs (GAC) is responsible for customs clearance, and the supervision and inspection of imported FCMs.
在国内食品接触材料是三部委联合规范。国家卫生健康委员会（NHC，卫康委）负责新食品接触材料上市前的审批和现有的食品接触材料的新的使用范围及使用量，实施食品相关产品的风险评估，制定和更新国家食品安全标准（NFSS）。新食品接触材料是尚未列入 GB 9685 或者卫康委公告允许使用的物质和添加剂。国家市场监管局（SAMR）负责监管和实施食品接触材料的生产和加工。最后，海关总署(GAC)负责清关，并对进口的食品接触材料进行监督检查。

The regulatory system for FCMs in China is based on a positive list approach and covers the entire supply chain. There are two primary mechanisms by which FCMs are controlled and regulated. Pre-market approval is required for FCM additives and polymer resins, while FCMs and finished packaging articles must meet compliance testing standards. Applicable NFSSs include:
国内的食品接触材料管理体系是基于允许使用清单的方式并覆盖整个供应链。FCM 添加剂和聚合物树脂需要进行上市前的审批，以及 FCMs 和成品包装制品必须符合对应的测试标准，这两个主要机制对 FCMS 进行控制和规范。适用的国家食品安全标准包括：

● General safety requirements (GB 4806.1);
通用安全要求(GB 4806.1)
● Positive list for additives permitted for use in FCMs (GB 9685);
食品接触材料中允许使用添加剂的清单(GB 9685)
● Standards for paper, plastics, coatings, rubber, metal and other materials (GB 4806.2-11);
纸类、塑料类、涂层类、橡胶类、金属类及其他一些材料的标准(GB 4806.2-11)；

● Positive lists for polymer resins (GB 4806.6, .10, and .11);
合成树脂类允许使用清单(GB 4806.6, .10, and .11)
● The good manufacturing practice (GMP) standard (GB 31603); and
生产质量管理规范标准(GB 31603)；以及
● Test method standards for individual substances and migration (GB 5009.156, GB 31604.1-49, and GB 4789.15);
各个组分和迁移量的试验方法标准(GB 5009.156, GB 31604.1-49, and GB 4789.15)；

In addition, food additives listed in GB 2760 may be used in FCMs.
另外，GB 2760 中的食品添加剂可用于食品接触材料中。

GB 4806.1 details the applicable requirements, compliance principles, testing methods, traceability and product information for FCMs. Principally, these should not migrate into food at levels harmful to human health, or impart changes to the ingredients, structure or properties of food (such as colour, taste and aroma), or have a technical effect on food.
GB 4806.1 规定了食品接触材料的基本要求，符合性原则，测试方法，可追溯性和产品信息。原则上，这些接触材料迁移到食品中的物质不应危害人体健康，或影响食物的成分、结构或性质（如颜色、味道和香味）的变化，或对食物产生技术功能。

Additionally, FCM producers should establish a traceability system that captures key information regarding raw and auxiliary materials, and which tracks the distribution and sale of FCMs. 'Raw and auxiliary materials' include additives, solvents, adjuvants, colourants, basic resins, printing inks, adhesives, lubricating oils and others.
此外，食品接触材料生产商应建立可追溯系统，该系统能够获取的关于原辅料的关键信息，并跟踪食品接触材料的分布和销售。原料和助剂包括添加剂、溶剂、助剂、着色剂、基体树脂、印刷油墨、粘合剂、润滑油等。

Supply chain participants, including suppliers of raw and auxiliary materials, should provide a Declaration of Compliance (DoC) that confirms authorisation and identifies usage restrictions and limitations to downstream users. The DoC should include:
供应链参加者，包括原材料和辅助材料的供应商，应提供符合性声明（DOC），确认许可和使用限量标识以及对下游用户的限制。确认声明 DOC 应包括：

● The authorising regulation and standards;
许可法规与标准
● A list of substances with applicable restrictions;
限制性要求物质名单
● An assessment of non-intentionally added substances (Nias); and
非有加物质的评价报告
● Supporting analytical reports.
支持性的分析报告

The use of an unauthorised substance in FCMs may be permissible if the substance:
在食品接触材料中使用未经许可的物质可能是允许的，如果物质：

● is not a carcinogen, mutagen, reproductive toxicant or nanomaterial;
不是致癌物、诱变剂、生殖毒物或纳米材料；
● is used behind an effective barrier layer; and
在有效阻挡层之外使用；和
● migrates into food at a level not exceeding 0.01 mg/kg food.
在食物中不超过 0.01 毫克/公斤的迁移量；

Finished products should be labelled with the text 'for food contact' or 'for food packaging' and the 'spoon and chopsticks' graphic, as appropriate.
成品应标有"食品接触用"或"食品包装用"和"勺子和筷子"图样的文字。

Manufacturers and importers of new FCMs, or existing FCMs with new or expanded uses, must obtain pre-market approval via a New Food-Related Product Registration (NFRPR). The NHC is in charge of receiving applications and its executive branch, the Centre for Food Safety Risk Assessment (CFSA), is responsible for the technical review.
新食品接触材料或现有的食品接触材料进行新用途的或扩大使用量的的制造商和进口商，必须通过新食品相关产品申报（NFRPR）获得上市前的审批。NHC 负责接收申请，其行政部门食品安全风险评估中心（CFSA）负责技术审查。

Once an application is approved, the NHC sets appropriate NFSSs and restrictions for the 'food-related product'. The NFRPR is not proprietary to the submitter; other manufacturers or importers of the same FCM may rely on the official NHC announcement without submitting additional registrations. US overview The Federal Food Drug, and Cosmetic Act (FFDCA), enacted by Congress in 1938, gives the FDA the authority to regulate FCMs. The term 'food additive' is defined in 21 U.S. Code § 321 as: "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognised, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use".
一旦申请获批，卫康委即时发布对应的国家安全食品标准和对"食品相关产品"的限制条款。新食品相关产品申报不是提交人专有的；同一食品接触材料的其他制造商或进口商可以直接采用卫康委官方的公告而不用再行注册。美国概述了联邦食品药品与化妆品法案（FFDCA），由国会于 1938 颁布，赋予 FDA 监管食品接触材料的职责。"食品添加剂"一词在美国法典第 21 卷第 321 节（21 U.S. Code § 321）中定义为："用来形成或预期形成直接或间接食品的一部分，或能够影响食品特征的任何食品（包括任何在生产、制造、包装、加工、制备、处理、装箱、运输及存储过程中预期使用，包括任何用于此类用途的辐射源。如果这些物质不被普遍认可，但经由那些科学训练和经验丰富的资深专家们按照科学程序对其安全性进行评估，并充分证明显示（或，在 1958 年 1 月 1 日之前的食品中使用过的物

质，通过科学程序或基于食品中常用的经验）在其预期使用条件下是安全的。
Regulations for the following categories of food additives are codified in the Code of Federal Regulations (CFR) Title 21, Parts 170-189:
下列类别的食品添加剂法规归类于《联邦法规》（CFR）第 21 卷，第 170—189 部分：
● direct food additives (substances added directly to food);
直接添加的食品添加剂（直接添加在食品中的物质）
● secondary direct food additives ("substances used in the manufacture or processing of food that are ordinarily not expected to be present in the final product"); and
直接使用的加工助剂(在食品生产或加工时,通常不希望出现在最终产品中物质。)
● indirect food additives (articles used in contact with food and substances used to manufacture them) and food contact substances, defined as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting or holding food, if such use is not intended to have a technical effect in such food".
间接食品添加剂（与食品接触的物品和用于制造食品的材料）和食品接触物质，定义为"任何用作制造、包装、包装、运输或持有食品的材料的成分的物质，如果不使用这种物质在这种食物中有技术效果。

The FDA's approach for regulating FCMs includes establishing quality standards, disseminating positive and negative lists, and authorising new substances via pre-market notification processes. The general provisions section for indirect food additives, codified in 21 CFR 174.5, details GMP and suitable purity requirements, and requires that additives not impact the organoleptic properties of food (that is, the adulteration of food is prohibited). Also included in 21 CFR 174.5 is the following positive list for substances that, under conditions of GMP and subject to any prescribed limitations, may be safely used as components of articles that contact food:
FDA 监管食品接触材料的方法包括建立质量标准，发布允许使用和禁用清单，并通过上市前审批公告对新物质许可。在 CFR 第 21 篇第 174.5 部中的间接食品添加剂的总则中详细说明 GMP 和合适的纯度要求，并且要求添加剂不影响食品的感官特性（即，禁止掺假）。在 CFR 第 21 篇第 174.5 中还包括下列物质的允许使用清单，这些物质符合 GMP 条件下并在任何规定的限制下，可以安全地用于接触食品的物品的成分。

● substances Generally Recognised As Safe (Gras) in or on food;
● substances Gras for their intended use in food packaging;
● substances used in accordance with a prior sanction or approval;
● substances permitted for use by regulations in 21 CFR parts 174.5 175, 176, 177, 178 and 179.45; and
● food contact substances (FCSs) used in accordance with an effective pre-market Food Contact Notification (FCN) submitted under FFDCA Section 409(h).

1) 食品中公认的安全物质（GRAS）；
2) 预期用于食品包装的公认安全物质

3) 根据前期认可或批准使用的物质；
4) 《联邦法规》（CFR）第 21 卷第 174.5、175、 176、177、178 和 179.45 章中允许使用的物质；
5) 在联邦食品药品与化妆品法案（FFDCA）第 409 节提到的根据实际的上市前食品接触物通报系统（FCN）中提交的使用于食品接触物质（FCSs）。
Lists of substances prohibited from use in human food and FCMs are codified in 21 CFR 189. The FDA authorises the use of new FCMs via pre-market notification processes, which include the Food Additive Petition (FAP), FCN, Threshold of Regulation (ToR) exemption, and Gras Notice (GrasN) processes.
在《联邦法规》（CFR）第 21 卷第 189 篇中列出了在人类食物和食品接触材料中使用的禁用物质清单。FDA 通过上市场前公告流程批准的新食品接触材料的使用情况，包括食品添加剂申报系统（FAP），食品接触物通报系统（FCN），法规阈值（Tor）的豁免，和 GRAS 通知（GRAN）流程。

The FAP process often includes lengthy review periods, typically lasting two to five years. It has largely been replaced as the primary process by which FDA authorises new FCS and new uses of existing FCS by the FCN process, which was established in 1997 via an amendment to the FFDCA.
食品添加剂申报系统（FAP）通常会个长期的审核过程，一般持续两到五年。这个申请的前期过程在很大程度上由 FDA 通过食品接触物通报系统（FCN）批准的新食品接触材料和现有食品接触材料的扩大使用范围所取代，FCN 是在 1997 通过联邦食品药品与化妆品法案（FFDCA）的修正案建立的

Submission of an FCN currently has no fee. The FDA review period is a mandated 120 days, an approved FCN is proprietary to the notifying party and the FDA does not disclose publicly information from a withdrawn submission. The agency also publishes and regularly updates an ‘Inventory of Effective Food FCS Notifications’.
食品接触物通报系统（FCN）的提交目前免费。FDA 审查期规定为 120 天，批准的 FCN 是告知方专有的，FDA 不披露撤回提交所公开的信息。该机构还公布并定期更新“有效食品接触材料通知目录”。
Under the ToR exemption notification process, which is detailed in 21 CFR 170.39, the FDA may approve the exemption of a food additive from regulation. To qualify for a ToR exemption, a substance may not be a carcinogen or suspect carcinogen, and exposure to it must not exceed the thresholds established in 21 CFR 170.39(a)(2).
根据在 21 CFR 170.39 中详述的法规阈值（Tor）豁免通知程序，FDA 可以批准食品添加剂豁免限值的规定。一种物质可能不是致癌物或可疑致癌物，为了获得法规阈值（Tor）豁免，暴露量不能超过 21 CFR 170.39(a)(2)中建立的阈值。

A ToR submission has a 60-90 day review period and no submission fee. An approved ToR is applicable and effective for the intended use regardless of the manufacturer or supplier. The FDA also publishes and periodically updates its list of ToR Exemptions.
法规阈值（Tor）提交有 60-90 天的评审期，没有提交费。获批的法规阈值（Tor）对于预期的使用都是适用的和有效的，与制造商或供应商无关。FDA 还发布并定期更新法规阈值（Tor）豁免清单。

Gras substances are the most complicated class of food additives. They may be

authorised for use by the FDA via a GrasN or certified by a Gras Panel to meet standards set by the FDA. Some approved Gras substances are listed in sections of 21 CFR and in the 'Gras Substances (SCOGS) Database', but a comprehensive list does not exist.
GRAS 物质是食品添加剂中最复杂的一类。依据 FDA 制定标准，FDA 可以通过 Gras 通知或由 Gras 专家组认证批准使用。一些批准的 Gras 物质列在 21CFR 章节和 "Gras 物质（SCOGS）数据库"中，但是没有全面的清单。

Comparison between China and US Regulations
中国与美国法规比较
Both Chinese and US FCM regulations are premised on a positive list approach, have GMP requirements and include authorisation processes for new substances. China's new system is an amalgamation of the FDA and EU food contact regulation frameworks, borrowing concepts such as functional barriers from the US and specific migration limit (SML) restrictions from the EU.
中美两国的 FCM 法规都以肯定的清单为基础，有 GMP 要求，并包括新物质的授权程序。中国的新体系是 FDA 和欧盟食品接触管制框架的融合，借用了来自美国的功能性障碍和欧盟特定的迁移量（SML）限定等概念。

Arguably, the most notable difference between the two systems is the concept of SML restrictions, which requires that migration of substances used in the manufacture of a FCM must not exceed levels approved by authorities in China. Although FDA regulations sometimes require migration testing, SML restrictions are a foreign concept in the US. Various aspects of the two regulatory systems are compared in Table
可以说，两种制度之间最显著的区别是迁移量（SML）限值的概念，它要求用于制造 FCM 的物质的迁移量不得超过中国当局批准的水平。尽管 FDA 法规有时需要迁移测试，但在美国，迁移量（SML）限值是一个陌生概念。两个监管系统的各个方面在表中进行了比较。

/	**China 中国**	**US 美国**
Agencies 机构	NHC, SAMR and GAC 卫康委，国家市场监督管理总局，海关总署	FDA 食品药品监督管理局
Definition of FCMs 食品接触材料的定义	Materials and products that may come into contact with food, excluding detergents, disinfectants and public water-transportation facilities 可能与食品接触的材料和产品，不包括洗涤剂、消毒剂和公共水运设施	Indirect food additives (articles used in contact with food and substances used to manufacture them) 间接食品添加剂（与食品接触的物品和用于加工食品的物体）
Positive lists 肯定清单	NFSS GB 9685 and GB 4806.6, .10,and .11 食品安全国家标准 GB 9685 and GB 4806.6, .10,and .11	21 CFR 174.5(d) 《联邦法规》（CFR）第 21 卷，第 170.5(d)
Negative lists 禁用清单	None 无	21 CFR 189 《联邦法规》（CFR）第 21 卷，第 189 部

New FCM authorization processes 新食品接触材料批准程序	NFRPR 食品相关产品申报	FCN, ToR, GrasN 食品接触物通报系统，法规阈值（Tor），和 GRAS 通知（GRAN）
Exemptions 豁免	Migration <0.01 mg/kg food if they not carcinogens, mutagens, reproductive toxins or nanomaterials 如果不是致癌物、诱变剂、生殖毒素或纳米材料的食品，迁移量小于 0.01mg/kg；	Substances that do not meet the definition of 'food additive' 不符合食品添加剂定义的物质；
Testing requirements 测试要求	Overall and specific migration limits 总迁移量和各迁移量	Use and substrate-dependent 根据使用情况或依据情况具体分析
DoC 符合性声明	Required 需要	Customer-driven 客户要求
GMP standard 良好生产规范标准	GB 31603	21 CFR 174.5 《联邦法规》（CFR）第 21 卷，第 174.5

Table 1 - Comparison of food contact regulations – China and US
表 1-中美食品接触材料法规比较

Conclusion 结论

Regulatory agencies in China and the US control FCMs by setting quality standards, authorizing substances via positive lists and notification processes, and taking punitive action against market participants when warranted.
中国和美国的监管机构通过制定质量标准、批准物质肯定清单和公告程序、以及在必要的情况下，对市场参与者采取惩罚性行动来监管食品接触材料。

The new NFSSs have moved the Chinese FCM regulations to a system more consistent with the US than previous Chinese FCM regulations. The systems are not identical, but it is likely that the Chinese regulations will continue to evolve and align more closely with international regulations over time.
相较于之前的中国 FCM 法规，新的食品安全国家标准已将中国的 FCM 法规发展成更贴近美国的 FCM 体系。这些体系并不完全相同，但随着时间的推移，中国的法规可能会进一步发展，并与国际法规紧密接轨。

The views expressed in expert articles are those of the authors and are not necessarily shared by Chemical Watch。

专家文章中所表达的观点是作者的观点。

北京 OCI 公司以 5A 的服务理念，为客户提供优质登记申报注册的产品合规服务。


高效迅捷
High efficiency
阶段透明
Stage transparency
信息安全
Information security
风险提示
Risk advisement
增值服务
Value-added Service