

## Geographical Indications for Traditional Food Products in Turkey

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### 1.- Introduction

The law of Turkey has been coming under powerful external pressures to change. After Turkey became a contracting party to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement 1994) on March 26, 1995, Turkey made major legislative changes to advance the protection of intellectual property rights.

One of those changes was the adoption of legislation specifically designed to protect “Geographical Indications (GIs)”. New rules have been introduced by the Turkish Decree Law No. 555 on the Protection of Geographical Indications (“Decree Law No. 555”)<sup>1</sup>, and the Regulation Concerning the Implementation of the Decree Law No. 555.<sup>2</sup>

As a consequence, the value of “Traditional Food” as an element of cultural heritage in Turkey is primarily protected through registration of GIs under the product origin classifications of Turkish Intellectual Property (IP) law.<sup>3</sup> Akin to a trademark, under these laws, a GI identifies a good, including a food, as originating in a particular region and in exceptional cases in a country where a given quality of the good is attributable to its

place of origin.<sup>4</sup> It should be noted that the Turkish regulations are very similar to the EU regulations in terms of protecting GIs.

Although a wide range of issues could be covered, especially from the international trade law point of view such as the significance of the Agreement on Technical Barriers to Trade and the standards of protection under the TRIPS Agreement 1994, this article mainly focuses on describing the general legal framework concerning protection in the Turkish jurisdiction and the Ministry of Food, Agriculture, and Livestock’s (Ministry) generalized policy of traditional food.

### 2.- General Operational Provisions Concerning Geographical Indications

Decree Law No. 555 defines “Geographical Indication” as an indication that marks an apparent quality, reputation, and other features of a product as related to its locality, area, region or country of origin where it is produced (in very rare cases), and categorizes GIs into two; namely protected designation of origin (PDO)<sup>5</sup> and protected provenance-geographical indication (PGI).<sup>6</sup> Unlike in the EU, however, there is no “Traditional Specialty Guaranteed” designation.

Protection is based on an application system and provided only upon the request of a third party.

The Turkish Patent Institute (TPI)<sup>7</sup> is the designated competent authority for the registration of GIs. It grants protection based on the results of an extensive application process. Producers, consumers, or other

(<sup>1</sup>) 555 Sayılı Co rafi aretletin Korunması Hakkında Kanun Hükmünde Kararname [Decree Law No. 555, On the Protection of Geographical Indications (Decree Law No. 555)] Anayasa Mahkemesi [Constitutional Court] No. 2009/16 of Mar. 12, 2009, Resmi Gazete [Official Journal] No: 22326, Jun. 27, 1995, available at <http://www.resmigazete.gov.tr/main.aspx?home=http://www.resmigazete.gov.tr/arsiv/22454.pdf&main=http://www.resmigazete.gov.tr/arsiv/22454.pdf>.

(<sup>2</sup>) See 555 Sayılı Co rafi aretlerin Korunması Hakkında Kanun Hükmünde Kararnameye li kin Uygulama Yönetmeli i [The Implementing Regulation for Decree Law 555 on the Protection of Geographical Indications] Resmi Gazete [Official Journal] No: 22454, Nov. 5, 1995, available at <http://www.resmigazete.gov.tr/main.aspx?home=http://www.resmigazete.gov.tr/arsiv/22454.pdf&main=http://www.resmigazete.gov.tr/arsiv/22454.pdf>.

(<sup>3</sup>) *Supra* note 1.

(<sup>4</sup>) *Id.* at art. 3.

(<sup>5</sup>) *Id.* at art. 3 para. 2 (defining “Protected Designation of Origin” (PDO) as follows: A product originating in a specific place, region (with defined boundaries), or in exceptional cases, a country, whose quality or characteristics of the product are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors, and the production steps all take place in the defined geographical area).

(<sup>6</sup>) *Id.* (describing “Protected Geographical Indication” (PGI) as follows: A product originating in a specific place or region, whose quality, reputation or other characteristics is essentially attributable to the geographical origin, and at least one of the production steps takes place in the defined geographical area).

(<sup>7</sup>) See <http://www.tpe.gov.tr/TurkPatentEnstitusu/?lang=en> (detailing the application process under the section entitled Geographical Signs).

interested parties such as local chambers of commerce apply for GI classification for their particular products. Applications are made public by being published in the Official Journal, in two national newspapers and in (at least) one local newspaper. After publication, there is a six-month appeal period for interested parties to object to the application. GIs protections are territorial; namely, a GI right acquired in one jurisdiction usually gives no rights to the GIs in other jurisdictions. In line with this principle, Turkey's system of GIs registration is only domestically enforceable. As a result, GIs owners with multinational interests must seek separate protection of their GIs in each jurisdiction of interest.

There are formal requirements for an application. To name a few:

- the description of the product, technical information, documents explaining the characteristics of the product and if necessary of the raw material;
- the production techniques of the product and if relevant the authentic and specific local techniques and conditions; and,
- documents evidencing that the product conforms to the respective definition of the GI.

In order to qualify for protection, the Decree Law No.555 explicitly states that the three criteria mentioned above under PDO and PGI must be met.

### 3.- Registered Turkish Food Products in Turkey and the EU

Despite its agricultural diversity and the variety present in Turkish cuisine, there were only 179 products registered with a GI in Turkey as of December 4, 2014<sup>8</sup>. Of these, only 124 were food and agricultural products. The number of registered Turkish foods in Europe is even lower than in Turkey. Within the EU, only "Gaziantep/Antep Baklava" was registered with a PGI indication on December 21, 2013.<sup>9</sup> Applications

have been submitted and are pending for four other goods: Malatya Apricots, Antalya Figs, Afyon Sujuk (spiced sausage), and Afyon Pastrami<sup>10</sup>.

Further, only three foreign products have been registered in Turkey: Prosciutto di Parma by Consorzio del Prosciutto di Parma (Parma Ham Consortium) registered on December 18, 2007, Scotch Whisky by the Scotch Whisky Association registered on June 2, 2008, and Hellim/Halloumi (cheese) by the Northern Cyprus Turkish Republic Chamber of Commerce on October 10, 2008. There are three pending applications at Turkish Patent Institute: Champagne<sup>11</sup>, Grano Padano<sup>12</sup> and Reggio Parmesai/Parmigiano Reggiano<sup>13</sup>.

Given Turkey's distinctive and vast gastronomical tradition, it is surprising that there have been only five GI applications for Turkish food and agricultural products in Europe. In fact, even the number of registered foods within Turkey is low considering the varieties.

Firstly, it could be related to the fact that there is still a lack of systematic research on the effects of GIs protection on companies' profitability, reputation and lack of systematic research on the marketing channels, customers' preferences and knowledge both in the local and international agri-food market. Therefore, Turkish producers may not be able to value the potential economic gains that could follow from acquiring GIs indications. Between whether to or not to use the protected GIs, they may find it unprofitable initially. However, there is actual value in protecting foods if only as a means of preserving cultural know-how and even world heritage. GIs create a niche in the market for the particular good and essentially gives a distinctive advantage within that niche to the registered product. GIs should be considered as an opportunity/strategic tool to move away from commodity markets (non-value added products) into more lucrative value-added niche markets through differentiation by the Turkish government's well structured support and promotion system.

<sup>(8)</sup> <http://www.tpe.gov.tr/TurkPatentEnstitusu/geographicalRegisteredList/> (last visited on 5/12/2014)

<sup>(9)</sup> See European Commission, Agriculture and Rural Development DOOR Database, [http://ec.europa.eu/agriculture/quality/door/list.html?jsessionid=pL0hLqgLXhNmFQyF11b24mY3t9dJQPflg3xbL2YphGT4k6zdWn34!&recordStart=0&filter.dossierNumber=&filter.cmoName=&filterMin.milestone\\_mask=&filterMin.milestone=&filterMax.milestone\\_mask=&filterMax.milestone=&filter.country=TR&filter.category=&filter.type=&filter.status=](http://ec.europa.eu/agriculture/quality/door/list.html?jsessionid=pL0hLqgLXhNmFQyF11b24mY3t9dJQPflg3xbL2YphGT4k6zdWn34!&recordStart=0&filter.dossierNumber=&filter.cmoName=&filterMin.milestone_mask=&filterMin.milestone=&filterMax.milestone_mask=&filterMax.milestone=&filter.country=TR&filter.category=&filter.type=&filter.status=) (last visited Dec. 5, 2014).

<sup>(10)</sup> <http://ec.europa.eu/agriculture/quality/door/list.html?jsessionid=pL0hLqgLXhNmFQyF11b24mY3t9dJQPflg3xbL2YphGT4k6zdWn34!> (last visited Dec. 5, 2014)

<sup>(11)</sup> See Application #C2011/053, <http://www.tpe.gov.tr/TurkPatentEnstitusu/geographicalList/> (last visited Dec. 5, 2014).

<sup>(12)</sup> *Id.* at application #C2014/044.

<sup>(13)</sup> *Id.* at application #C2011/002.

Secondly, it could be due to the fact that the degree of internal quality standardization achieved in Turkish jurisdiction is not precisely articulated within a specific regulatory framework. It is rather general and the definition of characteristics of the product specifications in the GIs denominations are not strictly described. Current control of GIs use is entirely dependent on producers' own self-directed controls and the internal control that is mainly carried out by their local trade associations. The lack of strict accreditation requirement in the current control mechanisms to ensure the quality and authenticity may discourage companies when they make decision whether to or not to use a protected GI.

#### 4.- The Ministry's Generalized Policy of Traditional Foods Registration

The distribution of competencies among the producers requires huge efforts to ensure that governmental authorities do not develop parallel conceptual general models within different governmental organizations concerning GIs. However, the Ministry has a parallel and arguably competing system of designating certain foods as "*Traditional Food*".

The Ministry published as an attachment to the Turkish Food Codex Regulation on Food Additives, a list of what it considers to be "some" of the "traditional" foods produced in Turkey under the heading "*Some Traditional Foods Produced in Our Country and the List of Additives Prohibited in Them*".<sup>14</sup> Whereas producers themselves must apply to the TPI for a GI denomination, the Ministry itself unilaterally determined and placed mainly 10 (ten) products on this list as traditional food<sup>15</sup> and prohibited "*only*" particular food

additives for use in most of them. This is concerning not only because it undermines the GI registration system outlined in the Decree Law No. 555, but also because it appears to have an ulterior motive of targeting specific food additives especially in conventional meat products and conventional bread types which could be considered a barrier to trade.

The products listed under the heading of Annex VI "Some of the Traditional Foods and the List of Food Additives Prohibited in Them" are: E-620-625, E 626 - 635 E 251-252 and coloring agents in Fermented Sujuk (Spiced Sujuk), Heat Treated Sujuk, Pastırma (Pastrami), Döner (Gyro), Döner Made From Poultry Meat (Gyro made from Poultry meat), Köfte (Meat Ball) and all additives in Pekmez (Syrup usually made from grapes also carob), all additives in Pide (Pita), all additives except citric acid in Mezzes (Appetizers, including Raw Meat Balls), and all food additives except propionic acid and propionates in packaged Bazlama (Flatbread).

A "Traditional Food/Product" is defined in the Turkish Food Codex Regulation in 2011 as "Products which can be differentiated from other like-products in the same category by the fact they have been produced with traditional raw materials or traditional components or a traditional production process."<sup>16</sup>

Furthermore, the Ministry published the Communiqué on Turkish Food Codex Meat and Meat Products (2012/ 74)<sup>17</sup> and defined in Fermented Sujuk (Sujuk/Sausage Type), Heat Treated Sujuk, Pastırma (Pastrami), Döner (Cyro), Döner Made From Poultry Meat (Gyro made from Poultry meat), Köfte (Meat Ball).<sup>18</sup> The definition of Traditional Product/Food and definitions of the aforementioned meat products are

<sup>(14)</sup> Published in the Official Journal No: 28693 on 30 June 2013.

<sup>(15)</sup> Fermented Sujuk (Sujuk/Sausage Type), Heat Treated Sujuk, Pastırma ( Pastrami), Döner (Cyro), Döner Made From Poultry Meat (Gyro made from Poultry meat), Köfte (Meat Ball), Pekmez ( Syrup usually made from grapes also carob), Row Meat Ball and Mezzes (Appetizers), Pide(Pita), Bazlama (Flatbread). The list can be found [www.resmigazete.gov.tr](http://www.resmigazete.gov.tr).

<sup>(16)</sup> See Türk Gıda Kodeksi Yönetmeli i [Turkish Food Codex Regulation], [Resmi Gazete] Official Journal No: 28157, art. 4(ç), Dec. 29, 2011, available at [www.resmigazete.com](http://www.resmigazete.com).

<sup>(17)</sup> Et ve Et Ürünleri Tebli i [Communiqué Concerning Meat and Meat Products] (No: 2012/74) [Resmi Gazete] Official Journal No: 28488, Dec. 5, 2012.

<sup>(18)</sup> *Id.* at art. 4(1)(h) (defining: "Fermented Sujuk (Sujuk): Fermented meat product which have not undergone any heat treatment whose cross section is in mosaic form and whose humidity ratio has been decreased to 40% and below having applied the procedures of fermentation on and drying at certain conditions the minced meats and fats of bovine and ovine animals, and filling in natural or artificial sheaths after mixing with flavors.

Art. 4 – (1)(i) Heat Treated Sujuk: Meat product having undergone a heat treatment procedure whose cross section is in mosaic form and whose humidity ratio has been decreased below 50% having applied the processes of fermentation and drying at certain conditions, comprised of the minced meats and fats of bovine and/or ovine animals or meats and fats of poultry, and filling in natural or artificial sheaths after mixing with flavors.

inadequate to be the basis for reliably attributing certain food products to regions where those foods are considered traditional, because under this definition, foods of the same name which may be made with varying raw materials, composition and/or manufacturing methods depending on the region it is made, can be uniformly labeled “traditional.” Moreover, there is no definition in the regulations for Pide (Pita), Bazlama, Raw Meat Ball and Mezzes.

Take for example, the listed foods “*Köfte (Meat Ball)*,” “*Pide (Pita)*” and “*Bazlama (Flatbread)*.” These foods may not be considered traditional products because there are many different recipes of these products in Turkey and all over the world and there is nothing specific in the definition of these products to differentiate them from other versions. Almost any type of red minced-meat balls could be considered as “köfte (meat ball)” and any type of basic form of dough with salt and water/bread could be considered as “pide (pita)” and “bazlama (flatbread)”. These products could be considered “*generic*” even in the Turkish jurisdiction, signifying the type of product, rather than its geographical indication. In other words, this definition has allowed the Ministry to take great liberties when placing broad categories of foods on its list without adhering to the standards found in the Decree Law No. 555.

Furthermore, it could be argued that the Regulation dilutes the GI’s value as well as discourages producers from making investment decision in GIs because it does not clearly define the term “traditional” nor does it set forth clear standards regarding which products can be thus labeled. Firstly, the heading of the list could be considered misleading. The word “some” in the heading implies that there is an infinite variety of “conventional foods” which could be regulated as “Traditional Foods” just by the arbitrary use of state

power by the Ministry, whereas in reality the foods that can be properly designated as traditional are limited by the TPI. Secondly, the wording of the Regulation risks the misunderstanding that the Ministry is implicitly or indirectly creating a GI for the identified products in the list by combining them with the name of “the country/Turkey” such as Turkish Pide (Pita), Turkish Köfte or Traditional Turkish Köfte and Traditional Turkish Pide (Pita) without designation by the TPI. Nothing would prevent the producers from labeling their products with the aforementioned statements. Such a general, wide-spread use of such statements on these products would diminish the value/level of Turkish GI protection denominated by the Turkish Patent Institute. For example, there would not be significant value difference between the products marked “Traditional Turkish Köfte” or “Traditional Köfte,” and those that have been given GI designation linked to “*the well defined, specific*” geographical area by the TPI such as “Akçaabat Köfte.”<sup>19</sup>

The Regulation’s ban on the use of particular food additives for meat products listed is a particular point of concern because it creates confusion where the Turkish government should be concerned with establishing uniformity and standards for labeling products as “traditional.” The Regulation unilaterally adds other criteria without any cooperation with the TPI. It could be argued that this list is intended to subtly undermine the use of certain food additives rather than to offer protection to the products listed therein.

## 5.- Concluding Remarks

As a World Trade Organization member, Turkey has been implementing a sui-generis system for the pro-

Art. 4 – (1)(z)(cc) Pastırma (Pastrami): Cured and dried meat product not treated with heat, subjected to inhibition and drying after curing and washing treatments of carved meats duly boned from bovine carcasses, and then re-dried after fenugreek application in accordance with their technology.

Art. 4 – (1)(d) Döner (Gyro): A type of meat product made of a mix of one or more of bovine or ovine meats, the animal fats of the same types of animals, and as desired, flavor enhancers, edible plant-based liquid oils and other food ingredients combined and placed in a cylindrical shape for roasting vertically or horizontally.

Art. 4 – (1)(r) Döner: Made From Poultry Meat, the ready-to-cook poultry meat mixture arranged in cylinder form on a döner shish or the meat product cooked by rotating vertically or horizontally, prepared by addition to one of the raw poultry meats turned into sheets or a mixture thereof, of one or more of tail fat, jacket fat, flavors and other food ingredients combined and placed in a cylindrical shape for roasting vertically or horizontally.

Art. 4 – (1) (t) of the Communiqué concerning Meat and Meat Products (No: 2012/74) Köfte (Meat Ball): Ready-to-cook bovine or ovine red meat mixture or cooked meat product prepared in various ways by the addition, when desired, of one or a few of the fats of the same kind of animals and other flavors to the mixture of raw red meat.”).

(<sup>19</sup>) Akçaabat is a town in the city of Trabzon in the Black Sea region of Turkey.



tection of GIs intended to (1) protect consumers allowing them to make informed choice while (2) limiting unfair competition. These main considerations are undermined by the fact that the competing frameworks give room for arbitrariness to regarding which conventional food/generic products are named a “traditional food” and/or receive GI protection.

The “traditional food” concept is closely related to cultural identity and heritage, which make it a rather complex concept and beyond basic perception. It is very difficult to draw the dividing line between traditional food and non-traditional/conventional food using the definitions in the mentioned legislations and the Ministry’s list alone. Developing parallel conceptual “general” models within different governmental organizations, as has occurred in Turkey between the TPI and the Ministry, can substantially and subtly change the functionality of the enforcement effect and

value of the GIs protection. Turkey should facilitate the protection of GIs by establishing improved quality control mechanisms and clearer product specifications.

## **ABSTRACT**

*The article evaluates the existing legal framework of the protection of traditional foods by geographical indications in Turkey and criticizes the possible consequences of the Turkish Food Codex Regulation on Food Additives Annex VI- a list of unilaterally determined traditional foods chosen by the Ministry of Food, Agriculture and Livestock without objective criteria about the specific characteristics of these products. The Ministry’s generalized policy towards traditional foods raises legal concerns because it could undermine the objective of geographical indications protections.*



## Ricerche

### China's Food Safety Law and its Ongoing Amendment

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#### 1.- Introduction

Beginning in the 1990s, rapid urbanization and industrialization have dramatically changed the food system in China. Low levels of governmental control and a set of poorly-coordinated food safety standards have contributed to food safety incidents, including the melamine crisis and its worldwide impacts.<sup>1</sup>

In February of 2009, China responded to this serious situation by enacting the *Food Safety Law of 2009* (hereafter "FSL"),<sup>2</sup> replacing the outdated *Food Hygiene Law of 1995* (hereafter "FHL").<sup>3</sup> The biggest changes in the new law are the adoption of a risk-based approach, the unification of food safety standards, more stringent legal liability, and the clarification of administrative authority. Having found industry efforts at self-regulation unavailing, the FSL now requires greater government oversight of the food market.

Since the enactment of the FSL, progress has been made towards establishing widespread sites for risk monitoring and standardizing the then extant 5,000 standards into a unified system of 1,000 food safety standards,<sup>4</sup> though the situation is still serious as evidenced by the numerous food safety incidents in recent years. In July of 2014, Shanghai Fuxi Company, supplier of many international restaurant

giants such as McDonald's and KFC, was investigated for selling expired meat products.<sup>5</sup>

In 2013, China began to modify the FSL again, outlining what might be the strictest food safety law in the history of food regulation in China. The first draft of amendment was published on July 2, 2014 for comments, aiming to further tighten food safety rules not only by adding new provisions, but also by clarifying existing mechanisms and thus making the system more workable. The amendment process is underway and will be discussed in the following chapters.

To a large extent the continuous improvement of food safety regulation, through legislative reforms and the harmonization of primary food safety standards, can be seen both as a response to food safety concerns and also as an expression of the PRC's strong interest in accessing international markets. Chapter 2 will introduce the status quo of 's food safety legislation, in which the FSL functions as the fundamental law. Then Chapter 3 discusses the motivation for modifying the FSL, including its defects and disappointments. Chapter 4 relates the latest developments in the FSL's amendment and, correspondingly, Chapter 5 provides some key problems that remain to be solved in the amendment process.

#### 2.- The Status Quo of 's Food Safety Legislation

##### 2.1. Overview of Food Safety Legislation

China has built its food safety regulatory structure upon the FSL, which functions as the main legislation.<sup>6</sup>

(<sup>1</sup>) See Lu Xiaojing, *The Cause and Effect Analysis of the Melamine Incident in China*, 5 *Asian Journal of Agricultural Research* 3, 2011, pp. 176-185.

(<sup>2</sup>) *Food Safety Law of the PRC* (Promulgated by the 7th Session of 11th Standing Committee of National People's Congress of the PRC on February 28, 2009, effective on June 1, 2009), an English version by the United States Department of Agriculture (USDA) is available at: <http://apps.fas.usda.gov/gainfiles/200903/146327461.pdf> (accessed on November 17, 2014).

(<sup>3</sup>) *Food Hygiene Law of the PRC* (Promulgated by the 16th Session of 8th Standing Committee of National People's Congress of the PRC on October 30, 1995, effective on October 30, 1995, expired on June 1, 2009).

(<sup>4</sup>) National Health and Family Plan Committee (NHFP), *Progress of work on food safety standards in 2013* (January 10, 2014), available at: <http://www.nhfp.gov.cn/sps/s3594/201401/b200e87c56b84824a2a9a76b759b8cb3.shtml>.

(<sup>5</sup>) See Chinasmack.com news, *McDonald's & KFC Meat Supplier Exposed Reusing Expired Meat* (July 21, 2014), available at: <http://www.chinasmack.com/2014/videos/mcdonalds-kfc-meat-supplier-exposed-reusing-expired-meat.html>.

(<sup>6</sup>) *Food Safety Law*, art. 1.

In addition to the FSL, China has adopted the *Agricultural Products Quality and Safety Law* of 2006,<sup>7</sup> governing raw agriculture production, and the *Animal Husbandry Law* of 2005,<sup>8</sup> governing the slaughter of livestock. These laws are supported by administrative regulations and policies promulgated by the State Council and relevant ministry-level departments at the national level, such as the regulation of pesticides by the Ministry of Agriculture (hereafter “MOA”) and the regulation of food additives by the Ministry of Health (hereafter “MOH”).

## 2.2. The FSL as the Main Legislation

### 2.2.1. The FSL’s Regulatory Framework

The FSL’s regulatory framework consists of three main components: risk-based analysis, the National Food Safety Standards (hereafter “NFSS”), and the licensing system.

The FSL uses risk-based analysis to track problems and make decisions regarding the likelihood and severity of threats. Typically, food safety risk analysis consists of three stages – risk assessment, risk communication and risk management. Under the FSL, a risk monitoring stage is added before risk assessment.<sup>9</sup> Risk monitoring indicates the long-term tracking of data concerning foodborne illnesses, food pollutants and harmful substances contained in food.<sup>10</sup> To satisfy the needs of food safety risk assessment, NFSS enactment and food safety administration,<sup>11</sup> MOH, with other departments’ help, formulates and

implements National Food Safety Monitoring Plan (hereafter “NFSMP”),<sup>12</sup> which contains monitoring content, task division, work requirements, organizational guarantee, performance evaluation and so on.<sup>13</sup> If any possible food safety problem is discovered through risk monitoring, correspondent risk assessment must be conducted immediately<sup>14</sup>.

Risk assessment is carried out by the experts of a regular Evaluation Committee for Food Safety Risk Assessment (hereafter “ECFSRA”), established by the MOH, who conduct scientific analysis of food monitoring information, scientific data and other relevant information.<sup>15</sup> Although the FSL and its administrative regulations do not comprehensively define the concept of risk assessment, they do introduce and define the concepts of “hazard,” “hazard identification,” “hazard characterization,” “exposure assessment,” and “risk characterization.”<sup>16</sup> These are the principles and definitions according to which risk assessment is to be conducted.<sup>17</sup> Results of the risk assessment are used as the scientific basis for developing and modifying NFSS, as well as regulating food safety.<sup>18</sup>

Although general procedures for “risk communication” or “risk management” have not yet emerged, the determinations of the ECFSRA assist in other regulatory processes. For example, the MOH has enacted regulations that require that a risk assessment be performed before new food additives are approved or old food additives are approved for new uses.<sup>19</sup>

The FSL’s NFSS are a set of mandatory standards covering all aspects of food safety.<sup>20</sup> NFSS are applied in regulating food production, food trading, food inspection and other activities related to food safety.<sup>21</sup>

(7) Agricultural Product Quality and Safety Law of the PRC (promulgated by the 21st Session of 10th Standing Committee of National People’s Congress of the PRC on April 29, 2006, effective on November 1st, 2006).

(8) Animal Husbandry Law of the PRC (promulgated by the 19th Session of 10th Standing Committee of National People’s Congress of the PRC on December 20, 2005, effective on July 1, 2006).

(9) Food Safety Law, art. 11.

(10) Id.

(11) Administrative Provisions on Food Safety Risk Monitoring (for Trial Implementation) (promulgated by the State Food and Drug Administration on October 10, effective on October 10) (hereafter “APFSRM”), art. 9.

(12) Food Safety Law, art. 11.

(13) APFSRM, art. 5.

(14) Food Safety Law, art. 14.

(15) Food Safety Law, art. 13.

(16) John Balzano, *China’s Food Safety Law: Administrative Innovation and Institutional Design in Comparative Perspective*, 13 *Asian-Pacific Law and Policy Journal* 23, 2012, pp. 68-69.

(17) Id. p. 69.

(18) Food Safety Law, art. 16.

(19) John Balzano, *supra* note 14, p. 70.

(20) Food Safety Law, art. 19.

(21) Food Safety Law, art. 20.

The FSL requires the unification of all existing food safety standards under NFSSs.<sup>22</sup> NFSS are reviewed and approved by the Evaluation Committee for National Food Safety Standards (hereafter “ECNFSS”), which is composed of experts from relevant scientific fields.<sup>23</sup> In the absence of NFSS, a local food safety standard can be developed to satisfy local needs.<sup>24</sup> While local governments are not allowed to issue stricter or more relaxed food safety standards than NFSS, companies are encouraged to apply more stringent ones to themselves.<sup>25</sup>

When enacting NFSS, the ECNFSS shall consider results of food safety risk assessment, and refer to relevant international standards as well as results of international food safety risk assessment.<sup>26</sup> The FSL also requires food companies and consumers’ opinions to be taken into account during the enacting process, however, there are no specific procedural requirements implementing this principle.<sup>27</sup> After being enacted, NFSS are required to be published for free, but the FSL doesn’t specify how and where NFSS shall be published.<sup>28</sup>

Apart from complying with NFSSs and other specific requirements under the FSL, a licensing approach is employed to regulate food safety. Companies that want to run food production businesses, food distribution and food catering services must obtain separate licenses for each business activity beforehand.<sup>29</sup> Producers of food additives must also obtain licenses pursuant to relevant laws and regulations on industrial products.<sup>30</sup>

To acquire licenses for their businesses, food companies have to submit materials in pursuance to Section 1-4 of Article 27 of the FSL.<sup>31</sup> Responsible agencies at

county level or above are authorized to, on the basis of submitted materials and on-site inspection if necessary, decide whether to approve their applications.<sup>32</sup> If agencies refuse to grant licenses, they shall explain the reasons to applicants in written form.<sup>33</sup> There are no formal ways for stakeholders to take part in the decision process on their applications, and the decisions are not made by independent officials such as administrative law judge (ALJ) in the China. If stakeholders are dissatisfied with the final decisions, they can request for administrative reviews, or they can also file administrative lawsuits at courts directly.

In addition, health food that claim to have health functions (hereafter “health food”) are subject to strict regulation under the FSL, yet the FSL does not specify, inter alia, the rules for market entry of health food producers, delegating regulation of health food producers to the State Council.<sup>34</sup>

## 2.2.2 The FSL’s Administrative Framework

China’s administrative structure involves 33 province-level regions, 333 prefecture-level municipalities and 2,861 county-level municipalities.<sup>35</sup> National and local government authorities are designed to work in cooperation with one another on administrative issues.<sup>36</sup>

At the national level, the State Council established the Food Safety Committee to develop general strategy on dealing with food safety issues.<sup>37</sup> The MOH bears the responsibility for coordinating relevant departments’ work and carrying out risk assessments, working out NFSS, releasing food safety information and so on.<sup>38</sup> Other key departments include the State

<sup>(22)</sup> Food Safety Law, art. 22.

<sup>(23)</sup> Food Safety Law, art. 23.

<sup>(24)</sup> Food Safety Law, art. 24.

<sup>(25)</sup> Food Safety Law, art. 25.

<sup>(26)</sup> Food Safety Law, art. 20.

<sup>(27)</sup> Food Safety Law, art. 23.

<sup>(28)</sup> Food Safety Law, art. 26.

<sup>(29)</sup> Food Safety Law, art. 29.

<sup>(30)</sup> Food Safety Law, art. 43.

<sup>(31)</sup> Food Safety Law, art. 31.

<sup>(32)</sup> Id.

<sup>(33)</sup> Id.

<sup>(34)</sup> Food Safety Law, art. 51.

<sup>(35)</sup> See Office of the United Nations Resident Coordinator in China, *Advancing Food Safety in China* (March, 2008), p.12 available at [http://bepast.org/docs/china%20health/food%20safety/China%20and%20Food%20Safety\\_2008\\_UN.pdf](http://bepast.org/docs/china%20health/food%20safety/China%20and%20Food%20Safety_2008_UN.pdf).

<sup>(36)</sup> Jason J. Czarneski, Lin Yanmei & Cameron F. Field, *Global Environmental Law: Food Safety & China*, 25 *Geo. Int’l Env’tl. L. Rev.* 261, 2013, p. 277.

<sup>(37)</sup> Food Safety Law, art. 4.

<sup>(38)</sup> Id.



Administration on Quality Supervision, Inspection and Quarantine (hereafter “AQSIQ”), which is in charge of food production, the Food and Drug Administration (hereafter “FDA”), which is in charge of catering services, the State Administration for Industry and Commerce (hereafter “SAIC”), which is in charge of food distribution,<sup>39</sup> and the MOA, which regulates slaughtering<sup>40</sup> and agricultural products quality.<sup>41</sup>

At the local level, these administrations have parallel food control authorities reporting to the MOH, MOA, SAIC and AQSIQ in their respective jurisdictions.<sup>42</sup> Generally, these regulatory authorities are directly responsible to their correspondent level of government body but receive instructions of a regulatory or technical nature from the national agency.<sup>43</sup> Food safety laws and regulations provide these agencies with enforcement tools, including site inspections, samplings, and audits, and empower the agencies, upon finding violations, to seize illegal products, issue fines, revoke business licenses, and shut down the violators.<sup>44</sup>

### 2.2.3 The FSL’s Enforcement Framework

Violation of the FSL may result in administrative, civil, and/or criminal penalties. A consumer who has been harmed by food that does not conform to food safety standards can seek compensatory damages from a responsible producer or trader, as well as punitive damages up to 10 times of the food’s sale price.<sup>45</sup> In addition to civil liability, violators are also subject to administrative penalties in the form of fines, revocations of licenses, or cancellation of qualifications to engage in food inspection. For example, in violation of

the FSL upon occurrence of a food safety accident, violators who destroy evidence relating to such an accident, are subject to a fine in the amount of 2,000 to 100,000 RMB, and in the event of serious infractions, violators’ business licenses may be revoked.<sup>46</sup> In order to fully protect consumers’ interests, when violators’ assets are not sufficient to satisfy civil compensation awards and administrative fines, civil compensation awards have first priority.<sup>47</sup> To further deter potential violations, the FSL also emphasizes that any violation resulting in a crime should be prosecuted under corresponding criminal law provisions.<sup>48</sup>

Apart from these administration provisions and legal liability provisions in the FSL as set forth above, China also has general civil and administrative laws governing civil liability and administrative process. China’s *Tort Liability Law* of 2009 (hereafter “TLL”) prescribes that if defective products are knowingly sold to consumers and cause injury to health or result in death, the injured consumers have the right to sue responsible parties for damages.<sup>49</sup> Different from civil liability under the FSL, the TLL does not set an upper limit on damages and does not stipulate damages as a fixed multiple of a product’s price.<sup>50</sup> Consumers can also bring suits to seek judicial review of an administrative authority’s failure to take proper action under the *Administrative Litigation Law* of 1989.<sup>51</sup>

## 3.- The necessity of modifying the FSL

### 3.1. Improving but still precarious Food Safety

The FSL of 2009 was important to the regulation of the food industry and ensuring food safety in China.

<sup>(39)</sup> Id.

<sup>(40)</sup> Responsibility on regulating pig slaughtering has been transferred from Ministry of Commerce to MOA. See the State Council Plan on Institutional Reform and Functional Transformation of 2013 (ratified by the 1st Session of 12th National People’s Congress of the PRC on March 14, 2013), art.3, available at: <http://politics.people.com.cn/n/2013/0315/c1001-20796789.html>.

<sup>(41)</sup> Agricultural Product Quality and Safety Law, art. 3.

<sup>(42)</sup> Jason J. Czarnecki, Lin Yanmei & Cameron F. Field, *supra* note 36, p. 277.

<sup>(43)</sup> Id. p. 277.

<sup>(44)</sup> Id. p. 277.

<sup>(45)</sup> Food Safety Law, art. 96.

<sup>(46)</sup> Food Safety Law, art. 88.

<sup>(47)</sup> Food Safety Law, art. 97.

<sup>(48)</sup> Food Safety Law, art. 98.

<sup>(49)</sup> Tort Liability Law of the PRC (promulgated by 12th Session of 11st Standing Committee of National People’s Congress of the PRC on December 26, 2009, effective on July 1, 2010), art. 47.

<sup>(50)</sup> Id.

<sup>(51)</sup> Administrative Litigation Law of the PRC (promulgated by 2nd Session of 7th Standing Committee of National People’s Congress of the PRC on April 4, 1989, amended on November 1, 2014, effective on May 1, 2015).

Several measures have been taken to realize the objectives of the FSL.

Risk assessment of food safety has been strengthened. ECNFSS, ECFSRA and the National Center for Food Safety Risk Assessment (hereafter “CFSA”) have been set up as required in the FSL. The CFSA has been established to identify and monitor areas with high food safety risks. As of June of 2014, 2,100 county-level monitoring sites for food pollutants and harmful substances have been established, covering 90 percent of all prefecture-level cities. 1,600 hospitals have monitoring sites for foodborne illness, covering more than 30 categories and 600 varieties of food. So far more than 5.47 million pieces of data have been acquired.<sup>52</sup>

Regarding NFSS, as of June 11, 2014, MOH has sorted out about 5,000 existing standards regarding food safety, and has already promulgated 429 new NFSS to replace parts of them,<sup>53</sup> including safety standards for: dairy; pollutants, mycotoxins, pathogenic microorganisms and pesticide residues in food; food additives and nutritional supplements; food production and trade; pre-packaged food labeling; nutrition labeling; and relevant food standards, sanitary requirements for production and trade, as well as supporting test methods.<sup>54</sup> MOH projects that the 5,000 current standards will be integrated into about 1,000 new NFSS by the end of 2015.<sup>55</sup>

Another significant progress happens on the aspect of administrative authorities. In order to better supervise and manage the food industry and food markets, administrative authorities are transforming. In March of 2013, the China State Food and Drug Administration (CFDA) was established to integrate the regulatory responsibilities of four different departments, the Office of Food Safety Committee (OFSC), SAIC, AQSIQ, and FDA.<sup>56</sup> Since then, the CFDA has

been responsible for the regulation of food production, distribution, and catering service.<sup>57</sup> In this way, the CFDA bridges previously existing administrative gaps, and also unifies regulatory oversight into one regulatory body, simultaneously eliminating overlaps in administrative jurisdiction. In addition, it paves the way for more stringent oversight of food safety issues.

In spite of these efforts, serious food safety problems persist in China. Southern Weekend, one of China's most influential newspapers, produced a special report on food safety in China at the end of 2011 that listed many food safety scandals exposed by the media including cadmium polluted rice, excessive amounts of antibiotics residue in aquaculture seafood, waste oil, salted duck eggs containing cancer-causing dyes, contaminated pork, and dyed bread, to name a few.<sup>58</sup> After Southern Weekend concluded that 2011 was China's food safety crisis year, it declared “what can we safely eat today?” is a national question that ordinary people have to ask every day.<sup>59</sup>

China's 2011 food safety incidents fit into three categories: environmental degradation in farms, excessive use of chemicals in agriculture production, and economic adulteration of food products. “Gutter oil” is a typical example of economic adulteration of food products.<sup>60</sup> “Gutter oil” refers to edible oil of poor qualities, such as waste oil from restaurants and oil that has been used repeatedly. Long-time consumption of “gutter oil” may cause illness, even cancer, and severely harms human health. Experts speculate that, so far, about 2 million to 3 million tons of “gutter oil” return to people's dinner tables every year, and the total amount of cooking oil consumption is about 22.5 million annually, meaning that consumers may encounter “gutter oil” once every 10 meals.<sup>61</sup>

Food safety incidents caused by environmental degradation are also serious because China's current

<sup>(52)</sup> JSRB.com news, First Amendment of FSL Since 4 years Ago (June 19, 2014), available at: [http://news.jcrb.com/jxsw/201406/t20140619\\_1406289.html](http://news.jcrb.com/jxsw/201406/t20140619_1406289.html).

<sup>(53)</sup> NHFPC, Progress of work on food safety standards, risk monitoring and risk assessment (June 11, 2014), available at: <http://www.nhfpc.gov.cn/sps/s3594/201406/8a7e0c4656a242bfb33813a6966d90bc.shtml>.

<sup>(54)</sup> NHFPC, *Supra* note 4.

<sup>(55)</sup> *Id.*

<sup>(56)</sup> State Council Plan on Institutional Reform and Functional Transformation, *supra* note 40, art. 3.

<sup>(57)</sup> *Id.*

<sup>(58)</sup> Jason J. Czarneski, Lin Yanmei & Cameron F. Field, *supra* note 36, p. 279.

<sup>(59)</sup> *Id.* p. 279.

<sup>(60)</sup> *Id.* p. 279.

<sup>(61)</sup> Ifeng.com news, It is Speculated That “Gutter Oil” Amounts to 10 Percent of All Cooking Oil (September 21, 2011), available at: [http://news.ifeng.com/mainland/special/digouyou/content-3/detail\\_2011\\_09/21/9351892\\_0.shtml](http://news.ifeng.com/mainland/special/digouyou/content-3/detail_2011_09/21/9351892_0.shtml).

measures are not adequate to protect the safety of the farm environment. For example, Chinese rice is heavily contaminated with cadmium. Rice is a staple food for 65% of the population in China.<sup>62</sup> In February 2011, a Caixin investigative article revealed that approximately 10% of Chinese rice may be polluted by cadmium, a heavy metal discharged in mine and industrial waste-water that makes its way into rice paddies, according to scientific studies by major Chinese universities.<sup>63</sup> The reporter found that inhabitants in Side, located in Guangxi Province, who ate the local rice with cadmium levels far exceeding the permitted limit suffered similar unbearable pains in their feet.<sup>64</sup> Zhou Shengxian, the Minister of the Ministry of Environment (MEP), said, "It is estimated that nationwide 12 million tons of grain are polluted each year by heavy metals that have found their way into soil."<sup>65</sup>

The general public still has little confidence and trust in the safety of food products, either domestically within China or internationally. According to a survey of Chinese consumers' attitudes towards food safety issues, conducted between October and December of 2013 with more than 8,500 participants from 35 different cities in China, 46.7 percent of interviewees did not feel that food safety had improved, 1.8 percent thought the situation had improved significantly, and 5.5 percent even felt the situation had worsened.<sup>66</sup> In addition, nearly half of all interviewees were dissatisfied with government's work on food safety, and only 17.8 percent said that they were satisfied or relatively satisfied.<sup>67</sup>

### 3.2. Main defects of the FSL

Though it is widely agreed that the food safety situation would be much worse off without the FSL, the law is far from perfect. The FSL does not substantively change the long-existing, segmented regulatory sys-

tem, under which SAIC, AQSIQ and FDA are in charge of production, distribution and catering service, respectively.<sup>68</sup> This design has long been criticized as causing disorder in supervision and management, as well as a lack of accountability.<sup>69</sup> In light of this fact, as introduced above, responsibilities of these three departments have been integrated into a new CFDA. In confirming this change by legislation, The FSL should be modified to formally authorize the CFDA to perform these functions. More importantly, to take full advantage of the new department's capacity, a more comprehensive and rigorous system should be built up to regulate upstream, midstream, and downstream activities of the food supply chain – from production, to distribution, to catering service.

Secondly, legal liability as provided for in the FSL is not severe enough to deter illegal behavior. The FSL limits punitive damages to 10 times the amount of the food's sale price; however, food prices are usually so low that the harm caused by the violation is disproportionate to the damages obtainable. Therefore, in order to effectively deter food companies from violating NFSS, some scholars suggest raising standards or even canceling the punitive damages cap, while others suggest relating the amount of punitive damages to the cost of harm.<sup>70</sup> In addition, some scholars argue that punitive damages should not require a showing of harm. In practice, while some court grants grant punitive damages absence harm, other courts require such a showing.<sup>71</sup>

While strengthening legal liability can help to avoid traditionally human-induced risks such as adulterated food, it is not equally useful in handling uncertain risks derived from developments in food science and technology, such as GM food, which could cause catastrophic outcomes if issues were to arise. As uncertain risks become increasingly salient in Chinese society, core regulatory processes should be placed upstream

<sup>(62)</sup> Jason J. Czarnecki, Lin Yanmei & Cameron F. Field, *supra* note 36, p. 279.

<sup>(63)</sup> *Id.* p. 279.

<sup>(64)</sup> *Id.* p. 279.

<sup>(65)</sup> *Id.* p. 280.

<sup>(66)</sup> See Shanghai Jian Tong University & Social Science Academic Press, 2014 China Livelihood Report (May, 2015), an excerpt is available at: <http://shipin.people.com.cn/n/2014/0516/c85914-25025624.html>.

<sup>(67)</sup> *Id.*

<sup>(68)</sup> Food Safety Law, art. 4.

<sup>(69)</sup> Qiao Hu, A Research on Regulatory Competence Loopholes in the Food Safety Law in China, 6 *Journal of Zhejiang University (Humanities and Social Sciences)* 82, 2013, pp.82-94.

<sup>(70)</sup> Jianghong Zhou, Suggestion for Modifying Article 90 of Draft Food Safety Law, 6 *Law* 137, 2008, pp.137-142.

<sup>(71)</sup> *Id.*

to eliminate these risks before they become material.<sup>72</sup> In response to this need, the FSL has a chapter dedicated to risk monitoring and risk assessment, requiring NFSS to be determined on the basis of risk assessment.<sup>73</sup> However, the provisions on risk monitoring are too general to be workable, and there is insufficient detail in the provisions regarding the connection between risk monitoring and risk assessment. In addition, risk information is not sufficiently communicated between government and the public, which obstructs public participation in the process.

Furthermore, the regulatory framework should be modernized to incorporate more stakeholders, including consumers, consumers associations, food industry, industry associations, news media and other stakeholders. Under the FSL, government's increased responsibility for supervising the food industry represents an important transformation in food safety policies, as well as a recognition of food companies' failure to self-regulate and ensure consumer trust. Five years later, companies are still not conscientious enough, and, at the same time, the public has begun to question government's competency to regulate food safety. Due to the inherent risks in a highly-dispersed food industry with numerous food varieties, the budget required for government to regulate the food market is huge, and past experience proves the consequences are not as desirable as expected. Food safety cannot be achieved by solely relying on "production" and "regulation," but also by relying on "consumption." Great public participation, in the form of information sharing and resulting purchasing decisions, should be sought to work alongside government.

Finally, the FSL should be modified to be more responsive to Chinese social conditions. In recent years China has witnessed continuously high risks and intense public concern for infant food, health food and centralized dining places. In response, the FSL should identify high-risk fields and strengthen their regulatory controls. Moreover, since the FSL was enacted five years ago, some new social conditions have arisen, bringing unexpected challenges to food safety regula-

tion. The most prominent change is the rapid development of online food transactions. In 2006, only 50 billion RMB's worth of transactions happened on the internet,<sup>74</sup> whereas in 2013 total volume of online retail sales in China reached more than 1,850 billion RMB, with year-on-year growth of 41.2 percent, causing China to become the biggest online retail market in the world.<sup>75</sup> In 2013, the total value of online food transactions reached 32.4 billion RMB, an increase of 47.9 percent on the amount from 2012.<sup>76</sup> As e-commerce develops rapidly, legal issues – such as the allocation of responsibility amongst online platform providers, food traders and food producers – should be clarified to prevent potential disputes.

#### *4.- The latest developments in the FSL Amendment*

##### *4.1. A brief introduction of ongoing legislative procedure*

In May of 2013, the State Council listed amendment of the FSL in its annual legislation agenda, and delegated CFDA to take the lead in the amendment process. In October of 2013, the CFDA submitted a draft of amendment of Food Safety Law to the State Council. Since then, the Office of Legal Affairs of the State Council (OLA) has asked for the opinions of relevant regulatory departments, local governments and industry associations, and has received more than 5600 comments from the public, conducted field investigations in 5 provinces and cities, and held meetings with companies, industry associations and experts on numerous occasions, all along compiling different departmental opinions. On the basis of these efforts, a revised version of the draft came out after the OLA repeatedly consulted with relevant departments such as the CFDA, NHFPC, AQSIQ, MOA and the Ministry of Industry and Information Technology. The 47<sup>th</sup> Executive Meeting of the State Council passed the draft and it was subsequently published for comments. In June of 2014, the 9<sup>th</sup> Session of the 12<sup>th</sup> Standing

<sup>(72)</sup> Xu Jiusheng & Gao Zhennan, Criminal Law System and Food Safety in Risk Society: Amendment of Criminal Law Amendment VIII, 5 Journal of Southeast University (Philosophy and Social Science) 81, 2013, pp. 81-91.

<sup>(73)</sup> Food Safety Law, chapter 2.

<sup>(74)</sup> See Chinamrn.com news, 2013 China E-Commerce Transaction Volume Goes beyond 10,000 Billion RMB (March 10, 2014), available at: <http://www.chinamrn.com/data/20140310/14731.html>.

<sup>(75)</sup> See mofcom.gov.cn news, 2013 E-Commerce Transaction Volume Reach beyond 10,000 Billion RMB (May 30, 2014), available at: <http://www.mofcom.gov.cn/article/difang/im/201405/20140500608068.shtml>.

<sup>(76)</sup> See ebrun.com news, 2013 Food E-Commerce Transaction Volume Reach 32.4 Billion RMB with a Year-on-Year Growth of 47.9 Percent (December 26, 2013), available at: <http://www.ebrun.com/20131226/88682.shtml>.



Committee of the NPC reviewed the draft for the first time. On July 2, the first version of the draft was published on the official website of the NPC ([www.npc.gov.cn](http://www.npc.gov.cn)) for comments (hereafter “Draft Amendment I”).<sup>77</sup> According to the requirements of the *Legislation Law* of 2000 and the legislative agenda of the Standing Committee of the NPC,<sup>78</sup> the Draft Amendment I is likely to be reviewed another two times in the future, and will also be publicly announced for comments twice.

In December of 2014, the Draft Amendment I was reviewed by the 12<sup>th</sup> Session of the 12<sup>th</sup> Standing Committee of the NPC again and after the review, a new version of the draft was published on the same website for comments (hereafter “Draft Amendment II”).<sup>79</sup> The Draft Amendment II basically maintained the principles underlying the first amendment, but adjusted and added several provisions to make the law become more comprehensive, workable and concise. Introduction to the amendment in the following pages will be generally arranged according to the Draft Amendment I, content of the Draft Amendment II will be provided at where it substantively changes the existing FSL or the Draft Amendment I.

#### 4.2. Principles underlying this Amendment

The amendments is built on the principle of “establishing the strictest food safety regulation system”, which was initiated by the Chinese Communist Party (hereafter “CCP”) during the Third Plenary Session of the 18<sup>th</sup> CCP Congress and which encompassed: strengthening rules on prevention priority and precau-

tion; establishing stringent rules for ‘whole-process’ regulation; establishing stringent rules on legal liability; and promoting cooperative governance between government and society.<sup>80</sup> Before discussing in detail how these general ideas are reflected in the Draft Amendment I and the Draft Amendment II, for the sake of clarity, changes to the food safety administrative system are introduced first.

The food safety administrative system was reformed in parallel with the changes in March of 2013 as introduced above. Unlike the segmental system under the FSL, responsibilities for regulating food production,<sup>81</sup> food trading activities and catering services are centralized under the CFDA<sup>82</sup> since then. In addition, the daily work of the Food Safety Committee is undertaken by the CFDA.<sup>83</sup> The National Health and Family Planning Commission (hereafter “NHFP”) under the State Council, in accordance with the FSL and the responsibilities delegated by the State Council, is set up to take over MOH’s all responsibilities on food safety, including organizing food safety risk monitoring and risk assessment, as well as developing and publishing NFSS.<sup>84</sup>

#### 4.3. Strengthening Rules on Prevention Priority and Precaution

Strengthening rules on prevention priority and precaution means “progressively improving basic systems such as food safety risk monitoring, risk assessment and NFSS, eliminating risks before they come into being”.<sup>85</sup>

The Draft Amendment I strives to perfect risk monitoring and risk assessment. To ensure consistency

(77) The text of the Draft Amendment I is available at: [http://www.npc.gov.cn/npc/xinwen/lfgz/flca/2014-06/30/content\\_1869695.htm](http://www.npc.gov.cn/npc/xinwen/lfgz/flca/2014-06/30/content_1869695.htm), an English version by (United States Department of Agriculture) USDA is available at: [http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20Safety%20Law%20%28Draft%20for%20Public%20Comments%29\\_Beijing\\_China%20-%20Peoples%20Republic%20of\\_7-21-2014.pdf](http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20Safety%20Law%20%28Draft%20for%20Public%20Comments%29_Beijing_China%20-%20Peoples%20Republic%20of_7-21-2014.pdf).

(78) Legislation Law of the PRC (promulgated by the 3rd Session of 9th National People’s Congress of the PRC on March 15, 2000, effective on July 1, 2000).

(79) The text of the Draft Amendment II is available at: [http://www.npc.gov.cn/npc/xinwen/lfgz/flca/2014-12/29/content\\_1891935.htm](http://www.npc.gov.cn/npc/xinwen/lfgz/flca/2014-12/29/content_1891935.htm), an English version by USDA is available at: [http://gain.fas.usda.gov/Recent%20GAIN%20Publications/China%20Publishes%20Food%20Safety%20Law%20\(Second%20Draft%20for%20Public%20Comments\)\\_Beijing\\_China%20-%20Peoples%20Republic%20of\\_1-12-2015.pdf](http://gain.fas.usda.gov/Recent%20GAIN%20Publications/China%20Publishes%20Food%20Safety%20Law%20(Second%20Draft%20for%20Public%20Comments)_Beijing_China%20-%20Peoples%20Republic%20of_1-12-2015.pdf).

(80) 12th Standing Committee of National People’s Congress of PRC, Explanation of Draft Amendment I of Food Safety Law (March 30, 2014), available at: [http://www.npc.gov.cn/npc/xinwen/lfgz/flca/2014-06/30/content\\_1869695.htm](http://www.npc.gov.cn/npc/xinwen/lfgz/flca/2014-06/30/content_1869695.htm).

(81) Food Safety Law, art. 4.

(82) Draft Amendment I of FSL, art. 5.

(83) Id.

(84) State Council Plan on Institutional Reform and Functional Transformation, *supra* note 40, art. 2 & art. 5.

(85) 12th Standing Committee of National People’s Congress of PRC, *Supra* note 81.

between the national risk monitoring plan and local risk monitoring plans, local governments at the provincial level are required to file their records at the NHFPC.<sup>86</sup> In response to information regarding food-borne illness and food poisoning reported by medical institutions, the national risk monitoring plan may be adjusted if necessary.<sup>87</sup> If the national plan on risk monitoring is adjusted, local plans must be accordingly revised based on local conditions.<sup>88</sup> To ensure the plans are effectively implemented, scientific organizations charged with risk monitoring must work according to plans and comply with the work rules promulgated by the NHFPC.<sup>89</sup>

Furthermore, six situations under which risk assessment must be conducted appear in the Draft Amendment I:<sup>90</sup> (1) food safety risk monitoring or report reveal possible safety problem for food, food additives, and food related products; (2) the need to provide a scientific basis for developing or revising national food safety standards; (3) the need to identify prioritized area or (food) variety in regulatory work; (4) discovered factors that may cause harm to food safety; (5) the need to judge whether a factor constitutes a food safety risk; and (6) other situations that the NHFPC deems necessary to conduct risk assessment.

The Draft Amendment I establishes a more comprehensive framework for risk communication than the one established under the FSL. In contrast to the limited communication of risks between departments of the State Council required by the FSL, the Draft Amendment I requires risk communication involving a wide variety of entities, including communication between the central government and local governments, communication between government and the public, as well as communication between govern-

ment and food producers, food traders, food industry associations, scientific organizations, consumer associations and news media.<sup>91</sup> Principles of science, objectivity, timeliness and openness should be applied in the process of risk communication.<sup>92</sup>

The Draft Amendment I tries to promote the process of integrating existing standards into NFSS. It explicitly requires relevant departments to actively support the NHFPC's work on NFSS.<sup>93</sup> In contrast to the language of "MOH *shall* integrate existing standards into NFSS" under the FSL,<sup>94</sup> the Draft Amendment I stipulates "NHFPC *shall accelerate* to integrate existing standards in to NFSS".<sup>95</sup> Nevertheless, according to the latest project, the integration work is likely to be accomplished by the end of 2015, thus the whole provision on NFSS integration disappears in the Draft Amendment II, but the importance and urgency of this work is clear. In addition, the Draft Amendment I clearly specifies the relationship between NFSS and local food safety standards. Before NFSS are enacted, local governments can determine their own standards pursuant to the FSL and must file with the NHFPC. These local standards are automatically repealed after corresponding NFSS are enacted.<sup>96</sup>

In order to enhance public participation and improve the scientific bases and practicability of NFSS, the Draft Amendment I requires the NHFPC to publish a draft of NFSS and solicit comments from the public.<sup>97</sup> In contrast with the ECNFSS under the FSL, which only consists of scientists and departmental representatives,<sup>98</sup> the ECNFSS under the Draft Amendment I also incorporates representatives of food industry and consumer associations.<sup>99</sup> To ensure that NFSS are updated to reflect evolving standards and situations, the Draft Amendment I requires NFSS and local food safety standards to be tracked and assessed, so that

<sup>(86)</sup> Draft Amendment I of FSL, art. 14.

<sup>(87)</sup> Draft Amendment I of FSL, art. 15.

<sup>(88)</sup> Id.

<sup>(89)</sup> Draft Amendment I of FSL, art. 16.

<sup>(90)</sup> Draft Amendment I of FSL, art. 19.

<sup>(91)</sup> Draft Amendment I of FSL, art. 21,23,24.

<sup>(92)</sup> Draft Amendment I of FSL, art. 24.

<sup>(93)</sup> Draft Amendment I of FSL, art. 29.

<sup>(94)</sup> Food Safety Law, art. 22.

<sup>(95)</sup> Draft Amendment I of FSL, art. 29.

<sup>(96)</sup> Draft Amendment I of FSL, art. 31.

<sup>(97)</sup> Draft Amendment I of FSL, art. 30.

<sup>(98)</sup> Food Safety Law, art. 23.

<sup>(99)</sup> Draft Amendment I of FSL, art. 30.

adjustments may be made accordingly.<sup>100</sup> In fact, such work is already being conducted by NHFPC without the FSL's requirement.<sup>101</sup>

#### 4.4. Setting up the strictest rules for 'Whole-Process' regulation

The strictest rules for 'whole-process' regulation indicates "for all activities concerning food safety including production, distribution and catering service, and items pertinent to food production and trade such as food additives and food related products, the FSL shall pointedly complement and strengthen relevant rules, raise standards and enhance the scope of regulation".<sup>102</sup>

Food producers and traders should be assigned with the primary responsibility for food safety.<sup>103</sup> In light of this view, the Draft Amendment I adds some provisions to compel food production companies to set up a more stringent quality control system. The Draft Amendment I requires companies to establish and conduct tests on raw materials as well as institute production processes safety management, storage management, facility management, disqualified products management and other food safety management systems.<sup>104</sup> For infant formula food, regulation of food production is especially stringent. In addition to complying with the requirements above, each batch of infant formula products exiting the factory must be inspected, infant formula food producers must report the raw materials used in the production process as well as the product formulas and labels to the provincial food and drug administrations for recording, and infant formula foods are not allowed to be produced by means of sub-contracting, OEM, or sub-packaging.<sup>105</sup>

With regards to distribution, on the basis of requiring

food producers and traders to examine their supply and keep records of the suppliers, the Draft Amendment I includes new provisions that subject wholesale traders and third-party-online-food-trading platforms (hereafter "TPOFTP") to regulatory oversight. Food traders engaged in wholesale business must accurately record buyers' information.<sup>106</sup> TPOFTP must require real-name registration of food traders that use the platform and examine their licenses if required, they shall stop and report traders' violation of the FSL in a timely manner, and they are obligated to provide information of traders to consumers if the consumers' interests are harmed.<sup>107</sup> In order to fully protect consumers, TPOFTP must compensate consumers in the event that they are unable to provide the valid information of the traders, and they must assume joint liability if they fail to perform their duties as set forth above and cause harm to consumers' legitimate interests.<sup>108</sup>

Regarding catering services, the Draft Amendment I primarily adds two articles for catering service providers and entities providing centralized dining such as schools. Catering service providers must develop and implement raw materials purchasing guidelines, and they must not purchase raw materials that fail to comply with food safety standards.<sup>109</sup> Entities that have cafeterias and provide centralized dining, such as schools, kindergartens and construction sites, must strictly abide by the applicable laws, regulations and food safety standards, to ensure food safety.<sup>110</sup> If such entities order food from third parties, they must order food from enterprises that have obtained food production and trade licenses, and these third-party food providers must process foods when ordered, and ensure that the food is safe and complies with nutrition requirements.<sup>111</sup>

While the Draft Amendment I strengthened regulation

<sup>(100)</sup> Draft Amendment I of FSL, art. 34.

<sup>(101)</sup> NHFPC, Food Department of NHFPC Held A Seminar on Track and Assessment of Food Safety Standards (October 20, 2014), available at: <http://www.nhfpc.gov.cn/sps/s3594/201410/e86efe58f8e24b4b9c32ef3fd58152c2.shtml>.

<sup>(102)</sup> 12th Standing Committee of National People's Congress of PRC, *Supra* note 56.

<sup>(103)</sup> Kai Ma, State Councilor and Secretary-General of the State Council, Explanation of the State Council Plan on Institutional Reform and Functional Transformation (March 10, 2013), available at: [http://news.xinhuanet.com/2013lh/2013-03/10/c\\_114969788.htm](http://news.xinhuanet.com/2013lh/2013-03/10/c_114969788.htm).

<sup>(104)</sup> Draft Amendment I of FSL, art. 42.

<sup>(105)</sup> Draft Amendment I of FSL, art. 69.

<sup>(106)</sup> Draft Amendment I of FSL, art. 50.

<sup>(107)</sup> Draft Amendment I of FSL, art. 73.

<sup>(108)</sup> *Id.*

<sup>(109)</sup> Draft Amendment I of FSL, art. 54.

<sup>(110)</sup> Draft Amendment I of FSL, art. 70.

<sup>(111)</sup> *Id.*

on food producers' and traders' activities concerning food safety, the amended law still didn't speak clearly on whether some activities that may affect food safety but are not conducted by food producers and traders are regulated under this law. For instance, food storage, transportation and loading service offered by some specialized companies. In light of this concern, the Draft Amendment II explicitly says that such activities are covered<sup>112</sup> and prescribes food safety requirements for them.<sup>113</sup>

Edible agricultural product safety is the prerequisite of food safety. Because use of high-poison pesticide has seriously impacted food safety situation, it must be strictly restricted. However, it is still not feasible to completely eliminate all use of high-poison pesticide, because there are no effective low-poison substitutes and they should be reserved for explosive pest attack,<sup>114</sup> thus the Draft Amendment II adopts mild words to encourage use of effective low-poison pesticide and accelerate to eliminate high-poison pesticide.<sup>115</sup> To reduce pesticide's impact on food safety as far as possible, the Draft Amendment II further stipulates the way that pesticide should be used in the process of agricultural product production.<sup>116</sup> In addition, in comparison to the ambiguity under the Draft Amendment I on whether circulation of edible agricultural products is regulated by the FSL, the Draft Amendment II explicitly confirms this regulation.<sup>117</sup>

In order to strengthen the accountability of food market participants, food traceability systems are to be established according to the Draft Amendment I.<sup>118</sup> Food producers must check the licenses of suppliers and the compliance certificates of products when purchasing raw food materials, food additives, and food related products.<sup>119</sup> Food producers must also establish a pur-

chase inspection and recording system for food raw materials, food additives, and food related products, and must record supplier information.<sup>120</sup> Food producers are required to keep inspection records for outgoing food and accurately record purchaser information.<sup>121</sup> Similarly, food traders must also establish an inspection and recording system, and accurately record the information of suppliers and the buyers.<sup>122</sup>

In response to some high-risk areas regarding food safety, the Draft further strengthens regulatory controls. In addition to stricter regulation on infant food production as discussed above, the Draft Amendment I also sets new requirements for food additives and food-related products. While the FSL had already adopted a licensing system for the production of food additives,<sup>123</sup> the Draft Amendment I specifies the application procedures for production licenses, and it also requires food additive traders to inspect licenses and record supplier information to support the traceability of food additives.<sup>124</sup> As for food-related products, the Draft Amendment I requires such products to meet relevant food safety standards, and high-risk, food-related products, such as food packaging materials, are subject to the licensing requirements of applicable industrial products licensing laws as well as the oversight of quality supervision authorities.<sup>125</sup>

In addition, health food are strictly regulated under the Draft Amendment I. Raw materials for health food production must be safe and harmless to human health, only the kinds incorporated in a catalog published by the government can be used and their use cannot exceed certain levels.<sup>126</sup> The health function claimed by the health food producer must have a scientific basis.<sup>127</sup> For health food that use new materials and

<sup>(112)</sup> Draft Amendment II of FSL, art. 2.

<sup>(113)</sup> Draft Amendment II of FSL, art. 32.

<sup>(114)</sup> 12th Standing Committee of National People's Congress of PRC, Explanation of Draft Amendment II of Food Safety Law (December 30, 2014), available at: [http://www.npc.gov.cn/npc/lfzt/spaqfxd/2014-12/30/content\\_1892288.htm](http://www.npc.gov.cn/npc/lfzt/spaqfxd/2014-12/30/content_1892288.htm).

<sup>(115)</sup> Draft Amendment II of FSL, art. 11.

<sup>(116)</sup> Draft Amendment II of FSL, art. 48.

<sup>(117)</sup> Draft Amendment II of FSL, art. 2.

<sup>(118)</sup> Draft Amendment I of FSL, art. 45.

<sup>(119)</sup> Draft Amendment I of FSL, art. 46.

<sup>(120)</sup> Id.

<sup>(121)</sup> Draft Amendment I of FSL, art. 47.

<sup>(122)</sup> Draft Amendment I of FSL, art. 49 & 50.

<sup>(123)</sup> Food Safety Law, art. 43.

<sup>(124)</sup> Draft Amendment I of FSL, art. 56.

<sup>(125)</sup> Draft Amendment I of FSL, art. 62.

<sup>(126)</sup> Draft Amendment II of FSL, art. 70.

<sup>(127)</sup> Draft Amendment I of FSL, art. 65.



health food that are imported for the first time, their producers and importers must register them with the CFDA.<sup>128</sup> Health food imported for the first time are subject to filing, and do not require registration if the safety and health function of the food's ingredients and materials could be assessed through general requirements (i.e. national standards and regulations) China.<sup>129</sup> The Draft Amendment II specifies that only health food that are used to supplement nutrients such as vitamins and minerals can be subject to filing and do have to be registered.<sup>130</sup> Compared to applicants for registration, applicants do not have to get permission prior to marketing for filing, which also requires submission of less information.

Remarkably, the Draft Amendment II for the first time stipulates that food producers and traders should label their GM food according to law.<sup>131</sup> At present, GM food labeling mainly applies a State Council's rule on Agro-GMO.<sup>132</sup> Because of the lack of law specialized on GM food labeling, practical situation of GM food labeling is far from satisfying. This new provision in the Draft Amendment II confirms the mandate of GM food labeling at the legislation level, and also provides for correspondent legal liability for violating this requirement.<sup>133</sup> It is likely that more detailed and specialized rules will be promulgated at the administrative level and their enforcement will be strengthened.

#### 4.5. Establishing the strictest rules for Legal Liability

The strictest rules on legal liability refers to "the adoption of comprehensive administrative, civil, and criminal liability; the imposition of the harshest punishments on illegal producers and traders; holding incompetent local governments and regulatory department

accountable; and imposing the strictest liability on inspection institutions found to be in violation of applicable laws".<sup>134</sup>

Liability for civil damages is strengthened under the Draft Amendment I. The FSL ambiguously stipulates that consumers can request compensation from traders or producers for harms caused by food that does not meet food safety standards.<sup>135</sup> In practice, difficulty in determining whether the producer or the trader is the responsible party usually leads to consumers' inability to obtain timely and adequate compensation. In light of this fact, the Draft Amendment I proposes holding producers and traders jointly and severally liable.<sup>136</sup> The Draft Amendment II further prescribes that who knowingly provides places or other conditions for illegal food production and operation activities shall also bear joint and several liability.<sup>137</sup>

In addition, in order to violators from hiding assets or dissolving before a lawsuit can be brought, the Draft Amendment I explicitly permits consumers to apply for property preservation in accordance with the Civil Procedure Law.<sup>138</sup>

The provision on punitive damage is also revised to be more effective in punishing responsible producers or traders and deterring them from violating food safety laws and standards in the future. While the FSL limits punitive damages to 10 times the product's sale price, which is widely criticized as being too lax to deter violations, the Draft Amendment I grants consumers the alternative to request a payment amounted to three times of the loss resulted from the harm.<sup>139</sup> The Draft Amendment II adds that if the amount of punitive damage is less than RMB 1,000, the amount shall be RMB 1,000, and exempts the food producers and traders, who use illegal food labels which has nothing to do with food safety, from taking punitive damage liability.<sup>140</sup>

<sup>(128)</sup> Draft Amendment I of FSL, art. 66.

<sup>(129)</sup> Id.

<sup>(130)</sup> Draft Amendment II of FSL, art. 71.

<sup>(131)</sup> Draft Amendment II of FSL, art. 64.

<sup>(132)</sup> Agro-GMO refers to GM animals, plants, microorganisms and their products used in agricultural production or agricultural products procession. This definition is from Regulation on Agro-GMO Biosafety Management (promulgated by the State Council on May 23, 2001, effective on May 23, 2001), available at <http://vip.chinalawinfo.com/newlaw2002/slc/slc.asp?db=chl&gid=35608>.

<sup>(133)</sup> Draft Amendment II of FSL, art. 116.

<sup>(134)</sup> 12th Standing Committee of National People's Congress of PRC, supra note 81.

<sup>(135)</sup> Food Safety Law, art. 96.

<sup>(136)</sup> Draft Amendment I of FSL, art. 138.

<sup>(137)</sup> Draft Amendment II of FSL, art. 113, 114, 128, 129.

<sup>(138)</sup> Id.

<sup>(139)</sup> Id.

<sup>(140)</sup> Draft Amendment II of FSL, art. 138.

The Draft Amendment I also strengthens administrative liability. It achieves this goal by three primary avenues: explicitly stipulating the circumstances under which licenses must be suspended; increasing the cap for fines; and explicitly stipulating the circumstances under which licenses for food inspection may be permanently revoked. For actions such as the production of food with non-food raw materials, chemical substances other than food additives, substances that may cause harm to human health, or recovered food, the FSL requires a finding of “serious circumstances” as a prerequisite for license suspension.<sup>141</sup> The Draft Amendment I eliminates this prerequisite.<sup>142</sup> In addition, for the above actions, the FSL stipulates a fine up to 10 times the products’ value,<sup>143</sup> whereas the Draft Amendment I enhances the maximum to 30 times the products’ value.<sup>144</sup> Under the FSL, any food inspection personnel issuing false inspection reports in violation of the FSL shall, if he/she has been subject to criminal prosecution or removed from office or dismissed, be prohibited from any food inspection work within ten years,<sup>145</sup> whereas such food inspection staff will be prohibited from engaging in any food inspection work for life under the Draft Amendment I.<sup>146</sup>

In addition to civil liability and administrative liability for market participants, liability for food regulators and local governments is strengthened and clarified under the Draft Amendment I. While the FSL provides that local governments and food regulators must be punished for violating their responsibilities under the FSL, it does not specify what kinds of punishment may be applied to what kinds of violations.<sup>147</sup> The Draft Amendment I fills in this gap by adding five articles.<sup>148</sup> For instance, if local governments delay, conceal, or falsely report food safety incidents, both the government officials that bear responsibility and the executives directly responsible must be punished by record-

ing a special demerit against them. For serious cases, they shall be demoted or removed from office and when severe consequences occur, key persons in charge of the government must admit responsibility and resign.<sup>149</sup>

Regarding criminal liability, the Draft Amendment I makes it clear that if the behavior constitutes a crime, the person, including the food producer, food trader, food inspector and food regulator, shall be prosecuted for criminal responsibility under *Criminal Law* of 1979 (Amended on Feb. 25, 2011).<sup>150</sup>

#### 4.6. Promoting Cooperative Governance between Government and Society

As set forth above, public participation in food safety regulation is enhanced by way of risk communication. In addition, other provisions are added to promote cooperative governance between government and society.

Firstly, people are incentivized to report violations to the FSL through monetary awards. Food and drug regulatory departments and quality supervision departments at the county level or above are required to publish their email or telephone numbers for inquires, complaints and reports.<sup>151</sup> Awards will be granted to people whose submitted reports are verified to be true.<sup>152</sup> In order to protect reporters from being revenged by reported companies, the Draft Amendment II further stipulates that reporters’ personal information must be kept classified, and their legitimate rights and benefits must be protected.<sup>153</sup>

Disclosure requirements of food safety information by government is further strengthened. In addition to requiring food regulators to release food safety information in an accurate, timely and objective way,<sup>154</sup> the Draft Amendment I further mandates food regulators to pro-

<sup>(141)</sup> Food Safety Law, art. 85.

<sup>(142)</sup> Draft Amendment I of FSL, art. 124.

<sup>(143)</sup> Food Safety Law, art. 85.

<sup>(144)</sup> Draft Amendment I of FSL, art. 124.

<sup>(145)</sup> Food Safety Law, art. 93.

<sup>(146)</sup> Draft Amendment I of FSL, art. 149.

<sup>(147)</sup> Food Safety Law, art. 95.

<sup>(148)</sup> Draft Amendment I of FSL, art. 141-146.

<sup>(149)</sup> Draft Amendment I of FSL, art. 142.

<sup>(150)</sup> Draft Amendment I of FSL, art. 153.

<sup>(151)</sup> Draft Amendment I of FSL, art. 114.

<sup>(152)</sup> Id.

<sup>(153)</sup> Draft Amendment II of FSL, art. 107.

<sup>(154)</sup> Food Safety Law, art. 82; Draft Amendment I of FSL, art. 118.

vide explanations for possible harm the may be brought by relevant food to avoid misleading the public.<sup>155</sup>

While the media is encouraged to publicize food safety laws, regulations, standards and information, as well as provide public oversight of acts that violate the FSL,<sup>156</sup> the Draft Amendment I emphasizes that reporting of food safety issues must be objective, true and just.<sup>157</sup> The Draft Amendment I specifically provides that no organization or individual shall disseminate false food safety information.<sup>158</sup> To realize this objective, the Draft Amendment I stipulates that if a news media entity intends to publish food safety information and this information may have a serious impact on society or the food industry, the news media entity is first required to verify the information with the relevant food and drug regulatory departments before publishing the information.<sup>159</sup>

Realizing that such requirement may compromise the timeliness of food safety information, the Draft Amendment II adopts another way to avert dissemination of untrue information. It deletes the requirement that food safety information must be verified with government departments before publishing.<sup>160</sup>

Simultaneously, it adds that if a media makes up and disseminate untrue food safety information, afterwards it will be punished by relevant regulatory departments, as well as directly responsible directors and other employees.<sup>161</sup> By this way, the media are compelled to keep quality of their information as long as they don't want to take punishment.

Food industry associations and consumer associations can be great powers in promoting cooperative governance on food safety. The Draft Amendment I generally requires food industry associations to strengthen industry self-discipline and guide food producers and traders to run their business according to

law.<sup>162</sup> The Draft Amendment II further details that food industry associations must establish and improve industry norms and internal reward-and-punishment mechanism, and provides services such as food safety information and technology for their members.<sup>163</sup> Moreover, the Draft Amendment II requires consumer association and other consumer organizations to supervise behaviors that violate the FSL and harm consumers' legitimate rights and benefits.<sup>164</sup>

Though food companies are not trusted to effectively self-regulate, the Draft Amendment I tries to mobilize them to play a more positive role in ensuring food safety. Food producers and traders are required to establish a food safety self-assessment system and regularly assess their own food safety situation.<sup>165</sup> If the production and trading conditions change and do not comply with food production and trading requirements any more, they shall immediately take rectification measures, and if the potential for food safety risks still exists, they shall immediately terminate production and trade, and report to the county level food and drug regulatory department.<sup>166</sup>

The Draft Amendment I encourages the formation of a liability insurance system and food producers and traders are encouraged to participate in this system<sup>167</sup>. Liability insurance plays an important social function in protecting consumers' rights and benefits when food companies are unable to compensate consumers for harms they have caused. Under Draft Amendment I, specific measures are authorized to be jointly developed by the CFDA and the China Insurance Regulatory Committee.<sup>168</sup> However, the Draft Amendment II deletes this authorization out of the concern that it may be construed to force companies to participate in the insurance, aggravating burden on companies and consumers.<sup>169</sup>

<sup>(155)</sup> Draft Amendment I of FSL, art. 118.

<sup>(156)</sup> Food Safety Law, art. 8 & art. 11.

<sup>(157)</sup> Draft Amendment I of FSL, art. 11.

<sup>(158)</sup> Draft Amendment I of FSL, art. 121.

<sup>(159)</sup> Id.

<sup>(160)</sup> Draft Amendment II of FSL, art. 111.

<sup>(161)</sup> Draft Amendment II of FSL, art. 131.

<sup>(162)</sup> Draft Amendment I of FSL, art. 10.

<sup>(163)</sup> Draft Amendment II of FSL, art. 9.

<sup>(164)</sup> Id.

<sup>(165)</sup> Draft Amendment I of FSL, art. 74.

<sup>(166)</sup> Id.

<sup>(167)</sup> Draft Amendment I of FSL, art. 78.

<sup>(168)</sup> Id.

<sup>(169)</sup> 12th Standing Committee of National People's Congress of PRC, supra note 90.

#### 4.7. Other new administrative instruments

Apart from the major changes discussed above, there are some other administrative instruments provided for in Draft Amendment I that may enhance administrative capacity and improve administrative efficiency, primarily the grading of risks, grading of food safety incidents, communication sessions with liable persons, and assaulting inspection.

Grading of risks can help regulatory departments allocate administrative resources to the riskiest areas and thus obtain the most cost-effective outcomes. To this end, the Draft Amendment I requires food and drug regulatory departments and quality supervision departments at the country level or above to identify key areas, approaches and frequency of regulatory work, on the basis of food safety risk monitoring, risk assessment and food safety situation.<sup>170</sup>

Under the FSL, local governments are required to formulate emergency plans for food safety incidents, but the FSL does not specify what substantive elements must be included in the emergency plans.<sup>171</sup> To enhance the reliability of emergency plans, the Draft Amendment I mandates that emergency plans include: the grading of incidents, a chain of command for incident response and the allocation of personnel responsibilities, a prevention and early warning system, incident handling procedures and measures to guarantee effective emergency incident handling.<sup>172</sup> Within these requirements, the grading of incidents is particularly helpful in improving governments' emergency response capacity.

Communication sessions with liable persons are an informal but effective approach to mobilize responsible parties to fulfill their obligations in China. The Draft Amendment I adds this mechanism by stipulating that if food producers and traders do not timely eliminate safety hazards, regulatory departments can arrange a communication session with a potentially liable person. If regulatory departments fail to timely discover systematic risks in the region, local government of the same level can arrange a communication session. If local governments fail to perform their food safety

duties properly, governments of a higher level can arrange a communication session.<sup>173</sup> The communication session and the rectification measures will be included in the food companies' credit records, as well as in the companies' evaluation and appraisal records,<sup>174</sup> which discourages irresponsible behavior. Assaulting inspection is mainly used in the event that regulatory departments do not properly fulfill their responsibilities. If risk monitoring information or complaints indicate the existence of gravely illegal behavior or serious food safety problems, regulatory department at the higher level government may conduct an on-site inspection of a food producer or trader without notice. Such a regulatory department may also supervise the work of the lower regulatory department that shall take responsibility.<sup>175</sup> In this way, regulatory departments at different levels are mobilized to fully perform their responsibilities as long as they do not want to be found incompetent.

#### 5.- Problems remaining to be solved

Through the substantive modification or addition of 55 articles, the Draft Amendment I has significantly strengthened the FSL's ability to handle food safety issues. In pursuance to the same principles, the Draft Amendment II adjusts about 30 articles to make the law become more comprehensive, workable and concise. With more precaution, greater oversight and broader participation, the updated system under the Draft Amendment I & II are likely to improve China's food safety situation. However, there are still changes waiting to be made. Some of them have already been mentioned generally in Draft Amendment I & II but need further clarification, such as the regulation of small workshops and street vendors, the incentivization of whistle-blowers, and the establishment of a liability insurance system. Some others have not been incorporated into the Draft Amendment I & II for various reasons, but are valuable tools for handling food safety problems.

Certain workshops and street vendors have long rep-

<sup>(170)</sup> Draft Amendment I of FSL, art. 105.

<sup>(171)</sup> Food Safety Law, art. 70.

<sup>(172)</sup> Draft Amendment I of FSL, art. 98.

<sup>(173)</sup> Draft Amendment I of FSL, art. 112.

<sup>(174)</sup> Id.

<sup>(175)</sup> Draft Amendment I of FSL, art. 113.



resented a headache for regulatory departments' due to their decentralized, mobile and concealed natures. As of June 2013, small workshops employing less than 10 persons only hold 9.3 percent food market share, but account for 60 percent of all food producer and processors.<sup>176</sup> Though the FSL tries to regulate them and delegates authority to local governments to enact their own regulations, only 10 provincial regions have done this; therefore, most workshops and street vendors are outside of the regulatory scope.<sup>177</sup> In spite of strong calls for stricter regulation, the Draft Amendment I & II maintain the original regulation. Because of the distinct nature of small workshops and street vendors, a licensing system is not useful, and a different regulatory approach should be employed. On the one hand, they should be encouraged to operate in a more formal manner, on the other hand, the grading of risks should be utilized to decrease the administrative costs of on-site inspections.

The Draft Amendment I attempt to incentive whistle-blowers by monetary awards. While supporting this change, some representatives of the NPC worry that whistle-blowers may be unwilling to accept the award for fear of retaliation, which has been proved to be highly possible in some regions. In light of this concern, one more sentence is added in the Draft Amendment II that requires preserving anonymity for reporters. But this is just the first step, more detailed rules and supporting system need to be established before this provision can effectively work, especially for company employees who are likely to acquire internal information but are usually fearful of being revenged by their powerful employers.<sup>178</sup>

Regarding food safety insurance, the Draft Amendment I & II encourages the formation of such a system but does not mandate that food producers buy insurance. In light of the fact that the food safety insurance market is far from mature and that a corresponding regulatory system has not been established, a voluntary regime with government support may be an

acceptable option at the present, in order to prepare the market for this change. However, in order to fully protect consumers' interests, a mandatory system may need to be established as soon as possible.

In addition to the problems set forth above, there are some other issues that are not mentioned in the Draft Amendment I & II, but that are also of great importance in improving food safety. For instance, public interest litigation of food tort cases remains an important issue. As the new *Environmental Protection Law*, which was amended on April 2014, allows social organizations to file environmental public interest suits against polluting companies,<sup>179</sup> the FSL should be modified to include the same provision because environmental protection cases and food safety cases share many common features, such as the universality and decentralization of potential plaintiffs, the power of polluting companies, and difficulties in proving causation. Such changes will likely evolve in an increasingly advanced legal system.

## 6.- Conclusion

In response to the precarious food safety situation, recent revisions to the FSL are likely to initiate substantive changes. The CFDA has been established to integrate the previously scattered responsibilities of the SAIC, FDA and AQSIQ, while a new NHFPC has been established to take over MOH's responsibilities for organizing risk monitoring, risk assessment and enacting HFSSs. Built upon the principle of "establishing the strictest food safety regulation system," major changes in the Draft Amendment I & II fall into four main categories: (1) the strengthening of the prevention framework; (2) the establishment of most stringent rules for 'whole-process' regulation; (3) the establishment of strict rules for legal liability; and (4) the promotion of cooperative governance between government and society.

<sup>(176)</sup> This data comes from Yuan Li's speech on 5th Food Safety Forum. Yuan Li is a high-level staff of the Legal Council of Standing Committee of the NPC, and has taken a primary role in the draft of Draft Amendment. Written version of his speech is available at: [http://www.ce.cn/cysc/ztpd/2013/food/lty/wzsp/201306/17/t20130617\\_513682.shtml](http://www.ce.cn/cysc/ztpd/2013/food/lty/wzsp/201306/17/t20130617_513682.shtml).

<sup>(177)</sup> This data comes from Longde Wang's interview. Longde Wang is a member of the Standing Committee of the NPC and also a respected medical expert. Citation of his interview is available at: [http://www.npc.gov.cn/npc/zgrdzz/2014-08/20/content\\_1874672.htm](http://www.npc.gov.cn/npc/zgrdzz/2014-08/20/content_1874672.htm).

<sup>(178)</sup> Jiangli, a member of the Standing Committee of the NPC, comes up with suggestion during the process of review, available at: [http://www.npc.gov.cn/npc/zgrdzz/2014-08/20/content\\_1874669.htm](http://www.npc.gov.cn/npc/zgrdzz/2014-08/20/content_1874669.htm).

<sup>(179)</sup> Environmental Protection Law of the PRC (promulgated by the 11st Session of 7th Standing Committee of National People's Congress of the PRC on December 26, 1989, amended on April 24, 2014, effective on January 1, 2015), art. 58.

More specifically, to eliminate or at least mitigate risks before they become material, risk-based approaches such as risk monitoring, risk assessment and risk communication are used in enacting food safety standards and daily regulatory work. To cover upstream and downstream activities of the food supply chain, food production, distribution, and services are further regulated through quality controls, registration requirements, and traceability requirement. High-risk areas like health food, infant food and centralized dining places are specifically provided for, as well as emerging areas such as online food transactions. To impose harsh punishments on violators, civil liability, administrative liability and criminal liability are comprehensively utilized and strengthened. To encourage more parties to participate in food safety management, an incentivized reporting system, information disclosure system, self-assessment system, and food safety liability insurance system are promoted.

In addition, some new administrative instruments have been created to streamline the otherwise daunting task of managing and supervising food safety issues. Such instruments include the grading of risks, grading of food safety incidents, communication sessions with liable persons and assaulting inspections. By applying these methods, regulatory departments can invest less administrative resources but leverage more effective outcomes, thus improving administrative efficiency.

While many changes have been achieved, there are still some problems that remain to be solved in the following revision process. Some of them have already been mentioned in the Draft Amendment I & II but

need further clarification, such as the regulation of small workshops and street vendors, the incentivization of whistle-blowers, and the establishment of a food safety liability insurance system. Some others have not been incorporated into the Draft Amendment I & II out of various reasons yet are valuable tools for addressing food safety problems, such as public interest litigation of food safety cases. With ongoing developments in Chinese food markets, financial markets, and the legal system, these changes are likely to occur in the not so distant future.

## ABSTRACT

*Food safety has been a big problem in China for a long time. Since the enactment of Food Safety Law in 2009, China's food safety regulation has been tightened, however, food safety situation is still far from satisfying. In a response, from 2013 China's government began to amend the Food Safety Law, hoping it can be more effective and efficient in resolving food safety issues. The ongoing amendment aims to build up a upgraded legal framework for food safety regulation by strengthening rules on prevention priority and precaution, establishing stringent rules for 'whole-process' regulation, establishing stringent rules on legal liability and promoting cooperative governance between government and society. This article tries to give an introduction to the background, current development and remaining problems of this amendment process.*

