

Food & Drug

E-ALERT

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China Enacts New Food Safety Law, Effective June 1, 2009

China's top legislative body, the Standing Committee of the National People's Congress, passed a new Food Safety Law on February 28, 2009. The new law will come into effect on June 1, 2009, replacing the 1995 Food Hygiene Law.

The new law restructures and clarifies the coordination of government agencies with responsibility over food safety, provides broader enforcement powers and harsher penalties for violations, mandates national harmonized standards for food products and additives, and more tightly regulates food ingredients and additives.

In recent years, shocking tainted food scandals in China have grabbed domestic or international headlines many times. Two scandals involved baby formula. In 2004, at least twelve babies in China died of malnutrition from being fed with infant milk containing little protein. In 2008, melamine added to baby formula to falsely inflate protein readings sickened more than 300,000 children and killed six babies. Shortly after the 2004 fake milk scandal, the Chinese government planned to amend its 1995 Food Hygiene Law. Later, the Chinese government decided to enact a new Food Safety Law. This Client Alert examines some of the key issues regarding the new law.¹

Restructuring of Government Food Safety Responsibilities

In China, more than ten agencies have played a role in enforcing laws relating to food safety. The line between the regulatory powers of these agencies was not clearly defined under the previous law relating to food regulation. This has caused confusion in food safety supervision. The new law tries to restructure the responsibilities of related agencies in several respects.

Formation of Food Safety Commission at Cabinet Level

Pursuant to the new law, the State Council must form a new Cabinet-level commission, the Food Safety Commission, to improve monitoring.² The new law does not specify the functions and responsibilities of the new commission, but leaves these to be determined by future regulations issued by the State Council.³

In 2008, the State Council had tried to organize a national leadership group for food safety enforcement actions. With the passage of the new law, however, it is likely that the State Council will form a Food Safety Commission based on the existing food safety national leadership group. It remains unclear when the

¹ Only qualified PRC nationals working in PRC law firms are permitted to practice PRC law. Accordingly, as is true for all non-PRC law firms, we cannot express any legal opinion concerning the interpretation or application of PRC law. If a formal PRC legal opinion is required in relation to any specific issues discussed herein, our practice is to arrange for such an opinion to be provided by one of our correspondent law firms in the PRC and to work closely with such PRC law firm in that exercise.

² Food Safety Law, Art. 4.

³ *Id.*

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State Council will announce the formation of the Food Safety Commission and the functions of such Commission.

Clarification of Responsibilities of the Key Regulatory Agencies

The new law makes it clear that the Ministry of Health (MOH), under which the State Food and Drug Administration (SFDA) was moved last year, will play the leading role in food regulation, with the powers to assess food safety risk, set national standards for food safety, release information relating to food safety, regulate food safety testing, and investigate serious food safety events. Two divisions in the Administration for Quality Supervision, Inspection, and Quarantine (AQSIQ) will be responsible for the supervision of food production and food import/export, while the State Administration for Industry and Commerce (SAIC) has the regulatory power to supervise the domestic wholesale and retail food sectors. The Ministry of Agriculture (MOA) will continue to be responsible for non-processed farm products.

The new law, however, addresses only generally which agency is responsible for the most important sectors. To avoid confusion, further clarification and detailed regulations will be needed. It is expected that the division of regulatory responsibility will be further defined by implementing regulations of the Food Safety Law issued by the State Council.

Requirements for Information Sharing and Cooperation

The new law includes provisions requiring government agencies to cooperate with one another⁴ and to share food safety information with other agencies.⁵ These provisions merely set forth the general requirements, however. Without detailed practical rules, it is unlikely that such general provisions will improve cooperation and communication among the agencies. It is unclear whether the Chinese government intends to promulgate rules in these areas.

Enforcement

Extensive Power Given to Agencies

The new law requires the enforcement agencies to conduct periodic or random test checks for food safety, and prohibits the granting of exemptions from such checks or inspections to any establishment or product.⁶ The new law provides that, as necessary for supervision of food safety, the agencies have the power to: (i) enter any establishment or premise; (ii) take sample products; (iii) review and make copies of relevant documents; (iv) seal up products, equipment, or tools; and (v) seal up establishments.⁷

Harsh Penalties for Violation

The new law increases the penalties against makers of unsafe and tainted food. The Chinese government has the power to confiscate tools, equipment, materials, and alleged illegal profits generated from manufacturing or selling unsafe or tainted food.⁸ Consumers may claim additional recompense of up to ten times of the price of the product in addition to monetary damages to compensate for any harm caused by tainted food. These amounts can be recovered from the manufacturer or from the wholesaler or retailer if those entities

⁴ *Id.*, Art. 6.

⁵ *Id.*, Art. 83.

⁶ *Id.*, Art. 60. Previously, certain large producers were able to obtain exemptions from required inspections.

⁷ *Id.*, Art. 77.

⁸ *Id.*, Arts. 77, 84, 85, and 86.

knowingly sold the tainted food.⁹

The new law provides for punishment of government officials who have the duty to supervise food safety, but who act irresponsibly. The new law requires that an investigation for irresponsibility and dereliction must be conducted when there is a food safety scandal.¹⁰ Moreover, government departments, food industry associations, food testing institutes, and consumer associations are prohibited from promoting food products.¹¹ If there is a violation, administrative or disciplinary punishments will be imposed upon responsible persons, and all illegal gains will be confiscated.¹²

Individuals or entities, including celebrities, who promote food products in misleading advertisements, will be jointly liable together with the manufacturer or seller for any harm that consumers suffer.¹³ Organized food stall market owners, food counters lessors, and trade fair organizers must fulfill a duty of diligence in checking the licenses and certificates of tenants engaging in food distribution and must report known violations of food safety regulations.¹⁴ If they fail to perform any of these functions, they will be jointly liable for any food safety events relating to such failure.¹⁵

Standards

The new law establishes three levels of standards: national, local, and enterprise.

Before the new law, there had been confusion in standard-setting for food safety in China. Different agencies published standards under the titles, "Quality and Safety Standards for Agricultural Food Products," "Standards for Food Hygiene," and "Standards for Food Quality." Industrial associations also promulgated specific standards.

The new law requires MOH to publish uniform national standards for food safety based on existing standards, including standards for food inspections. Before uniform national standards are published, manufacturers must comply with the existing standards.¹⁶ If no national standard applies, the MOH affiliate at the provincial government level may issue local standards.¹⁷ If neither a national standard nor a local standard applies, the manufacturer must set an enterprise standard to be used in food manufacturing.¹⁸ The law also encourages (but does not require) food manufacturers and distributors to adopt good manufacturing practices (GMP) and hazard analysis and critical control point (HACCP) systems.¹⁹

The new law requires that all standards must be made available to the public.²⁰

Ingredient and Additives

The Chinese government paid special attention to ingredients and additives for food products when drafting the new law because of the melamine scandal. The new law provides that use of a new ingredient or new additive for food products is subject to

⁹ *Id.*, Art. 96

¹⁰ *Id.*, Art. 75.

¹¹ *Id.*, Art. 54.

¹² *Id.*, Art. 94.

¹³ *Id.*, Art. 55.

¹⁴ *Id.*, Art. 52.

¹⁵ *Id.*

¹⁶ *Id.*, Art. 22.

¹⁷ *Id.*, Art. 24.

¹⁸ *Id.*, Art. 25.

¹⁹ *Id.*, Art. 33.

²⁰ *Id.*, Art. 26. The standards are to be "examined and adopted" by a National Food Safety Standards review committee, which consists of experts from medicine, science, agriculture, food, and nutrition.

premarket approval.²¹ Evidence of safety is required for such approval and MOH will have sixty days to review the submission and decide whether to approve the use of the new ingredient or additive.²²

Additives may be used only when they are technically necessary and have been proven safe.²³ MOH is required to promulgate and regularly update standards for additive use.²⁴ No chemicals other than approved additives are allowed to be added in the manufacture of food products.²⁵ Additives must be shown on the label, with directions for use as needed, and packaging of the food products to which the additives have been added are required to display the words “food additive.”²⁶ If there is any false indication about the additive on the label or directions for use, the food products to which such additive has been added will be excluded from the market.²⁷

Other Provisions

The law regulates “functional” foods that make health-related claims. Advertisements, labels, and instructions cannot make therapeutic claims asserting that a product is effective in the prevention or treatment of disease. Foods that claim to affect health must not cause disease and labels and instructions must clearly indicate the active ingredients and what types of people should and should not consume the food.²⁸

The law implements a mandatory recall system. If food does not conform to designated safety standards, the producer bears the responsibility to stop production, “promptly” notify distributors, consumers, and government agencies, and, “if necessary,” recall the products.²⁹ If the producer fails to do so, the local affiliate of AQSIQ, SAIC, or SFDA may order the producer to recall the food.³⁰

The new law also imposes strict recordkeeping requirements on agricultural producers and food producers regarding raw materials, production, food additives, inspections, and exports. Records must be kept for two years.³¹

The law requires food imported into China to comply with national food safety standards. If a food product or additive is not covered by relevant national standards, the importer must apply to MOH for a safety evaluation before import. Foreign food manufacturers who export food to China must register with AQSIQ. Imported food will continue to be inspected by the entry/exit authorities in coordination with AQSIQ.

Conclusion

Under the new Food Safety Law, the supervision mechanism for food safety will be restructured, the regulatory powers of agencies will be better defined, agencies will have more enforcement tools to address food safety concerns, violations of food safety provisions will be subject to harsh penalties, and ingredients and food additives will be subject to tight control. In this manner, the new law represents the Chinese government’s effort to solve food safety issues by imposing greater responsibilities on food

²¹ *Id.*, Art. 44.

²² *Id.*

²³ *Id.*, Art. 45.

²⁴ *Id.*

²⁵ *Id.*, Art. 46.

²⁶ *Id.*, Art. 47.

²⁷ *Id.*, Art. 48.

²⁸ *Id.*, Arts. 48, 51.

²⁹ *Id.*, Art. 53. An earlier draft of the law indicated that a recall would be triggered by “unsafe” food, whereas the law as enacted uses food that “does not conform to safety standards” as the impetus for recall.

³⁰ *Id.*

³¹ *Id.*, Arts. 35, 36, 37, and 39.

manufacturers, processors, and distributors, as well as the government agencies that supervise these enterprises.

The above goals can be met, however, only if implementing regulations are clear and the new law is effectively enforced. Given the huge scope of China's food production chain,³² plus the existence of serious corruption, malfeasance, and local protectionism in both the Chinese administrative and legal systems, it is unclear whether the new law will bring an immediate improvement in the safety of food products manufactured in China.

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³² Some recent estimates indicate that China has more than 500,000 food production companies.