

China Releases Second Draft Food Safety Law for Public Comment

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Food & Drug

China's National People's Congress (NPC) has released a second proposed [draft](#) of the Food Safety Law for public comment (Second Draft FSL). Comments are due by January 19, 2015. The FSL is the primary piece of legislation governing food safety standards, food additives and contact materials, food processing and manufacturing, distribution, and import/export activities, as well as the prevention and remediation of food safety incidents, such as those related to foodborne illness and contamination. The Second Draft FSL reflects NPC revisions made in response to comments by NPC delegates, administrative agencies in China, and other stakeholders on an earlier draft released in July of 2014 (First Draft FSL, see our alert, [here](#)).

The following alert describes and analyzes some of the changes in the Second Draft FSL. Foreign and domestic food and dietary supplement companies doing business in China should continue to monitor developments related to the FSL and consider submitting comments.

- **Storage, transport, and loading:** One important change appears to be that storage, transport, and loading of food are now clearly articulated as within the FSL's scope. The Second Draft FSL requires that entities that engage in storage, transport, or loading of food products meet certain standards to ensure safety and sanitation.
- **Non-governmental supervision:** The explanation accompanying the draft states that the Second Draft FSL is intended to strengthen the mechanisms for supervision of compliance by groups and individuals outside of the government. First, the Second Draft FSL includes a new anti-retaliation provision to protect the identity of complainants who report food safety violations.¹ Second, it increases the flow of information about food safety incidents by deleting a provision that required that reports first be confirmed by the China Food and Drug Administration (CFDA) before being released. At the same time, it increases the punishments for those who fabricate food safety stories in the media. Third, it encourages the further development of food industry associations. Although not officially administrative agencies, these associations are government-controlled in China. The Second Draft FSL calls for them to develop guidelines for the industry and systems of rewards and punishments for members, and to provide "food safety information" and technical services.

¹ CFDA recently released a [proposed revision](#) to its 2011 regulations on complaints and reporting related to food and drug law violations. The comment period ends on January 15, 2015. The proposed revision also contains a provision requiring that the complainant be protected, including by protecting the confidentiality of the process.

- **Genetically modified food labeling:** The Second Draft FSL also includes a new article that effectively would require that labels indicate whether foods contain genetically modified organisms (GMOs). Specifically, the new article states that “genetically modified foods must be labeled according to regulations.” Chinese food regulation already requires GMO labeling. The inclusion of this provision in the FSL will likely strengthen its visibility and China’s commitment to the GMO labeling requirement.
- **Health food notification system:** The Second Draft FSL makes changes to the new proposed notification system for some health foods. Currently, all health foods must go through a registration process, which is time-consuming and expensive. Both the first and second draft FSLs have proposed to establish a shorter notification system for domestic health foods using existing ingredients and existing imports. Health foods with new ingredients and first-time imports will still need to go through a registration process. The First Draft FSL included an exception to the registration requirement for first-time imports if their safety and their “health promoting function” could be evaluated according to an existing national standard.

In response to comments from agencies that this exception was too vaguely worded, the NPC has now modified the provision to indicate that first-time imports that are part of the category of “nutritional substances,” such as vitamins and minerals, can use the notification system. The terms “nutritional substances” and “vitamins and mineral supplements” are not defined in the FSL, but CFDA has created a category of health foods called “nutritional supplements,” which includes vitamin and mineral supplements. A proposed revision to the nutritional supplement regulation issued by CFDA in the fall of 2014 expressly describes nutritional supplements as including the category that is now being proposed in the FSL, i.e., “nutritional substances, such as vitamins and minerals.”

The Second Draft FSL also requires that CFDA revise its existing catalogues (or lists) on health food ingredients to be more detailed. Specifically, CFDA must issue a catalogue of ingredients that may be used in health foods, but not in general foods, and include details as to the permitted amounts of those ingredients. As noted in our prior alert, CFDA must also issue a revised catalogue of permitted health food claims.

- **Inspections of foreign enterprises:** The First Draft FSL contained an article providing for inspections of foreign enterprises that import food into China. At the suggestion of delegates to the NPC, agencies, and companies that these inspections may be governed by bilateral agreements, this provision has been removed from the Second Draft FSL altogether.
- **Further increased penalties:** Like its predecessor, the Second Draft FSL also increases the penalties for violations of its provisions. These penalties can include seizures, administrative fines, cancellation of licenses and blacklisting from the industry, civil liability, and referral to criminal authorities for detention and prosecution. For example, with respect to civil liability, the Second Draft FSL further increases the punitive damages against those who produce or market food products that violate food safety standards. The First Draft FSL stated that the awards in these cases could include punitive sums of either ten times the purchase price of the food or three times the loss. In addition to that provision, the Second Draft FSL now also states that the award may not fall below 1,000 RMB. This change is in line with the trend in China of the government encouraging the courts to award compensation for purchasers of defective food, even if that sum is still small by other countries’ standards.

Still, the primary deterrents in the FSL appear to be administrative and criminal penalties. Notably, the Second Draft FSL now includes a period of criminal detention by the Public Security Ministry of between 5-15 days for the managerial and other personnel directly responsible for certain severe violations of the FSL. These severe violations include, among others, using inedible substances, drugs or other dangerous chemical substances as food additives; production of nutritionally substandard food for infants and other special groups; and distribution of substandard meat or meat products.

- **Exemptions from liability:** There are also some new exemptions from liability. The Second Draft FSL creates an exemption from “punishment,” but not civil liability, for distributors that complied with their obligations in good faith and unknowingly distributed defective food. To receive this exemption, distributors must prove that they had the requisite internal controls on receivables and that they had no knowledge of a violation of food safety standards. This exemption does not protect against product seizure. The Second Draft FSL also exempts minor defects in labeling that do not affect the safety of the product.

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