CFDA Announces Draft Regulation to Implement China's New Food Safety Law

On December 9, China Food and Drug Administration (CFDA) released the draft Regulation on the Implementation of the Food Safety Law of the P.R. China[1] (hereinafter “Regulation”) for public comments by January 8, 2016. This extensive Regulation includes 200 articles, detailing issues surrounding the implementation and enforcement of the Food Safety Law (hereinafter "Law"), which entered into force in October of this year. This draft Regulation, once adopted, will have a significant impact on overseas food producers and operators, especially for those in the industry of health food and infant formula. It also further defines some key terms to the food industry, e.g., edible agricultural product, food in special dosage forms with unified consumption amount, food repacking, and food in bulk.

In the next few weeks, we will walk you through important sections of the Regulation and focus on different topics via our e-newsletter, "China Regulatory Matters." This issue will provide you with a snapshot of the articles in the Regulation that will likely have a major impact on the food import business, particularly foods imported into China that have been under a high level of scrutiny, such as health food and infant formula.

I. Government Management of Imported Food

The Regulation is designed to establish a management system of food import per food category and safety risk level, taking into account various factors (e.g., food safety risk, safety control capability of the enterprise, and food safety condition of the exporting country/region). [2] For food, food additives and food related products [3] at high risk level, samples will be retained and tested under entry inspection; for products with ordinary risk, sampling testing will be carried out; and for products with low risk, only on-site inspections will be conducted. [4]

Food incidents taking place overseas (e.g., food recall in foreign countries) may result in further control measures (e.g., import restriction, import suspension, goods returned or destruction, etc.) by the Chinese authorities. [5]

II. Foreign Food Producers, Exporters and Chinese Food Importers

The Regulation also sheds more light on product compliance by foreign food producers/exporters and local importers. For example, Article 112 requires foreign food producers/exporters to prevent any deliberate destruction by others to food and edible agricultural products via chemical, biological or physical means at different stages of food production and operation (e.g., raw material control, production, packaging, storage and transportation, etc.).

Furthermore, local food importers are under an obligation to establish a regime to audit the food producer and exporter overseas. [6] Details regarding the design and function of the audit system can be found in the Administrative Measures for the Audit and Inspection of Overseas Companies by Food Product Importers (draft for
for comment) [7] published by the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) in September this year. In short, the draft Measures impose heavy responsibilities on the local importer to ensure the safety of food products that they plan to distribute in China. 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, health food, infant formula, formulation food for special medical purposes and meat products. Such on-site inspection can be authorized to an accredited third party (see: Keller and Heckman China Regulatory Matters: China’s Food Safety Law Takes Effect Today: Are You Ready).

III. Specially Controlled Food Products

According to the amended Law, pre-market approval (i.e., notification or registration) from the Chinese Government is a prerequisite to the distribution and operation of health food, infant and young children formula food and foods for special medical purposes (hereinafter “specially controlled food products”) in China.

The Regulation uses the term ‘food in special dosage form with unified consumption amount’ to capture all food in the form of capsule, tablet, liquid oral dosage, medicinal granules, etc., which is subject to a pre-set daily intake amount or consumption amount. [8] We expect to see more detailed rules published by the Chinese government in the future in terms of its regulation of food in special dosage form.

a. Health Food

The Regulation further clarifies some issues in the existing rules targeting health food (see: Keller and Heckman China Regulatory Matters: China Announces New Draft Regulations on Health Foods). In particular, not only does the Regulation explicitly block the use of the novel food registration procedure to clear an ingredient reserved for health food use, it also provides details of the to-be-published inventory of food ingredients for health food use (see: Keller and Heckman China Regulatory Matters: China’s Food Safety Law Takes Effect Today: Are You Ready). Specifically, the inventory will include specifications for the ingredient name, the use level, manufacturing process, functional components and test methods. Further, an ingredient that differs substantially from the ingredient listed (resulting from extraction and purification) will be deemed new, thus, is excluded from the scope of the inventory under Article 81.

With regard to imported products, “health food imported for the first time” suggests no health food made per the same formula has been imported from the same country and the same producing company in the past. [9] When the health food is imported for the first time, it must be registered with CFDA in advance, unless it falls under the scope of vitamins and minerals, which are only subject to notification procedures. Once the notification number is issued to a health food to be imported, the actual import must be carried out within three months and the proof of customs clearance as well as the testing report must be filed with the food and drug administration at the provincial level. [10]

To register a health food product, sample products must be manufactured in a plant which has implemented Good Manufacturing Practice (GMP). [11] As to the product claim, it must strictly follow the language set forth in the function claim catalogue and no alteration is allowed (see: Keller and Heckman China Regulatory Matters: China
ina Announces New Draft Regulations on Health Foods. [12] Health food that shares the same registration certificate or filing number shall use the same trademark. [13]

b. Infant and Young Children Formula

Since infant and young children formula food have repeatedly fallen under the spotlight in various food scandals in China, the Regulation includes many articles intended to address issues related to the production and operation of infant formula as well as product registration/notification procedures.

More specifically, the Regulation requires infant and young children formula to be developed in accordance with Chinese regulations and standards. In principle, one company shall not have more than 3 series of products and 9 product formula. Substances that are subject to optional additions (e.g., choline, inositol, taurine in infant formula) cannot be reflected in the product name of infant and young children formula. [14] Imported formula of milk powder for infants and young children, per Article 90, must be registered.

Further, prior to the marketing of infant and young children formula food, the producer must notify relevant authorities of the information regarding product raw materials, food additives, formula and product label. [15] Article 47 imposes an obligation for review of formulation registration certificate on the operator of infant and young children formula where applicable.

IV. Food Labeling

Given a large amount of noncompliant food issues arise from the product label, the Regulation elaborates on food labeling issues in various chapters. Of particular note is the proposed prohibition of sticker use on imported food products. Under the draft Regulation, all prepackaged food must be directly printed with a Chinese label before it is imported to China. [16] Additionally, food shall not be labeled with any pre-set amount of consumption or designated daily consumption, unless it is a health food, infant and young children formula food or foods for special medical purposes. [17]

Claims such as “non addition of” or “non-use of” substances that are prohibited in pertinent food safety national standards are to be banned. For example, colostrum is currently banned in infant formula. [18] Accordingly, under the draft Regulation, “no addition of colostrum” is not a permitted claim on the label of an infant formula milk powder product. Similarly, GMO food or raw materials that have not yet been approved by the Chinese government shall not bear a “non-GMO” label.

The draft Regulation, for the first time, clearly defines “defects with food label,” which refers to non-compliance which has no impact on food safety and will not mislead consumers in their safe consumption of food (e.g., spacing between letters, font size, use of simplified or traditional characters and rounding intervals, etc.). [19] Under the updated Law, a food label with a defect no longer constitutes a cause for consumer compensation of ten times the purchasing price or three times the loss. [20] However, food labels or instruction manuals non-compliant with food
d safety national standards can become the subject of a Class III food recall even if no health damage is expected. [21] Notably, under a Class III recall, a food possessing a non-compliant label can continue to be sold as long as the label is fixed, mitigation measures have been taken to guarantee product safety, and public notice has been given about the mitigation measures. [22]

V. Cross-border E-Commerce

Nowadays, “cross-border e-commerce” (CBEC) has become a term commonly used in the food industry, particularly as it relates to the import and export of food to China. The Regulation, under Article 117, explicitly mandates food imported via CBEC shall follow the Law and the Regulation. In the meantime, the Regulation authorizes the quality supervision inspection and quarantine department under the State Council with other relevant departments to jointly establish the rules for supervision and management of imported food, food additives and food related products via CBEC. [23]

In fact, this October, AQSIQ published Supervision and Management Rules for the Safety of Imported Food via Cross-border E-commerce in Online Shopping Bonded Mode (draft for comment) [24] to regulate the operation and safety supervision of imported food that is delivered to bonded warehouses via CBEC and then redistributed to Chinese consumers upon individual orders.

VI. Food Repackaging and Toll Manufacturing

Food repackaging is a very common practice among food importers and distributors, and the Regulation newly defines this action and establishes some restrictions. Notably, at the stage of food operation, if food in large packs is redistributed into small units for sale without repackaging, it does not fall under the definition of “food repackaging.” [25] When a food operator repackages food, no modification to the production date or extension of the shelf-life is permitted. [26]

In the toll manufacturing of food or food additives, while the toll manufacturer must obtain a production license and be responsible for the production activity, the company procuring the tolling service is ultimately responsible for the food safety. [27]

VII. Transportation

Following up on the amended Food Safety Law, which expands its scope of regulation to cover food transportation and storage, the Regulation in several articles focuses on the qualification of logistic companies and warehouses in the food business. Food companies doing business in China should carefully select their local partners. By way of example, food producers/operators are obligated to examine the storage/transportation company's capability in guarantying food safety. [28] A written contract must be reached in commissioned food storage and transportation, describing each party's obligations to comply with the food safety requirements in China. [29]
Article 105

'Food related product', under the Law, refers to food packaging materials, containers, detergent, disinfectant, utensils and equipment for food production and operation.

Article 109

Article 116

Article 110

Article 195

Article 195

Article 84

Article 88

Article 115

Article 87
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[16] Article 114

[17] Article 78


[19] Article 195

[20] Article 125 and Article 148, Food Safety Law

[21] Article 65

[22] Article 66

[23] Article 117


[25] Article 195

[26] Article 75

[27] Article 34

[28] Article 49

[29] Article 52