

China Issues Revised Food Safety Law

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On April 24, 2015, the Standing Committee of China's legislative body, the National People's Congress (NPC), approved the final revision of the 2009 Food Safety Law (FSL), the main piece of legislation governing the manufacturing and distribution of food, including special foods such as health foods (similar to the dietary supplement category in other countries) and infant formula. The final FSL reflects several rounds of revisions, and three drafts that the government published for notice and comment, including two published by the NPC itself in 2014 (First Draft FSL, see our alert [here](#); Second Draft FSL, see our alert [here](#)). The final FSL will become effective on October 1, 2015. The China Food and Drug Administration (CFDA) and other agencies with jurisdiction over food, such as the National Health and Family Planning Commission (NHFPC), will likely draft or revise implementing regulations soon.

The following alert describes some of the key features of the final FSL. Food and dietary supplement companies, including those that manufacture and distribute foods for special medical purposes and infant formula for the China market, should continue to monitor for implementing regulations in the coming months that may impose new requirements on them.

Significant Changes to the Final FSL

The final FSL includes many changes in a number of different areas. Some of those changes are as follows:

- The final FSL requires manufacturers and distributors to establish a food tracing system and perform self-audits, and encourages manufacturers and distributors to participate in a food safety liability insurance system. CFDA is developing that insurance system along with the All China Insurance and Regulatory Commission, which is China's insurance regulator.
- In addition to strengthening provisions on manufacturing and distribution, the final FSL adds the regulation of shipping and storage to its scope.
- The final FSL further incorporates "food related materials," which include packaging and other food contact substances, into the regulatory scheme governing food ingredients, such as food additives and food raw materials. For example, food related materials will be subject to risk assessments that form the basis for food standards, similar to the way in which the NHFPC assesses the safety of food additives.
- The final FSL contains some limited provisions on sale of the foods online. It retains an earlier proposed requirement that third-party e-commerce platforms register the names of the food distributors that sell products on their platforms and examine their licenses. The FSL also requires that those platforms cease sale of any violative products and report FSL violations to the authorities. A platform that fails to perform these

requirements may be deemed jointly liable with the distributor for any resultant consumer harm. Despite these additions, more substantive regulation, if any, of the expanding cross-border e-commerce sales will have to wait until relevant implementing regulations.

Changes Affecting Special Foods

The final FSL contains a revised chapter on “special foods,” which are now subject to a number of different heightened regulatory requirements. These special foods include health foods, foods for special medical purposes and infant formula.

Health Foods

Similar to earlier drafts, the final FSL retains the streamlined notification procedure for certain health foods. Under the final FSL, registration and approval for imported and domestic products, a process that can be time-consuming and expensive, will only be required for health foods that use new ingredients not included in an ingredient catalogue issued by CFDA, or for certain health foods being imported for the first time.

Registration and approval will not be required for health foods using existing ingredients or for first-time imports if those imported products are considered “nutritional substances,” such as “vitamins and mineral supplements.” Health foods that are exempt from registration and approval will be permitted to enter the Chinese market after completing a notification procedure with CFDA (for imported health foods) or the provincial FDAs (for domestic health foods). This is a significant departure from current regulatory requirements that all health foods must undergo pre-market registration. The final FSL also requires that imported health foods have marketing authorization in their exporting countries.

The final FSL retains the previously proposed requirement that CFDA revise its existing catalogues for health food ingredients and functional claims. The ingredient catalogue will include the names and permitted amounts of ingredients and their corresponding functional claims.

In addition to regulating the registration and notification processes for health foods, the final FSL also imposes labeling and advertisement requirements on these products, including that the label and any advertisements contain the disclaimer that the health food cannot be a substitute for medicine. The final FSL specifies that the annual regulatory work plans of provincial FDAs shall prioritize, among other matters, oversight of health food manufacturing, labeling and marketing.

Food for Special Medical Purpose

The final FSL adds a new category of food subject to special regulation, “foods for special medical purposes” (FSMP). Although the category is not defined in the FSL, China enacted a national food safety standard in 2013 on special formulas developed for people over the age of one with limited food intake, digestion, absorption or metabolic disorders, or those with special nutritional needs due to medical conditions. It is not clear whether the relevant agencies will maintain this standard in the future, or enact other implementing regulations.

The FSL requires that FSMP undergo pre-market registration and approval with CFDA, which will include the submission of information on formulation, manufacturing, labeling, safety and

clinical efficacy. The FSL also specifies that advertisement of these foods must abide by advertisement laws and regulations applicable to drugs. That could mean that FSMP advertisements will be subject to the same approval requirements as non-prescription drug advertisements, which must be reviewed by a provincial FDA with jurisdiction prior public release.

However, despite the fact that these new provisions treat FSMP like drugs in some respects, their inclusion in the FSL indicates that they will still be regulated as a food in other ways and, therefore, it is not yet clear, for example, whether they will be subject to the same rigorous clinical trial requirements as drugs. The details of this marketing pathway will likely be determined by implementing regulations and standards from CFDA and the NHFPC.

Infant Formula

The final FSL substantially strengthens the regulation of infant formula by including new pre-approval requirements that were not in the Second Draft FSL. In addition to requiring manufacturer notification of ingredients, additives, formulation and labeling to provincial FDAs, the final FSL now also requires that manufacturers undergo a registration process for their product formulations. Under this pre-approval requirement, manufacturers will have to submit to CFDA materials establishing the safety of their products.

In the areas of manufacturing and quality control, the FSL retains the proposed requirement that manufacturers implement a quality control system that covers the entire manufacturing process, including everything from raw material purchase to the batch testing of the finished product. The final FSL also bans infant formula manufacturers from “sub-packing” their products and states that the same manufacturer must not use the same formula to produce different brands of infant formula. The FSL has not codified some other restrictions on infant formula manufacturing in CFDA regulations, such as the restriction of contract manufacturing. The fate of those regulatory requirements will have to wait until CFDA issues implementing regulations.

Increased Penalties

In line with prior drafts, the final FSL has increased the administrative penalties for violations. These penalties include confiscation of unlawful gains and illegally produced or distributed foods, fines, orders to cease manufacturing, revocation of licenses and blacklisting from the industry. Specific provisions on civil liability are also stronger. Whereas previously consumers were permitted to seek up to 10 times the purchase price of the food in punitive damages for clearly substandard food products, they are now permitted to seek 10 times the purchase price or three times the amount of compensation for loss, and the damages must not fall below 1,000 RMB (approximately 162 U.S. dollars). In addition -- continuing with the growing trend of criminal prosecutions for food safety violations that stemmed from an amendment to the Criminal Code in 2011 -- the final FSL now expressly requires CFDA and other administrative agencies to promptly report suspected food safety crimes to the Ministry of Public Security (China’s police force), which must then timely review and investigate the allegations. The inclusion of this provision likely means that the criminal law will remain a substantial tool in deterring and handling future food safety law violations.

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If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug practice group:

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|-------------------|------------------|--|
| Shaoyu Chen | +86 10 5910 0509 | schen@cov.com |
| John Balzano | +1 212 841 1094 | jbazano@cov.com |
| Miriam Guggenheim | +1 202 662 5235 | mguggenheim@cov.com |
| Jessica O'Connell | +1 202 662 5180 | jpoconnell@cov.com |
| Nan Lou | +1 202 662 5097 | nlou@cov.com |

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