

China's Food Safety Law Takes Effect Today: Are You Ready?

Thursday, October 1, 2015

Today, October 1st, is an important day for any company in the food industry doing business in **China**. More specifically, the **Food Safety Law**^[1] (FSL) is now in effect. As you may recall, on April 24, 2015, in response to several high-profile food safety scandals and the need to harmonize with the global practice of food safety management, China passed sweeping amendments to its FSL. The effective date has now arrived and, therefore, it is important to be aware that a number of significant changes have been made to China's food regulations and new mechanisms have been established to deepen the reforms.

As the fundamental law regulating food safety in China, the revised FSL builds up the basic legal framework for food safety supervision and management; however, like most framework documents, it is short on detail. To put some meat on its bones, in the past few months, the National Health and Family Planning Commission (NHFPC), China Food and Drug Administration (CFDA) and General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), along with other administrative agencies, published several important regulations and national food safety standards. The purpose of this article is to alert you to what has transpired since the FSL was passed, what we can expect to see in the future, and what the prospects are for several key food industries under China's new food regulatory regime.

All Food Business

- *Management Regulations for Food Operation License (Draft for comment)*^[2] & *Food Production License (Draft for comment)*^[3] were issued by the CFDA to manage the licensing regime for food production and restaurant service. For the first time, the production license for food additives is explicitly incorporated into the scope of the food production license. Furthermore, the current food distribution license and restaurant service license will be combined and subject to one food operation license which will be issued by food and drug administration.
- *Measures for the Administration of Supervision and Inspection of Food Production and Operation (Draft for comment)*^[4] regulate the supervision and inspection of food producers and operators per corresponding requirements mandated by the new FSL. The appendix section of the Measures attaches compliance check-lists for a) producers of foods/food additives, b) producers of health foods, c) food distributors, and d) restaurant service providers, respectively, for the enforcement officers at the local level to examine compliance.
- *Interim Regulations on Food Advertisements Publication (Amended) (Draft for comment)*^[5] issued by the State Administration of Industry and Commerce (SAIC), provides detailed guidance on regulation of food advertising, capturing not only conventional foods (e.g., dairy products for infants) but also health foods. This draft is based on the currently effective version which was issued in 1998.
- *Measures for the Administration of Food Recalls*^[6] which were issued by CFDA and became effective on September 1 of 2015, provide the food recall requirements for regular foods, food additives and health foods. Food recalls were previously administered by the *Management Regulations of Food Recalls*^[7] which



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were announced in 2007 by AQSIQ. Further coordination and implementation on food recalls between the government bodies remains to be seen.

- *Measures for the Administration of Food and Drug Complaints (Draft for comment)*^[8] establish the requirements for FDA officers to handle complaints for foods, drugs, medical devices and cosmetics with respect to safety and product quality during R&D, production, distribution and usage processes.
- *Administrative Measures for the Audit and Inspection of Overseas Companies by Food Product Importers (Draft for comment)*^[9] impose heavy responsibilities on the local importer to ensure the safety of food products that they plan to distribute in China. According to the Measures, at least once in every three years, domestic food importers are obliged to conduct on-site audit of facilities outside of China that produce, for example, infant formula, formulation food for special medical purposes, health foods, and meat products. Such on-site inspection can be authorized to accredited third party.^[10] Annex 1 of the Measures contains a voluntary *Guideline for Risk Control and Protection Plan for the Safety of Foods Imported to China* ("Guideline").
- *Administrative Measures for the Supervision of Imported Food Inspection at Port (Draft for comment)*^[11] were released by AQSIQ on September 28, 2015, to guide local ports of China on their inspection of imported food products. A categorization system per risk level and risk assessment result will be established under the Measures to manage the inspection. The Measures reinforce the legal obligations under the FSL on oversea food producers and exporters as well as those on the local importers. Detailed conditions for imposing/lifting a temporary ban on food import are also specified in the Measures. All interested stakeholders should submit their comments by October 29, 2015.
- *General Code of Hygienic Practice for Food Additives (Draft for Comment)*^[12] incorporates requirements on food additive production and applies to all domestic production of food additives. The Code sets forth the requirements and management code for production sites, facilities and personnel in raw material procurement, processing, packaging, storage and transportation of food additives. Reference must be given to this general Code in the future establishment of specifications for any individual food additive.
- In the past few months, several national food safety standards of great importance entered into force or were published for public comments.^[13] Given their compulsory nature, they should be closely examined and strictly followed by relevant participants in the food industry. In particular, starting from May 24, 2015, the use of food additives in food products to be distributed in China must follow the amended General Standards for the Use of Food Additives (GB 2760-2014). Products labeled with food additive names no longer valid under the amended GB 2760 can be continued to be sold through June 30, 2016, prior to their expiration date.

Health Foods

On July 28, 2015, the China Food and Drug Administration (CFDA) promulgated three draft regulations on health foods for public comment:

- Regulation on the Registration and Notification for Health Foods (Draft for comment)*^[14]
- Regulation on Health Food Labeling (Draft for comment)*^[15]
- Regulation on Health Food Function Claim Catalog and Ingredient Catalog (Draft for comment)*^[16]

This represents significant progress from the current registration-only system for health foods to a registration plus notification system, which helps to ease the regulatory burden on industry without compromising the quality and safety of health food products. Please see more details of [these three draft regulations in our "China Regulatory Matters!"](#) alert, dated September 21, 2015.

In addition to the above draft regulations, CFDA has published an *Announcement on Further Standardization of Health Food Naming*^[17] to prohibit any health foods having any expressions of product function in the product name. For instance, terms such as "weight losing", "beautifying", and "lung moistening" are no longer permitted in the name section of health foods. Approved products which have such expression are subject to a mandatory name change by December 31, 2015.

While the above regulations have already entered the stage of comment solicitation, there still are a number of regulations and rules under review which will play an important role in shaping the health food industry. For example, *Rules for the Application and Review of Health Food with New Function Claim*,^[18] *Management Rules for*

Formulated Foods for Special Medical Purposes

- *Measures for the Administration of Formulated Foods for Special Medical Purposes (Provisional) (Draft for comment)*^[21] is a result of the new requirement raised by the FSL that all foods formulated for medical purposes must obtain a pre-market approval from the responsible food and drug administration. Since these types of products are usually designed to meet the need of a special group of consumers (e.g., individuals suffering from diabetes, etc.), its food safety and effectiveness is subject to individual review by the authorities.

Infant Formula

- *Measures for the Administration of Infant Formula Milk Powder Formulas Registration (Provisional) (Draft for comment)*^[22] was published by the CFDA this September to implement the infant formula registration mechanism under the FSL. The draft requires the recipe of China-produced formulated milk powder for infants and young children to be registered with the CFDA.

Agricultural Products

- *Administrative Measures for the Supervision of Markets of Edible Agricultural Products*^[23] was published by the CFDA to coordinate with the current agricultural product regulations. In the past, both the production and distribution of agricultural products were regulated by the *Agricultural Product Quality Safety Law* and managed by administrative departments for agriculture in the country. The amended FSL, for the first time, explicitly expands its scope to cover the distribution of edible agricultural products on the market. The Measures provide more guidance to the industry in this regard.

E-commerce

- *Measures for the Administration of Supervision of Foods Operation via Internet (Draft for comment)*^[24] will apply to all online food (including edible agricultural products and food additives) trading activities taking place within the border of the Peoples Republic of China. The Measures echo the amended FSL regarding food recall obligations for online food distributors. The Measures echo the amended FSL regarding food recall obligations for online food distributors. For example, whenever an online trading platform discovers unsafe food, it is under an obligation to immediately cease the distribution and recall affected products based on a negative investigation result.

Local Rules

While the central government has published or is drafting regulations to enforce the FSL, local governments also are actively developing new implementing rules, which should be closely monitored by the industry.

For instance, Shanghai announced the *Management Rules for Tracing the Food Safety Information of Shanghai ("Rules")*^[25], which, beginning October 1, 2015, require the industry to trace safety information related to food and edible agriculture products produced, distributed and served by restaurant service providers within the administrative region of Shanghai. Shanghai FDA also issued specific notice on September 24 to address the licensing requirements for food production in the Shanghai Free Trade Zone (FTZ).

In Guangdong, the local government promulgated the *Regulation of Guangdong Province on Food Safety*^[27] ("Regulation") to detail local food safety management. In particular, for imported food, the operator must verify the product name and batch number against the record on the quarantine and inspection permit or sanitary certificate of the product.^[28] Further, FDA of Guangdong province released the *Rewarding Measures for Reporting Serious Violations in Food and Drug Production and Trading (Provisional)*^[29] in May 2015 to implement the whistleblower rewarding mechanism established under the new FSL.^[30]

[1] http://www.npc.gov.cn/npc/cwhhy/12icwh/2015-04/25/content_1934591.htm

[2] <http://www.sda.gov.cn/WS01/CL0053/128340.html>

[3] <http://www.sda.gov.cn/WS01/CL0053/128320.html>

- [4] <http://www.chinalaw.gov.cn/article/cazjqq/201508/20150800478817.shtml>
- [5] <http://www.chinalaw.gov.cn/article/cazjqq/201507/20150700399956.shtml>
- [6] <http://www.sda.gov.cn/WS01/CL0053/115580.html>
- [7] http://www.aqsiq.gov.cn/zwqk/jlqg/zjl/20072008/200708/t20070831_37794.htm
- [8] <http://www.chinalaw.gov.cn/article/cazjqq/201412/20141200397864.shtml>
- [9] http://www.aqsiq.gov.cn/gzcypt/cazxyj/20150908_5/wyyj/
- [10] See Article 7 and Annex 2 of the Measures
- [11] <http://www.aqsiq.gov.cn/gzcypt/cazxyj/20150928/wyyj/>
- [12] <http://www.chinabeverage.org/news.php?id=6623>
- [13] For example, *107 Draft National Food Safety Standards for Food Additives* (e.g., lactic acid, food processing enzyme preparation, sorbic acid, carrageenan), <http://www.nhfpc.gov.cn/zhuzhan/zqyj/201508/6185f9dcf72348aaa056fad12539814b.shtml>; *36 Draft National Food Safety Standards for Hygienic Practices of Food Product and Testing Methods (including Hygienic Practices of Chocolate and Candy Production, Puffed Food Production)*, <http://www.nhfpc.gov.cn/zhuzhan/zqyj/201508/53a9648d88814901bc13aaec168e2f4c.shtml>
- [14] <http://www.chinalaw.gov.cn/article/cazjqq/201507/20150700400099.shtml>
- [15] <http://www.chinalaw.gov.cn/article/cazjqq/201507/20150700400100.shtml>
- [16] <http://www.chinalaw.gov.cn/article/cazjqq/201507/20150700400101.shtml>
- [17] <http://www.sda.gov.cn/WS01/CL0087/127860.html>
- [18] <http://www.sda.gov.cn/WS01/CL0780/75896.html>
- [19] <http://www.sda.gov.cn/WS01/CL0782/108868.html>
- [20] <http://www.sda.gov.cn/WS01/CL0782/108868.html>
- [21] <http://www.sda.gov.cn/WS01/CL0782/128401.html>
- [22] <http://www.sda.gov.cn/WS01/CL0782/128400.html>
- [23] <http://www.chinalaw.gov.cn/article/cazjqq/201508/20150800478693.shtml>
- [24] <http://www.sda.gov.cn/WS01/CL0782/128401.html>
- [25] <http://www.shanghai.gov.cn/nw2/nw2314/nw2319/nw2407/nw33192/u26aw44656.html>
- [26] <http://www.shfda.gov.cn/qb/node2/yjj/n5100/u1ai47457.html>
- [27] <http://www.fzb.gd.gov.cn/publicfiles/business/htmlfiles/gdsfzb/lfyijz/201507/12642.html>
- [28] Article 19 of the Regulations
- [29] <http://ffc.qzfd.gov.cn/publicfiles/business/htmlfiles/jyj/hydt/201509/108845.html>
- [30] See Article 115 of the Food Safety Law of China

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