

# FCM regulations in China and the US - a comparison

[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.

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.

## China overview

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).

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.

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, packing, 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".

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.

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:

- general safety requirements (GB 4806.1);
- positive list for additives permitted for use in FCMs (GB 9685);
- standards for paper, plastics, coatings, rubber, metal and other materials (GB 4806.2-11);
- positive lists for polymer resins (GB 4806.6, .10, and .11);
- the good manufacturing practice (GMP) standard (GB 31603); and
- test method standards for individual substances and migration ([GB 5009.156](#), [GB 31604.1-49](#), and GB 4789.15);

In addition, food additives listed in GB 2760 may be used in FCMs.

[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.

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.

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:

- the authorising regulation and standards;
- a list of substances with applicable restrictions;
- an assessment of non-intentionally added substances (Nias); and
- supporting analytical reports.

The use of an unauthorised substance in FCMs may be permissible if the substance:

- is not a carcinogen, mutagen, reproductive toxicant or nanomaterial;
- is used behind an effective barrier layer; and
- migrates into food at a level not exceeding 0.01 mg/kg food.

Finished products should be labelled with the text 'for food contact' or 'for food packaging' and the 'spoon and chopsticks' graphic, as appropriate.

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.

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".

Regulations for the following categories of food additives are codified in the Code of Federal Regulations (CFR) Title 21, Parts 170-189:

- direct food additives (substances added directly to food);
- 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
- 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”.

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:

- 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).

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.

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.

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’](#).

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).

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](#).

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.

## Comparison between China and US Regulations

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.

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 1.

	China	US
Agencies	NHC, SAMR and GAC	FDA
Definition of FCMs	Materials and products that may come into contact with food, excluding detergents, disinfectants and public water-transportation facilities	Indirect food additives (articles used in contact with food and substances used to manufacture them)
Positive lists	NFSS GB 9685 and GB 4806.6, .10, and .11	21 CFR 174.5(d)
Negative list	None	21 CFR 189
New FCM authorisation processes	NFRPR	FCN, ToR, GrasN
Exemptions	Migration <0.01 mg/kg food if they not carcinogens, mutagens, reproductive toxins or nanomaterials	Substances that do not meet the definition of 'food additive'
Testing requirements	Overall and specific migration limits	Use and substrate-dependent
DoC	Required	Customer-driven
GMP standard	GB 31603	21 CFR 174.5

Table 1 - Comparison of food contact regulations – China and US

## Conclusion

Regulatory agencies in China and the US control FCMs by setting quality standards, authorising substances via positive lists and notification processes, and taking punitive action against market participants when warranted.

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.

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