

Prosecutions Loom Large In China's Food Regulatory Regime

Law360, New York (July 24, 2014, 11:12 AM ET) --

China's legislature, the National People's Congress, has released a draft of the revised Food Safety Law for public comment. The comments are due on July 31, 2014. The FSL was last revised in 2009, when the government changed the law's name from the Food Hygiene Law and altered most of its content. Since then, the law has been one of the focal points of the increasingly intense discussion in China and abroad regarding numerous incidents of misbranded, or at times dangerously adulterated human food produced by some farmers and food manufacturers in China.

The NPC is the final level of review before any law is passed and implemented. In addition to reviewing input received in this latest round of comments, according to Chinese law, the NPC Standing Committee must deliberate on the draft FSL three times before voting on it. However, the NPC has not adopted a timeline for its final enactment of the law. Once the revisions to the FSL are adopted, China Food and Drug Administration and other agencies will likely revise and draft new implementing regulations. Those agencies will also likely seek stakeholder comment in that process.

We summarize some of the more significant amendments in the 2014 Draft FSL below. According to the "drafting explanation" accompanying the 2014 Draft FSL, the revisions fall into four broadly defined categories: (1) strengthening preventative regulation, (2) establishing the "strictest" and most comprehensive supervision over the entire process for food from its manufacture to distribution and sale to consumers; (3) establishing the "strictest" system of legal liability; and (4) implementing social supervision. We explain the general contours of each of these areas below.

First, in the area of preventative regulation, the 2014 Draft FSL focuses on risk assessment and management. It requires increased attention to government monitoring of specific risks (i.e., foodborne illnesses, illegal additives and other forms of contamination), assessment of those threats by a centralized government body and the subsequent enactment of standards or adoption of other mitigation measures that are proportional to the size of the risk. Since the last FSL amendment in 2009, China has established a Risk Assessment Committee within the National Commission on Health and Family Planning, as well as a National Risk Assessment Center to assist the committee in conducting technical analysis of specific issues. The 2014 Draft FSL adds a considerable amount of detail to prior provisions governing the functions and procedures of this risk monitoring and assessment system.



John Balzano

New provisions in the 2014 Draft FSL also require greater responsibility on the part of manufacturers and distributors of food. For example, the draft requires self-audits by food manufacturers. The 2014 Draft FSL also requires a consultation system between the person responsible for food safety or other legal representative within the manufacturing enterprise and either the local food and drug regulatory authority or — if the local FDA does not handle the problem — its supervising local government, to discuss how to resolve food safety issues as they occur.

In the second area of a more comprehensive approach to regulation, the 2014 Draft FSL imposes additional requirements on entities in various segments of the food industry and in different parts of the supply chain (manufacturing, distribution and retail) to ensure safety. For example, it requires that infant formula manufacturers implement special good manufacturing practices and that they self-audit and report on those audits to local food and drug authorities. It also prohibits contract manufacturing by infant formula manufacturers. Both of these measures are likely intended to further the government's stated goal of more strictly supervising the infant formula industry after safety scandals damaged faith in domestic manufacturers in 2004 and 2008.

The 2014 Draft FSL also imposes responsibilities on "third-party Internet service providers," which permit food distribution on their networks. It requires that these providers keep records and make food safety responsibilities clear to participating food distributors, as well as conduct a review of the licenses of the food companies on their network. In addition, it establishes greater clarity about the management of testing and inspections of imports and exports. This is an area that has also been developing on the regulatory level since the last revision of the FSL in 2009.

The 2014 Draft FSL also requires that the General Administration for Quality Inspection Supervision and Quarantine increase supervision of those companies manufacturing food-related products, presumably referring to packaging and containers and other food contact substances. Companies that manufacture "high-risk" food contact substances must obtain a manufacturing license appropriate to their specific industry.

The 2014 Draft FSL adds additional detail on the regulation of health foods, or foods that claim a health-promoting function. The CFDA already has regulations setting forth substantial requirements for health foods. However, the 2014 Draft FSL "supplements" the existing regulations on the systems for pre-marketing notification and approval, as well as promotion. It makes it clear that health-food claims must be supported by "scientific evidence," and the CFDA will release a catalog of permitted claims. It also requires that new health-food ingredients and health-food products imported for the first time be subject to registration (or licensure) procedures. However, if the new imported products and their ingredients may be evaluated according to national standards or guidelines, then manufacturers are only required to notify the CFDA. The CFDA will release and periodically amend a catalog of these products. For all other health-food products, the manufacturers need only notify the provincial-level food and drug regulatory authorities. The 2014 Draft FSL also describes the materials that manufacturers must submit when applying for registration or notifying the authorities, as the case may be.

The third area — penalties — is perhaps the most publicized aspect of the 2014 Draft FSL. The 2014 Draft FSL increases penalties and liabilities significantly. Specifically, the draft increases administrative fines by agencies for FSL violations, the potential for civil compensatory and punitive damages in related litigation and the potential for criminal prosecution. These changes are accompanied by significant developments in other areas of law and policy. For example, the increase in civil liability is accompanied

by a recent judicial interpretation by the Supreme People’s Court, which places the burden on the manufacturer to prove that its food was compliant with food safety standards. Building on this development, the 2014 Draft FSL provides that if there are “clear violations of food standards,” plaintiffs may collect punitive damages of either 10 times the price they paid for the food or three times the loss they incurred. The former penalty was in the 2009 prior FSL, but almost no plaintiffs were successful in obtaining punitive damages. The treble damages provision is new, and has the potential to result in substantially larger damage awards.

Perhaps more ominous is the pledge to strengthen the “link” between food safety regulation and criminal penalties. The 2014 Draft FSL calls for “prompt” reporting of suspected food safety crimes by the CFDA and other administrative agencies to the Ministry of Public Security (i.e., China’s police force) for immediate investigation. China has already cracked down on violators of food safety standards through the Criminal Code over the last several years. There have been thousands of such prosecutions since the NPC enacted enhancements to food-related provisions in the Criminal Code in 2011. The 2014 Draft FSL cross-references the Criminal Code for various violations. These provisions, along with a new bureau within the Ministry of Public Security for investigating food and drug law violations, indicate that criminal prosecutions could likely continue to increase once the law is adopted.

Fourth, and finally, the 2014 Draft FSL encourages citizens to “supervise” the food manufacturers or distributors that are in violation of the law. It incorporates a system of monetary rewards for whistleblowers that the CFDA introduced into prior regulations. It also encourages the development of a food safety liability insurance system for food manufacturers and distributors. The 2014 Draft FSL tasks CFDA with working with the All China Insurance Regulatory Commission (China’s chief insurance regulator) to establish concrete regulations governing such a system. What exactly is intended by “food safety liability insurance” will likely become clearer once those implementing regulations are put into place.

The 2014 Draft FSL, if adopted, will likely generate significant regulatory changes in the food regulatory oversight system. Stakeholders should consider submitting comments to the NPC and monitor for the law’s adoption, as well as the many implementing regulations that will follow from the CFDA and other relevant agencies.

—By Shaoyu Chen, Miriam Guggenheim, John Balzano and Nan Lou, Covington & Burling LLP

Shaoyu Chen is a partner in Covington & Burling's Beijing office.

John Balzano is special counsel in Covington & Burling's New York office.

Miriam Guggenheim is a partner and Nan Lou is an associate in Covington & Burling's Washington, D.C., office.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.