

MEMORANDUM

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Re: **China's CFDA Proposes Significant New Food Safety Implementing Rules under Its 2015 Food Safety Law**

We recently learned that the U.S. Department of Agriculture (USDA), in coordination with the Office of the U.S. Trade Representative (USTR), intends to submit comments on the draft rules implementing changes to the Chinese food safety laws. Any companies that are interested in submitting comments have until Feb 19, 2016 (Friday) to share comments with USDA. In this memorandum, we provide a brief summary of the proposed changes and identify the specific questions for which USDA is requesting comments.

By way of brief background, on December 9, 2015, China Food and Drug Administration (CFDA or “国家食品药品监督管理总局”) released its “Draft Implementing Rules for the 2015 Food Safety Law” (Draft Rules) for public comment. ^{1/} These proposed food safety rules, once implemented, would have far-reaching and lasting effects on the world's largest consumer market for food and beverage products by implementing new food safety and labeling requirements. Because China is the largest international market for U.S. food and agricultural products, accounting for 20 percent of all U.S. farm exports, the new requirements could have a significant impact on U.S. exporters and producers. ^{2/} While CFDA only provided until Jan 9, 2016, for interested parties to submit their comments, USDA plans to combine comments it receives by February 19 into a set of official comments to China.

I. Summary

From melamine in infant formula to floating dead pigs in the Huangpu River, food safety scandals in China have substantially undermined Chinese consumers' confidence in their domestic products. To address the rising concerns regarding food safety, on April 25, 2015, the Standing Committee of China's National People's Congress (NPC or “全国人民代表大会常务委员会”), passed its

^{1/} See “国家食品药品监督管理总局对外公开征求《食品安全法实施条例》修订草案的意见,” available at: <http://www.sda.gov.cn/WS01/CL0782/137340.html>. An unofficial English translation “China: Draft Implementing Rules for the 2015 Food Safety Law,” published by USDA Foreign Agricultural Service, is available at: <http://www.fas.usda.gov/data/china-draft-implementing-rules-2015-food-safety-law>. While we find this unofficial English translation largely accurate, we caution against solely relying on the unofficial translation for assessing the legal and regulatory changes. This memorandum is based on the official Draft Rules in Mandarin Chinese.

^{2/} See “United States Department of Agriculture Foreign Agricultural Service: China” available at: <http://www.fas.usda.gov/regions/china>.

amendment to China's food safety law, the 2015 Food Safety Law. ^{3/} The Draft Rules, which contain 200 articles, provide more details to the 2015 Food Safety Law by requiring stricter food safety monitoring and supervision methods, tougher safety standards, and more severe punishments for offenders. Many of these requirements are clearly drafted with domestic food manufacturers in mind, who have been implicated in the majority of the Chinese food scandals. For example, the Draft Rules would require that local governments in China refer food safety cases to the police department for investigation in three working days when certain serious food violations are identified. ^{4/} While U.S. food manufacturers are rarely found in violation of the Chinese food production standards, it would nonetheless be prudent to be familiar with these requirements, especially when working closely with Chinese partners.

Among the 200 articles of the Draft Rules, the ones likely of greatest interest to U.S. food exporters and producers would be those regarding the labeling of prepackaged foods, the special requirements for health foods (comparable to U.S. dietary supplements) and infant formulas, and the new regulatory framework for imported foods. The popularity of E-commerce in China has given the 1.3 billion consumers direct access to many packaged U.S. foods. While the current legal framework allows class action-type litigation, food labeling class action litigation is practically unheard of in China due to the relatively limited damages that can be collected. ^{5/} Unlike the U.S. Federal Food, Drug, and Cosmetic Act, the Chinese Food Safety Law contains provisions that encourage private causes of action by consumers. ^{6/} The Food Safety Law creates "professional consumers" or bounty hunters specializing in identifying food labeling violations and seeking monetary damages. ^{7/} While the Draft Rules contain provisions that might help some food companies in fending off these "professional consumers," we find many of the labeling requirements for prepackaged foods (e.g., GMO labeling) troubling as they are inflexible and prone to be abused by the bounty hunters. ^{8/}

Chinese food products of dubious quality have also allowed many U.S. food companies to gain market share in China. This is especially true for health foods and infant formulas where many Chinese consumers are prone to view the U.S. brands as being of higher quality. The Draft Rules contain special requirements for health foods and infant formulas. These include, but are not limited to, the establishment and publication of health food ingredients and claims lists, branding of infant formulas, as well as new authority for CFDA to conduct on-site inspections of foreign health food and infant formula producers. ^{9/} The Draft Rules also contain provisions that set out the regulatory framework for imported foods. ^{10/} As the enforcement of food safety regulations in China is known to be haphazard, every U.S. food exporters and producers should closely examine the relevant provisions and assess how they will affect their operation in China.

^{3/} See "中华人民共和国食品安全法," available at: http://www.gov.cn/xinwen/2015-04/25/content_2852919.htm. An unofficial English translation "China: China's Food Safety Law (2015)," published by USDA Foreign Agricultural Service, is available at: <http://www.fas.usda.gov/data/china-china-s-food-safety-law-2015>.

^{4/} See Article 157 of the Draft Rules.

^{5/} See Article 52 of "中华人民共和国民事诉讼法," available at: http://www.npc.gov.cn/npc/xinwen/2012-09/01/content_1735841.htm.

^{6/} See Article 148 of the 2015 Food Safety Law.

^{7/} See http://news.xinhuanet.com/legal/2015-10/22/c_1116899007.htm.

^{8/} See Articles 77, 78, 114, and 195 of the Draft Rules.

^{9/} See Articles 80, 81, 88, 92, and 115 of the Draft Rules.

^{10/} See Articles 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, and 117 of the Draft Rules.

II. Highlights of Major Provisions

• Labeling of Prepackaged Foods

The provision of the Draft Rules that has the most immediate effect on the U.S. food exporters is probably Article 77, which requires that all prepackaged foods manufactured using GMO ingredients shall be clearly labeled as such pursuant to the “Regulations on Administration of Agricultural Genetically Modified Organisms Safety” (GMO Regulations or 农业转基因生物安全管理条例). ^{11/} Under the GMO Regulations, the term “GMO” is broadly defined to include “additives and other products containing ingredients of genetically modified animals, plants and microorganisms or their products.” ^{12/} Many prepackaged food and beverage products contain ingredients derived from genetically engineered (GE) corn and ingredients derived from GE microorganisms (e.g., enzymes and many of the organic acids.) Unlike the GE labeling requirements established in the state of Vermont or the European Union, the Draft Rules contain no exemption for processing aids. The Draft Rules would require GMO labeling for any food that contains ingredients derived from GE animals, plants, and microorganisms. Also of concern is the absence of any threshold level or the acknowledgment of the adventitious presence of GMO materials. As such, even if no GMO ingredient is intentionally added, the prepackaged foods may still be subject to GMO labeling under the Draft Rules due to incidental contamination. The Draft Rules also would require that all the prepackaged imported foods have Chinese labels printed on the product package. ^{13/} The previous practice of having stickers with information printed in Chinese over the foreign language labels would no longer be permitted.

The Draft Rules would establish a definition for “technical food labeling deficiency” and would exempt any such technical deviations from the private cause of action provision under the 2015 Food Safety Law. ^{14/} However, the “technical food labeling deficiency” would be defined narrowly in the Draft Rules as only including relatively minor deviations such as “errors in space between words, size of the font, punctuation, simplified/traditional Chinese characters, rounding intervals, etc.” that would not otherwise affect food safety or mislead consumers. ^{15/} Food labeling non-compliance such as GMO labeling, the use of stickers, or the failure to provide a Chinese label would fall outside the exemption and be subject to private causes of action.

Health Foods

A health food is defined as “any food claiming to have special health benefits that are suitable for particular subsets of the general population, helpful with regulating physiological functions, and not intended to cure diseases.” ^{16/} Under the 2015 Food Safety Law, health foods are subject to either pre-market registration or notification requirements. CFDA is currently finalizing several specific draft regulations on health foods. ^{17/} Under the Draft Rules, CFDA would coordinate with other

^{11/} See “农业转基因生物安全管理条例,” available at: http://www.gov.cn/flfg/2005-08/06/content_21003.htm. An unofficial English translation, published by the Peking University, is available at: <http://www.lawinfochina.com/display.aspx?lib=law&id=12849&CGid=>.

^{12/} See *id.*

^{13/} See Article 114.

^{14/} See Article 195.

^{15/} See *id.*

^{16/} See “保健食品管理办法,” available at: <http://www.sda.gov.cn/WS01/CL0056/10749.html>.

^{17/} See “食品药品监管总局关于征求《保健食品保健功能目录原料目录管理办法（征求意见稿）》意见的通知,” available at: <http://www.sda.gov.cn/WS01/CL0780/125502.html>.

regulatory agencies in China to develop and publish a list of health food ingredients and a list of permissible health food claims. 18/

The Draft Rules would dictate that the published list of health food ingredients shall include the raw material names, dosage, manufacturing process, efficacy, testing methods, as well as any other technical requirements. 19/ The proposed requirement would undoubtedly raise confidentiality concerns among U.S. manufacturers. Moreover, the Draft Rules would prohibit any conventional foods, other than health foods, from making or implying that the food products have any health benefits. 20/ The provision would extend to claims regarding the food in reducing the risk of disease (i.e., “health claims” in the United States) and claims regarding the effect of the food on the structure or function of the body (i.e., structure/function claims in the United States). The Draft Rules also would give CFDA the authority to conduct on-site inspections of oversea health food producers. 21/

Infant Formulas

The Draft Rules also made changes to the existing regulatory framework for infant formulas. In particular, under the Draft Rules, manufacturers shall not produce or market infant formulas in China when the trademarks, company name, and address are only registered overseas. 22/ The Draft Rules further require that to the extent milk is used in producing infant formula, only milk from cows and goats can be used. 23/ Also, in principle, each company should not register more than three lines of products and nine product formulations. 24/ The infant formula product names shall not contain optional nutrients under the national standard. 25/ The Draft Rules also give CFDA the authority to conduct on-site inspections of oversea infant formula producers. 26/

Imported Foods

China Inspection and Quarantine Services (CIQ) has the main jurisdiction over the import and export of food products. 27/ While CFDA inspects food products once they are in the domestic market, CIQ conducts sampling and inspection of foods, food additives, and food-related products during importation. 28/ According to the Draft Rules, CIQ will implement a tiered, risk-based system for inspection. 29/ For foods, food additives, and food-related products with high risks, CIQ will detain the products for inspection. 30/ For products with common risks, CIQ will conduct sampling. 31/ For products with low risks, CIQ will conduct on-site inspections during importation. 32/

Food importers in China are now required to establish audit systems to review foreign food exporters and producers under the Draft Rules. 33/ Also, for foreign food safety or public health incidents that

18/ See Article 80.

19/ See Article 81.

20/ See Article 78.

21/ See Article 115.

22/ See Article 92.

23/ See *id.*

24/ See *id.*

25/ See *id.* In China, infant formula must also comply with the standard as set by GB 10765-2010, include macro and micro nutrient requirements with minimum and maximums as necessary.

26/ See *supra* note 21.

27/ See Article 104.

28/ See Article 109.

29/ See *id.*

30/ See *id.*

31/ See *id.*

32/ See *id.*

33/ See Article 110.

could affect products in the Chinese domestic market, according to the Draft Rules, CIQ shall timely publish alerts and take the following measures as appropriate: (1) detain and inspect; (2) reject or destroy; (3) import with conditions; (4) suspend or prohibit import; (5) initiate an emergency response plan for imported food. 34/

III. Comments to USDA by Feb 19

USDA has asked the food industry to provide comments on the Draft Rules by February 19. USDA is particularly interested in the following information:

- Explain how the measure would restrict your ability to export. In particular, how compliance with the new regulation will affect your operations, prevent sales or add cost to meet compliance requirements.
- As best as possible, quantify the impact the measure will have on U.S. exports. For example, it is estimated that the draft language on labeling in this measure will restrict 90 percent of U.S. processed food exports to China.
- Provide any suggestions for making the measure workable. Is there a solution available?

Companies interested in submitting comments should send their comments to USDA at lisa.allen@fas.usda.gov.

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We will continue to closely monitor all developments related to China's CFDA's implementation of its 2015 Food Safety Law.

If you have any questions regarding the new law, or if we can be of any assistance in assessing how the legal and regulatory changes would affect your business in China, please do not hesitate to contact us.

34/ See Article 116.