China Food Safety Legal and Regulatory Assessment

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I. Executive Summary

The regulation of food safety in China has evolved in several stages, with growing comprehensiveness and cohesion resulting from successive rounds of legal and regulatory change. The formal concept of food safety took hold between 1984 and 2000. A top-down government oversight mechanism was fashioned, with the Ministry of Health (MOH) taking the chief responsibility for overall food safety control and the Ministry of Agriculture (MOA) responsible for the production of primary agricultural products. The first decade of the 21st century saw the emergence of a horizontal multi-ministry, production step control system, and a litany of food safety incidents, which unveiled oversight loopholes and severely undermined consumer confidence in domestic food. The most infamous example is the 2008 milk scandal, where an estimated 300,000 infants were fed milk contaminated with melamine. In response, China's State Council promulgated special regulations and the Food Safety Law (2009) was passed, but food scares continued to plague the country. Poor inter-agency coordination, regulatory redundancy, overlapping and contradictory standards, and ineffective enforcement were highlighted as the primary challenges.

Resolved to transform its food safety landscape, China has revamped its institutional and legal frameworks over the past five years. Institutionally, the creation of the China Food and Drug Administration (CFDA) in 2013 heralds an era of centralized food safety management, and CFDA enjoys vertical authority over food production, distribution, and consumption and falls within the oversight of the MOH. Other ministries, such as the MOA, also play important roles in the streamlined new system.

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Legally, the amended Food Safety Law (2015) is the culmination of decades of trial and error. Hailed as the most stringent and comprehensive food safety law in Chinese history, the new law delineates legal requirements for a wide variety of actors, covers previously unchartered domains such as traceability and rules governing on-line platforms, lays down rules for cooperation and coordination, and imposes harsh penalties. Of note, the new legal structure signals a paradigm shift from a reactive to a risk-based anticipatory approach, industry self-regulation, and enhanced sanctions. A number of salient aspects of the most recent wave of legal reform and their respective implementation challenges will be elaborated below. Food production and distribution, including traceability and inspection, and law enforcement are the focal points of the analysis. Other regulations, such as the Agrifood Quality and Safety Law (2006) and the amended Criminal Code (2011), jointly undergird the food safety regime.

Overall, the most recent round of legal reform in the food safety sphere holds significant promise for fostering a more comprehensive, cohesive, and well-enforced system. Unlocking this potential, however, will require tackling a number of challenges. First, human, technological, and financial capacities remain insufficient in local jurisdictions. Second, stakeholders' poor awareness of food safety laws and standards is a recurrent impediment to implementation of the legal system. Third, the fragmented nature and composition of the food industry, dominated by small- and medium-sized entities with scarce resources and little financial incentive for compliance, present perennial barriers to enforcement. Fourth, private participation in food safety systems, via proactive compliance, third-party services, and civil society, has remained tepid. Fifth, the one-size-fits-all formula for implementation is suboptimal in light of steep variations in economic development, geography, and enterprise size across the country. Finally, institutional coordination, cooperation, and integration require additional focus.

This paper is part of a larger series of work on China's legal and regulatory system for food security developed in partnership by the Syngenta Foundation for Sustainable Agriculture (SFSA) and New Markets Lab (NML). This assessment will be complemented by industry case studies designed to highlight how implementation of the relatively new system impacts companies.[2]

II. Institutional Framework

A number of institutional actors, domestic and international, jointly regulate China's food safety system. Domestic regulators are further comprised of national and local actors. Domestically, China has implemented a major institutional overhaul to promote inter-agency coordination and slash regulatory redundancy, both of which have been key regulatory stumbling blocks in prior rounds of implementation of the food safety system. Figure 1 below lays out the institutional landscape after the recent food safety reform.

With the central control of the State Council, four principal institutions, supported by an array of entities, govern food safety in China. Among them, the CFDA is the main food safety actor. CFDA was created in 2013 by merging the Office of Food Safety Commission of the State

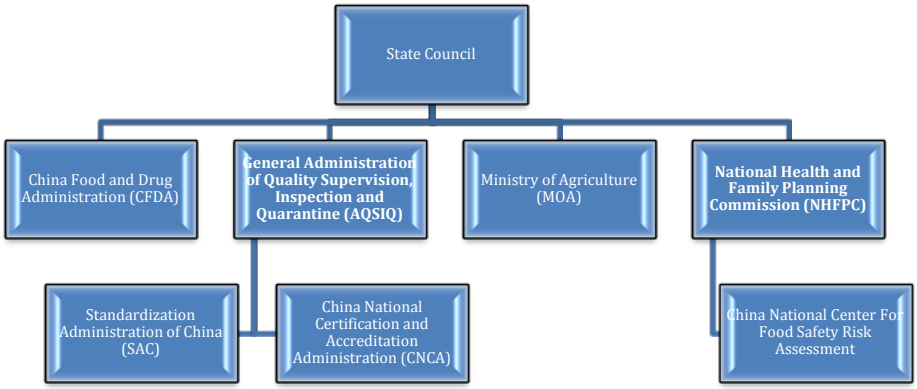
[2] *See* Kuhlmann, Katrin, Wang, Mengyi, and Zhou, Yuan. *China Horticulture Case Study*. Syngenta Foundation for Sustainable Agriculture, publication forthcoming.

Council, the State Food and Drug Administration (SFDA), and the food safety functions of the State Administration for Industry and Commerce (SAIC).

CFDA is the first centralized authority in charge of food safety. It administers and jointly regulates the entire domestic supply chain with the MOA.[3] The regulatory remit of CFDA covers production, distribution, safety management, storage, and transportation.[4] To that end, CFDA enjoys comprehensive legislative, supervisory, managerial, investigative, and educational authority.[5] More specifically:

- In its *rule-making capacity*, CFDA drafts laws, regulations, and policy plans for the administration and oversight of food safety, takes part in the formulation of food safety standards, and draws up food risk management and monitoring mechanisms;[6]
- In its *supervisory role*, CFDA supervises their implementation;[7]
- In its *managerial role*, CFDA guides, supervises, coordinates national and local regulators;[8] for instance, it delegates authority to and supervises provincial and local government;[9]
- In the face of *emergency and food safety incidents*, CFDA guides emergency responses, conducts investigation, and organizes punishment;[10] and
- CFDA is also responsible for *education, training, and information collection and dissemination*, such as establishing a credibility system.[11]

Figure 1: China's Food Safety Institutions

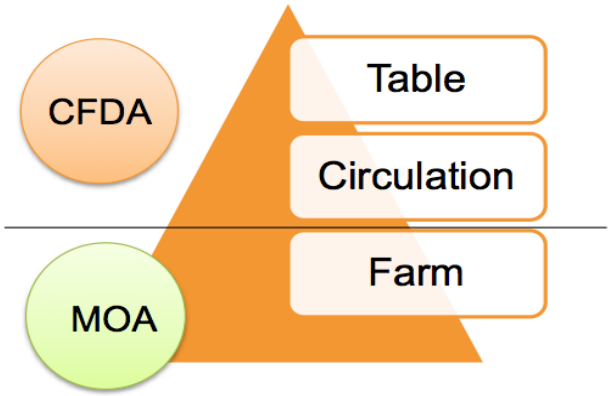


[3] The Amended Food Safety Law (2015), Article 5.
[4] The Amended Food Safety Law (2015), Article 2.
[5] CFDA website: http://eng.sfda.gov.cn/WS03/CL0756/
[6] CFDA website: http://eng.sfda.gov.cn/WS03/CL0756/
[7] CFDA website: http://eng.sfda.gov.cn/WS03/CL0756/
[8] CFDA website: http://eng.sfda.gov.cn/WS03/CL0756/
[9] CFDA website: http://eng.sfda.gov.cn/WS03/CL0756/
[10] CFDA website: http://eng.sfda.gov.cn/WS03/CL0756/
[11] CFDA website: http://eng.sfda.gov.cn/WS03/CL0756/

Source: New Markets Lab, 2016[12]

MOA is responsible for the supervision and management of edible agricultural products, prior to their processing or circulation in the market. MOA also regulates agricultural inputs, such as seeds, chemicals and veterinary drugs, along with animal slaughter, disease prevention and quarantine.[13] Figure 2 depicts the division of labor along the supply chain between CFDA and MOA.

Figure 2: The Division of Labor between CFDA and MOA



Source: Laura Wang, Reach24H Consulting Group, 2015

The General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) is another ministerial administrative organ. With 19 in-house departments, AQSIQ chiefly handles national quality, entry-exit animal and plant quarantine, import-export food safety, certification and accreditation, and standardization.[14] Further, AQSIQ performs duties in relation to international law and organizations. It participates in standard–setting international organizations such as the International Organization for Standardization (ISO)[15] and implements two food safety related agreements under the World Trade Organization (WTO): the WTO Technical Barriers to Trade Agreement (TBT Agreement) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).[16] The SPS Agreement requires WTO Members to base their SPS measures on the analysis and assessment of objective and accurate scientific data; encourages them to establish measures consistent with international standards, guidelines, and recommendation; and obligates them to notify other countries of any new or changed SPS requirements that affect trade. The TBT Agreement covers non-SPS technical regulations, voluntary standards, and procedures, such as nutrition and labeling.

Two vice-ministerial-level departments within AQSIQ are central to food safety regulation. First, the Certification and Accreditation Administration (CNCA) manages, supervises, and

[12] The information is derived from official ministry webpages and WTO Trade Policy Review of China (2016).
[13] MOA website, http://english.agri.gov.cn/aboutmoa/mandates/; WTO Trade Policy Review of China (2016); the Amended Food Safety Law (2015), Article 2.
[14] AQSIQ, http://english.aqsiq.gov.cn/AboutAQSIQ/Mission/;WTO Trade Policy Review of China (2016).
[15] AQSIQ, http://english.aqsiq.gov.cn/AboutAQSIQ/Mission/;WTO Trade Policy Review of China (2016).
[16] AQSIQ, http://english.aqsiq.gov.cn/AboutAQSIQ/Mission/;WTO Trade Policy Review of China (2016).

coordinates certification and accreditation activities across the country.[17] Second, the Standardization Administration (SAC) manages standardization in the country pursuant the Standardization Law.[18]

The National Health and Family Planning Commission (NHFPC) has two primary roles in food safety: food safety standard setting and risk assessment.[19] NHFPC was created by combining the former MOH and the National Population and Family Planning Commission. Notably, NHFPC hosts the China National Center for Food Safety Risk Assessment (CFSA),[20] a technical institution that conducts food safety risk assessment and provides technical support for food safety risk management and standard development and revisions.[21] Internationally, CFSA also participates in the work of the Codex Alimentarius Commission (CAC), which houses the international body of standards on food safety.[22]

Apart from these four main institutions (CFDA, MOA, AQSIQ, and NHFPC), other national actors perform supporting functions. The Ministry of Commerce (MOFCOM) devises plans and policies for catering services and circulation of alcohol products and takes the lead on WTO-related issues, such as SPS/TBT Committee meetings. It also pioneered and is fine-tuning a national traceability system for vegetables and meat. The State Administration for Industry and Commerce (SAIC) supervises the advertisement related to food.[23] The Ministry of Public Security is integral to the enforcement mechanism.[24]

Local authorities also oversee food safety management. Under the supervision and coordination of local people's governments, local branches of national ministries administer and manage food safety in their respective local jurisdictions. Local authorities have wide legislative, administrative, and enforcement power. For instance, they establish standards,[25] sometimes filling voids in the national standards or setting more stringent standards. Additionally, the new Food Safety Law also sets forth extensive obligations for local authorities, demonstrating the policy shift towards the local management model.[26]

Local institutional reforms that replicate the national institutional restructuring have been underway. The last three years have seen sweeping integration of FDAs, AQSIQs, and

[17] AQSIQ, http://english.aqsiq.gov.cn/AboutAQSIQ/Mission/;WTO Trade Policy Review of China (2016).
[18] AQSIQ, http://english.aqsiq.gov.cn/AboutAQSIQ/Mission/;WTO Trade Policy Review of China (2016).
[19] NHFPC website, http://en.nhfpc.gov.cn/2014-05/07/c_46917.htm; Trade Policy Review of China (2016).
[20] CFSA website:
http://www.chinafoodsafety.net/Singel.aspx?channelcode=089BC3C676E66C69ED579F05E01E2A89E4965ECFE6840A04&code=02B6EB4E283B8EBA17E90C4149F69C4D94A589955C768578;
http://www.chinafoodsafety.net/Singel.aspx?channelcode=089BC3C676E66C69ED579F05E01E2A89E4965ECFE6840A04&code=B60BA1DF45A7C5734F7F4C4F771BC3417BCD5E5496C1CED8
[21] CFSA website:
http://www.chinafoodsafety.net/Singel.aspx?channelcode=089BC3C676E66C69ED579F05E01E2A89E4965ECFE6840A04&code=0DBE70F8A2FA85542570821655FB4741B4DC5B68F3701FC8
[22] CFSA website:
http://www.chinafoodsafety.net/Singel.aspx?channelcode=089BC3C676E66C69ED579F05E01E2A89E4965ECFE6840A04&code=0DBE70F8A2FA85542570821655FB4741B4DC5B68F3701FC8
[23] CFDA website: http://www.sda.gov.cn/WS01/CL0050/80623.html
[24] CFDA website: http://www.sda.gov.cn/WS01/CL0050/80623.html
[25] *See*, e.g. http://www.sc.gov.cn/10462/10758/10759/10763/2014/7/19/10318065.shtml
[26] Linhai Wu, Dian Zhu, Food Safety in China: A Comprehensive Review, pg. 213.

Administration for Industry and Commerce (AIC) at city and district levels. However, provincial integration has been slow and does not have any definitive deadlines. Local capacities vary sharply among local jurisdictions, which reflects uneven economic development across the country.

National and local actors interact through delegation and supervision. For instance, MOA delegates authority to the following local branches: provincial department of agriculture, municipal bureau of agriculture, and country bureau of agriculture. The central government also actively supervises and guides local authorities. For instance, on August 29, 2016, the State Council issued a regulation detailing the evaluation procedures of local authorities.[27] The procedures include self-evaluation, potentially unannounced visits, and grading.[28]

Internationally, the CAC and WTO are the two key players. China, via CFSA, is an active member of the CAC, which creates international food standards, guidelines, codes of practice, and other recommendations.

III. Legal Framework

The legal framework governing food safety in China is composed of hierarchical laws, regulations, and standards that allocate responsibilities among different players and regulate their relationships. The amended Food Safety Law, as the primary piece of legislation on food safety, knits together previously fragmented supply chain management and places responsibility in the hands of CFDA. Other legal instruments supplement the new law.

This section is organized in two parts. First, it explains different sources of law and legal hierarchy within the food safety framework. Second, more substantively, it elaborates on the following aspects of food safety: 1) food safety standards, 2) food production and distribution, 3) cross-border trade, and 4) law enforcement. Wherever applicable, the requirements under the amended Food Safety Law will be highlighted.

A. Chinese Legal Framework

China's domestic legal framework is made up of three tiers of national law. The first and highest level includes basic laws, enacted by the National People's Congress, China's top legislative body.[29] Food safety related basic laws include the amended Food Safety Law (2015), the Agrifood Quality and Safety Law (2006), the Product Quality Law (1993, last amended 2009), the Agriculture Law (1993, last amended 2012), the Law of Standardization (1989), and the Law on the Inspection of Import and Export Commodities (1989, last amended 2013).[30]

[27] CFDA website: http://www.cfda.gov.cn/WS01/CL1605/163890.html
[28] CFDA website: http://www.cfda.gov.cn/WS01/CL1605/163890.html
[29] Chenhao Jia and David Jukes, The National Food Safety Control System of China — A Systematic Review (2013).
[30] Chenhao Jia and David Jukes, The National Food Safety Control System of China — A Systematic Review (2013).

The second level consists of subordinate laws, including administrative regulations of the State Council, regulations promulgated by ministries and committees at the ministry level, and food standards.[31] Examples include Administrative Measures on the Safety of Import and Export Food (AQSIQ Decree No. 144) and Regulations on Implementation of the Law on the Entry and Exit Animal and Plant Quarantine (1996).

Local regulations make up the third level and are tailored to meet local needs.[32] They often serve to beef up supervision and enforcement in the aftermath of food safety incidents.[33] For example, the "staining bread" scandal, where unscrupulous merchants treated expired corn bread with colorants and preservatives and sold it in more than 30 supermarkets in Shanghai, prompted the local government to promulgate a regulation to enhance supervision of crops.[34]

B. Food Safety Standards

As shown by Table 1, relevant food safety standards can be categorized along two metrics: 1) international vs. domestic and 2) private vs. public.

Table 1 Different Types of Food Safety Standards

	Public	Private
International	Promulgated by a public standard-setting body (e.g. Codex Alimentarius)	Promulgated by the private sector (e.g. International Food Standard SQF 1000/2000/3000)
Domestic	National standards Local standards	Industry standards Enterprise standards

Source: New Markets Lab, 2016

All four categories of standards are interrelated. For instance, international and domestic standards interface: a regulation based on applicable Codex standards is deemed compliant with the WTO SPS Agreement, and the standard framework and most standards in China are in line with Codex.[35] Within the domestic standard regime, the interplay among various domestic standards is addressed by the amended Food Safety Law and its 2016 Draft Implementation

[31] Chenhao Jia and David Jukes, The National Food Safety Control System of China — A Systematic Review (2013).
[32] Chenhao Jia and David Jukes, The National Food Safety Control System of China — A Systematic Review (2013).
[33] Chenhao Jia and David Jukes, The National Food Safety Control System of China — A Systematic Review (2013).
[34] Chenhao Jia and David Jukes, The National Food Safety Control System of China — A Systematic Review (2013).
[35] China National Food Safety Standards & Codex, presentation by Junshi Chen, China National Centre for Food Safety Risk Assessment.

Regulation.[36] For instance, the State encourages enterprises to establish enterprise standards that are much more stringent than national and local standards.[37] Additionally, while provincial health departments and the FDA of the same level may develop local food safety standards, these standards are annulled upon the establishment of relevant national standards.[38]

Domestically, the most legally significant group of standards is national standards ("guóbiāo" or "GB"). National food safety standards are all mandatory and have broad coverage.[39] Figure 3 below shows the national food safety standard system.

Figure 3: National Food Safety Standard System[40]

Source: Presentation by MOH Director General Su Zhi, International Symposium on Food Safety Risk Assessment, Beijing, September 2012.

In the past, the prevalence of redundant and inconsistent standards was a major challenge to coherent food safety management. Now NHFPC has resolved to unify existing standards and address missing ones. More specifically, NHFPC, with the technical support from CFSA, has been harmonizing and consolidating nearly 5,000 existing food standards.[41] Further, in creating a considerable number of new standards, two areas have received sustained attention: 1) items in the general standards category and 2) products implicated in known food safety incidents or with

[36] At the time of writing, the most recent version of the Draft Implementation Regulation was issued in 2016. For sake of comparison, this report occasionally references the 2015 version of the Draft Implementation Regulation.
[37] The Amended Food Safety Law (2015), Article 30.
[38] The Amended Food Safety Law (2015), Article 29; 2016 Draft Implementation Regulation Article 26.
[39] The Amended Food Safety Law (2015), Article 25.
[40] USDA, The Food Safety Management System in China (2013).
[41] CFSA website: http://www.chinafoodsafety.net/Singel.aspx?channelcode=089BC3C676E66C69ED579F05E01E2A89E4965ECFE6840A04&code=0DBE70F8A2FA85542570821655FB4741B4DC5B68F3701FC8

potential risks for high consumption within the product standard category.[42] For instance, on August 5, 2016, China notified the SPS Committee of the WTO of its draft standards on 1,058 maximum residue limits (MRLs) for 160 pesticides.[43]

Notably, compliance with national standards now unequivocally extends to imported products. Pursuant to Article 92 of the amended Food Safety Law, imported food and food additives, and food-related products must comply with China's national food safety standards.

C. Food Production and Distribution

a. General Rules

The amended Food Safety Law has an extensive chapter on production and distribution, in which four key themes emerge.

First, *self-regulation and governmental oversight* work in tandem. On the one hand, a growing emphasis on self-regulation is evidenced by producers' and distributors' obligation to establish and maintain 1) a traceability system, preferably using information technology,[44] 2) a health management system for their practitioners,[45] and 3) a self-inspection system.[46] The Draft Implementation Regulation further obligates producers and distributors to record and keep separate expired/rotten/recalled foods, food additives, or food-related products.[47] Specific rules govern the production and distribution of edible agricultural products. During production, enterprises and specialized farmer cooperatives must establish a production record.[48] They must also fully abide by the food safety standards and relevant State regulations regarding agricultural inputs such as pesticides, fertilizers, veterinary drugs, feed, and feed additives, including application intervals and non- application.[49] The Draft Implementation Regulation sets forth an entire section regulating the distribution of edible agricultural products, which establishes obligations for both market operators and traders.[50]

Additionally, the State provides considerable guidance and supervision, from eligibility of operation, to post-market supervision, to market design. Indeed, all parties engaged in food production and distribution, except for the sale of edible agricultural products, must first obtain

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[42] USDA, The Food Safety Management System in China (2013); 2016 Draft Implementation Regulation, Article 10.
[43] AQSIQ website: http://www.tbt-sps.gov.cn/tbcx/getTbcxContent.action?mid=18960&TBType=1; *See also* China Notification to WTO: https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=232152,231449,230449,227483,226585,226586,226587,226588,226591,226592&CurrentCatalogueIdIndex=2&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True
[44] The Amended Food Safety Law (2015), Article 42.
[45] The Amended Food Safety Law (2015), Article 45.
[46] The Amended Food Safety Law (2015), Article 47.
[47] 2016 Draft Implementation Regulation, Article 49.
[48] The Amended Food Safety Law (2015), Article 49.
[49] The Amended Food Safety Law (2015), Article 49.
[50] 2016 Draft Implementation Regulation, Chapter 4, Section 3.

licenses from the State.[51] Moreover, traceability is the focal point of the State's engagement with the whole supply chain. Ministerial and national food safety traceability systems have been launched or planned.[52] In the 2015 version of the Draft Implementation Regulation, local governments were encouraged to put in place their own e-traceability systems tailored to high-risk food categories, large-size food producers, and traders;[53] however, that provision was removed in the 2016 Draft Implementation Regulation.

Notably, both producers and distributors are charged with ensuring the quality of products of their downstream and upstream actors. For producers, a detailed verification record must be established for incoming food raw materials, food additives, and Food-Related Products. Producers must also check the supplier's license and the product's compliance certificate, in order to verify their compliance with food safety standards.[54] For outgoing food, producers must establish and maintain an inspection record.[55]

Second, the State has actively pursued *larger scale production through consolidation or up-scaling*, for two reasons. First, the fragmented nature of Chinese food industry, with 190 million farms for crops, milk, and meat, has made management and supervision of upstream supply chain links daunting and prone to food safety incidents.[56] For instance, on average, a Chinese farm has 1.6 acres, compared to 441 acres for its U.S. counterpart.[57] Larger scale production, on the other hand, fosters regulatory enforcement by reducing the number of actors to be monitored, decreasing the number of monitors needed, partially internalizing supervision, and driving output and efficiency.[58] Second, larger scale production helps root out financial and educational deficiencies of small actors, which has been a major contributor in past food safety incidents.

Larger scale production as a policy tool has been underway for more than a decade, with the amended Food Safety Law and land reform as two cardinal instruments.[59] Indeed, the amended Food Safety Law pointedly mandates local authorities at all levels to encourage larger scale production and chain operation and distribution of food. Thus far, meat production and processing lead the way in reducing fragmentation.[60] Overall, however, industry fragmentation is still high, and large-scale production remains scarce.[61] The impact of the amended Food Safety Law on market structures is yet to be tested. An empirical question is whether the detailed and

[51] The Amended Food Safety Law (2015), Article 35.
[52] The Amended Food Safety Law (2015), Article 42.
[53] 2015 Draft Implementation Regulation, Article 63.
[54] The Amended Food Safety Law (2015), Article 50.
[55] The Amended Food Safety Law (2015), Article 51.
[56] PricewaterhouseCoopers, Managing Upstream Risks in China's Food Safety Chain (2015), http://www.pwccn.com/webmedia/doc/635766405555290452_food_supply_chain_risk_aug2015.pdf
[57] [57] The Wall Street Journal, On China Farms, Push For Consolidation is Growing (2008), http://www.wsj.com/articles/SB121694931839083387
[58] PricewaterhouseCoopers, Managing Upstream Risks in China's Food Safety Chain (2015), http://www.pwccn.com/webmedia/doc/635766405555290452_food_supply_chain_risk_aug2015.pdf
[59] PricewaterhouseCoopers, Managing Upstream Risks in China's Food Safety Chain (2015), http://www.pwccn.com/webmedia/doc/635766405555290452_food_supply_chain_risk_aug2015.pdf
[60] PricewaterhouseCoopers, Managing Upstream Risks in China's Food Safety Chain (2015), http://www.pwccn.com/webmedia/doc/635766405555290452_food_supply_chain_risk_aug2015.pdf
[61] PricewaterhouseCoopers, Managing Upstream Risks in China's Food Safety Chain (2015), http://www.pwccn.com/webmedia/doc/635766405555290452_food_supply_chain_risk_aug2015.pdf

enhanced obligations would push smaller actors to seek mergers and acquisitions for cost reduction or to shift resource allocation in order to appear law-abiding. For instance, a small farm struggling financially could covertly use non-compliant pesticides to compensate for the additional cost of operating within the enhanced traceability system.

Third, the reform now *broadens its scope and extends regulation to new domains*. The new Food Safety Law delineates responsibilities relating to storage and transportation. In particular, anyone undertaking storage and transportation, regardless of their specific role, must conform to hygiene requirements and avoid harmful or toxic materials.[62] The Draft Implementation Regulation stipulates additional requirements related to commissioned storage and transportation services, traceability records, and record-filing for food storage and transportation companies that do not produce foods.[63]

Likewise, it also *clarifies rules governing food additives and Food Related Products*. Food additive producers must obtain a license and can only use food additives that fall within the list of National Food Safety Standard for Use of Additives (GB2760-2014).[64] Companies could apply to add additional additives to the positive list, and NHFPC will make the determination by performing risk assessment.[65] With respect to Food Related Products, products with a high risk, such as packaging materials that come into direct contact with food, must acquire a production license on relevant industrial products per national provisions of the product license administration.[66] Food producers and traders are also required to recall affected products upon the discovery of unsafe food, an online trading platforms do have obligations to stop and report violations when discovered.

b. Traceability

Traceability, through both private and public mechanisms, is a centerpiece of regulatory reform. In promoting traceability system, the State Council seeks to achieve multiple purposes, including facilitating product recall and mobilizing public participation in food safety management.[67]

MOFCOM first pioneered a traceability system for a select category of vegetables and meat in 2010 in a number of cities and is in the middle of expanding and optimizing its system. Building on MOFCOM's precedent, the amended Food Safety Law now mandates the establishment of private (food producers and distributors) and public traceability systems.[68] Private sector actors are encouraged to deploy information technology,[69] and the State is slated to build a national traceability system by 2020.[70] Notably, neither the law nor its Draft Implementation Regulation introduces detailed guidance or concrete criteria, including which elements should be traced.

[62] The Amended Food Safety Law (2015), Article 33.
[63] 2016 Draft Implementation Regulation, Articles 52, 59-62.
[64] The Amended Food Safety Law (2015), Articles 39 and 40.
[65] USDA, Food and Agricultural Import Regulations and Standards - Narrative (2016).
[66] The Amended Food Safety Law (2015), Article 41.
[67] CFDA website, http://www.sda.gov.cn/WS01/CL1686/141622.html
[68] The Amended Food Safety Law (2015), Article 42.
[69] The Amended Food Safety Law (2015), Article 42.
[70] The Amended Food Safety Law (2015), Article 42.

Striking the right balance between traceability, which tends to carry a high cost, and acceptance of food by the public will remain an ongoing challenge.

With regard to implementation, the Opinion of the State Council on the Acceleration of Construction of Traceability System ("the Opinion") and subsequent ministerial opinions and interpretations shed light on the challenges and focus of national, ministerial, local and private traceability systems.[71] The Opinion addresses implementation difficulties shared among stakeholders and proposes broad-stroke policy antidotes.

The first challenge is to balance experimentation and innovation with coordination and ultimate national data integration. As acknowledged in the Opinion, since traceability is a recent phenomenon, experimentation and innovation at different levels of governance will be conducive to configuring an optimal system. In reality, however, various ministries, their local branches, and private actors have launched a wide array of systems, absent of a coherent standard or model system. For instance, MOFCOM has experimented with vegetable and meat traceability systems in 58 cities. By the end of 2015, MOA had launched its own version targeting a select category of products such as apple and pork. Multinational retailers, such as Carrefour and Walmart, have sophisticated internal traceability systems.

However, formulation and maintenance of disparate traceability systems and portions of the supply chain can result in inefficient coordination and impede data collection. In particular, supervision could become redundant and potentially inconsistent, such as between MOFCOM and MOA. An absence of a concrete definition of traceability aggravates the problem, and misguided interpretations abound. For instance, some farmers equate traceability with "real-time monitoring of production activities" and have installed cameras in their farms for consumers to inspect remotely. Moreover, interoperability of information stored in different platforms and formats poses an acute problem for uploading and integrating all information onto the national platform.

Seeing the tension between experimentation and unification, the government has rolled out policies to harmonize various traceability mechanisms. To that end, the State Council has prompted governmental organs to promote best practices and set baseline standards. For instance, the Opinion explicitly calls for expedient establishment of key common standards, unified elements for data collection, transmission formats, interface specifications, and coding rules. The outcome of these policies is yet to be seen.

The second challenge is limited private sector participation. This mostly concerns small- and medium-sized enterprises (SMEs), the predominant group of producers and distributors. Weak private sector participation has three causes: low level of awareness of rules and regulations, financial constraints, and ineffective government intervention. The low level of awareness is pervasive among small distributors who have not formed a habit of obtaining a written record of

[71] *See* CFDA website: http://www.sda.gov.cn/WS01/CL1686/141622.htmll; MOA website, http://www.moa.gov.cn/govpublic/ncpzlaq/201606/t20160623_5184476.htm; CFDA website, http://www.sda.gov.cn/WS01/CL0852/164862.html; http://www.mofcom.gov.cn/article/h/redht/201603/20160301266680.shtml; Shanghai Municipal Government website, http://www.shanghai.gov.cn/nw2/nw2314/nw2315/nw32813/nw32817/nw32834/userobject82aw14087.html?4

the sources of their supplies. Even among SMEs that are aware of the legal requirements, financial constraints are pervasive. SMEs generally have little incentive or inadequate financial resources to launch complex traceability systems, let alone to keep detailed or consistent records. Indeed, wholesale market vendors who have to source the same product from a number of producers, which could only produce limited quantities, find traceability particularly onerous and pay little heed to it. This means that an even smaller number of enterprises are willing and able to outsource their traceability mechanisms to third party technology service providers. Weak demand for third party service providers will lead to the vicious circle of an underdevelopment of relevant technology services and may delay reductions in prices. Government intervention has thus far remained at a high level of generality and does not address the root causes of the challenges. For instance, the Opinion urges industry associations to mobilize participation of their members, advocates for channeling direct investment capital flow into developing the traceability services sector, and mentions preferences through government procurement.

Another challenge is the lack of clear safeguards for sensitive business information, which could deter private participation. Relevant laws and regulations have so far touted full traceability on the national level which, when completed, would enable consumers to gather logistical flows, ingredients, and other information of a given producer or distributor. This would give business competitors unlimited access to otherwise confidential or sensitive business information. However, mechanisms for protecting confidential business information remain unclear.

c. Inspection

Increased inspection is another prominent feature of the legal reform. Inspection will take various forms. In line with the emphasis on industry self-regulation, the amended Food Safety Law requires regular self-inspection for food producers, distributors, and wholesale market operators.[72] Additionally, governmental agencies are obliged to redouble their efforts in inspection through random and regular inspections.[73] The Draft Implementation Regulation further proposes full-time food safety inspector teams to carry out on-site inspections for above-scale food producers and stipulates unannounced inspection by higher level FDAs.[74]

Strengthened inspection, if enforced properly, could substantially advance food safety. In the past, industry observers and participants have noted that the frequency of inspection and probability of being caught are highly correlated with voluntary compliance with relevant standards, and insufficient inspection was a major contributor to food safety incidents. As an illustration, producers of edible agricultural products are known to calculate the probability of being caught based on the inspection of their downstream retailers/supermarkets and to maintain and tailor their compliance with pesticides standards accordingly. Since high-end retail markets and exports are subject to more frequent inspection, compliance rates with pesticides standards turn out to be significantly higher. In contrast, products destined for low-end wholesale or retail markets are less likely to be inspected, and pesticides are more likely to exceed the maximum levels allowed.

[72] The Amended Food Safety Law (2015), Articles 47 and 64.
[73] The Amended Food Safety Law (2015), Article 87.
[74] 2016 Draft Implementation Regulation, Articles 135 and 155.

Since the entry into force of the amended Food Safety Law in October 2015, regular and unannounced inspections in major cities have increased overall, with regional divergences. For instance, in parts of Beijing, local FDA inspectors now conduct weekly inspections in lieu of monthly inspections. In contrast, inspections in other regions have either increased mildly or stagnated. Geography is a limiting factor for the reach and frequency of inspections. In particular, Western China is characterized by an expansive area of mountains and relatively underpopulated provinces where farmlands are scattered in the local jurisdictions. Consequently, inspection incurs substantial travel time and is much more limited.

Weak capacity is a chronic challenge to inspection. Economic and structural factors account for weak technological and human capacities. Economically, the heterogeneous level of economic development in China dictates wide discrepancies in testing capabilities. Some testing, such as the authenticity of honey, requires sophisticated and capital intensive equipment that is only available in the most economically advanced cities. Accordingly, local CFDAs must send samples to the few cities with the requisite equipment. Structurally, the creation of local CFDA through the merger of FDAs, SAICs, and AQSIQs obligates, for instance, former SAIC inspectors to expand their responsibility from advertisement-related inspection to the whole universe of food safety inspections. Familiarization with the Food Safety Law and other regulations and standards requires additional investment in time and continuing training. However, to date, guidelines on "how, when, who, and what to train" and how to evaluate the results of training are still absent.

Of note, the significant growth in private food testing agencies is driving increased inspection. From 2009 to 2012, the food safety testing market grew at an average rate of 20 percent, with a projected value of USD 791.5 million by 2020.[75] The private sector seized a large portion of market share. These data reflect implementation of the food safety testing system and growing public participation, particularly via consumer associations.

The space for private food testing agencies was created by formally severing the ties between all public food testing agencies and their affiliated inspection authorities. This means that inspection authorities can engage either public or private food testing agencies to test their samples. Likewise, public food testing agencies transact with both governmental and non-governmental entities and compete with private food testing agencies. The infusion of market pressure into the industry has spurred technological advancement, exerted downward pressure on prices, boosted additional private investment and diversity of services, and paved the way for more public participation in food testing and reporting. The degree of competition varies across the country. In some cities, old ties between governmental inspection authorities and affiliated agencies breed favoritism, whereas in other cities, local CFDAs have instituted annual bidding processes for testing services.

[75] Businesswire, China Food Safety Testing Market & Regulations Report 2015-2020. http://www.businesswire.com/news/home/20160325005111/en/China-Food-Safety-Testing-Market-Regulations-Report; Quality Assurance and Food Safety, China Food Safety Testing Industry 2013 Analysis Released, http://www.qualityassurancemag.com/article/china-food-safety-testing-report/

d. Labels, Descriptions, and Advertisements

In regulating labels, descriptions, and advertisements, a number of laws, regulations, and standards are in force. With regard to labeling, the amended Food Safety Law prescribes a detailed list of information that must be included on pre-packaged food, including shelf life and storage requirements. It mandates compliance with relevant national food safety standards.[76] Notable national standards include the General Standard for the Labeling of Prepackaged Foods **(**GB 7718-2011**),** Standard for Nutrition Labeling of Prepackaged foods (GB 28050-2011), and General Rules for the Labeling of Prepackaged Food for Special Dietary Uses (GB 13432-2013). In addition to these standards, CDFA has published the Announcement on Further Standardization of Health Food Naming, which bans the expression of product function in the product name. [77] Moreover, the amended Food Safety Law prohibits false information, exaggerated information, or statements about disease prevention and treatment functions.[78] Both producer and distributor are liable for violations of labeling requirements.[79]

The Draft Implementation Regulation calls for additional requirements with respect to specific products and circulation, such as clear labeling of genetically modified food,[80] which also have a basis in Article 69 of the Amended Food Safety Law. For labels that are non-compliant with food safety standards but do not pose health related harm, a Grade III recall applies,[81] which would allow a 72-hour window for food producers and traders to initiate a food recall based upon knowledge of food safety risks that would not result in health impairment.[82]

With respect to advertisement, the amended Food Safety Law provides disciplines for false information or claims of disease prevention or treatment functions. Additional laws and guidance are stipulated in the amended Advertising Law (2015) and the Interim Regulation on Food Advertisements Publication.

e. Special Food

The amended Food Safety Law identifies three types of special foods and subjects them to "strict supervision and administration."[83] The three types are health care food, foods for special medical purposes, and infant formula food.[84] Both the Draft Implementation Regulation and subsequent draft regulations issued by CFDA have supplied detailed rules in relation to each of the three types of special food.

Some key provisions highlight this area of focus. Baby formula food, an area with sustained attention after headline food safety scandals, is subject to stringent regulation. Producers of infant formula must file ingredients, food additives, formula and labels with provincial-

[76] The Amended Food Safety Law (2015), Article 71.
[77] CFDA announcement: http://www.sfda.gov.cn/WS01/CL0087/145300.html
[78] The Amended Food Safety Law (2015), Article 67.
[79] The Amended Food Safety Law (2015), Article 71.
[80] 2016 Draft Implementation Regulation, Article 79.
[81] 2016 Draft Implementation Regulation, Article 67.
[82] 2016 Draft Implementation Regulation, Article 67.
[83] The Amended Food Safety Law (2015), Article 74.
[84] The Amended Food Safety Law (2015), Articles 92 and 96.

level FDAs and must also maintain full-process quality control from incoming materials to outgoing finished products. Outgoing infant formula food must be inspected batch by batch.[85] In conjunction with provisions regulating imports, imported baby formula food must adhere to Chinese regulations and standards and must be registered.[86]

For health care food, CFDA is directed to develop, adjust, and publish the catalogue of health food materials and the catalogue of health foods permitted to have health function claims.[87] Additionally, health care food can only be sold from specific counters or in areas that are clearly marked as "special area/counter for health foods."[88]

D. Cross-border Trade

The AQSIQ is required to construct the framework of imported food management based on food safety risk, the importer's capacity to control food safety, and the food safety status of exporting countries. [89] The new law specifies three risk levels and obligates the China Inspection and Quarantine Services (CIQ) to undertake different inspections per the risk level.[90] High risk products would be detained for inspection; products of common risks would be subject to sampling tests; and products of low risks would go through on-site inspections.[91]

Food importers shoulder a heavy burden to ensure food safety. First, food importers, importing agents, and manufacturers of imported food products must all register with the AQSIQ. Second, importers must establish an import and sale record of food, food additives, and Food-Related Products with detailed information such as production date and preservation relevant credentials. Third, importers must operate a review system for overseas exporters and producing enterprises.

E. Enforcement

Two enforcement systems undergird the food safety system. On the one hand, a formal legal route allows for administrative, civil, and criminal penalties. On the other hand, credibility systems complement the formal legal system.

a. Formal Legal System

The formal legal system follows the Food Safety Law and has several remarkable enforcement features. First, an extended list of activities and actors are subject to legal liabilities, including:

1) Food producers or distributors who produce or distribute food with potentially harmful non-food raw materials or chemicals other than food additives or who fail to meet food safety standards;

[85] The Amended Food Safety Law (2015), Article 81.
[86] The Amended Food Safety Law (2015), Article 74.
[87] 2016 Draft Implementation Regulation, Article 83.
[88] 2016 Draft Implementation Regulation, Article 91.
[89] 2016 Draft Implementation Regulation, Article 111.
[90] 2016 Draft Implementation Regulation, Article 114.
[91] 2016 Draft Implementation Regulation, Article 114.

2) Food operators of central trading markets, stall leasers, and organizers of trade fairs who fail to perform their inspection or reporting obligations;
3) Anyone who refuses, impedes, or intervenes with relevant departments, authorities, and their officials in carrying out their food safety related duties;
4) Certification agency that provides false certifications;
5) Media outlets that fabricates or disseminates false food safety information; and
6) Negligence of government officials in performing their food safety related official duties.

It is noteworthy that the Food Safety Law works in concert with the Advertising Law and disciplines a broad range of actors. For instance, an advertiser or publisher who designs, directs, or publishes false food advertisements and civil societies or other organizations or individuals who recommend a food to consumers may be jointly and severally liable with the food producer and distributor.[92]

Second, the amended Food Safety Law lays down heightened and detailed administrative, civil, and criminal penalties. Administrative penalties encompass a revocation of licenses, confiscation of unlawful gains, and fines. Article 122 of the amended Food Safety Law specifies that food producers or distributors who violate the Law shall be subject to a fine of RMB 50,000 - 100,000 if the total value of the food or food additive is less than RMB 10,000, or a fine between 10 and 20 times the total value of the commodity if the total value of the commodity exceeds RMB 10,000. With respect to civil liabilities, rectifying China's weak tort law, the amended Food Safety Law allows a consumer harmed by a product non-compliant with food safety standards to sue either the producer or distributor. The consumer can demand compensation 10 times the purchase price or 3 times the damage, at a minimum of RMB 1,000, in addition to the compensation for the loss thereof.[93] Further, in line with the growing criminal sanction food safety violation under the amended Criminal Code (2011), the new Food Safety Law now expressly obligates CFDA and other administrative agencies to promptly refer suspected food safety crimes to the Ministry of Public Security, which must then investigate the allegations in a timely fashion.[94] Wherever the Ministry of Public Security deems that criminal facts exist, it shall put the referred case on file to investigate.[95] The heightened criminal punishment is widely hailed as an important deterrence to ensure compliance.

A compulsory minimum fine of RMB 50,000, however, has become a primary impediment to administrative enforcement. As mentioned, SMEs, with narrow profit margins, dominate the food industry. In a country where annual income of urban households amounted to RMB 21,809 in 2014, RMB 50,000 is such a hefty fine that most violators prefer to close down their business and relocate than to pay the fine. Local CFDA officials, well aware of the predictable outcome and concerned about increased unemployment, opt to issue warnings instead. The warnings, however, do not lead to further sanctions and dampens the intended deterrence effect of the fine.

[92] The Amended Food Safety Law (2015), Article 140.
[93] The Amended Food Safety Law (2015), Article 148.
[94] The Amended Food Safety Law (2015), Article 121.
[95] The Amended Food Safety Law (2015), Article 121.

As a general matter, setting a number that optimally balances punishment and incentives is a delicate task. A one-size-fit-all approach is unproductive in a country with such wide economic disparity. Further, legislators in Beijing may not possess sufficient data points about other regions, and the unrepresentatively high living expense and consumer prices in Beijing may have additionally skewed their measurement.

Third, the new law underscores cooperation and coordination among different administrative, judicial, public security authorities. For instance, joint issuance of relevant measures by the CFDA, the Ministry of Public Security, the Supreme People's Court, Supreme People's Procuratorate, and the Office of State Council's Food Safety Commission were released in December 2015.[96] Additionally, several provinces have founded special units targeting food and drug violations, usually within the police force (the "food and drug police"). In the same vein, a vertically integrated national system was jointly proposed by the Ministry of Public Security and CFDA in 2014,[97] although details of the national system have not yet been announced. Further, the Draft Implementation Regulation has multiple provisions that account for transfer and referral of cases and evidence between administrative and criminal cases and provision of technical support.[98]

An examination of inter-departmental coordination reveals a mixed picture. On the bright side, both police and prosecution have prioritized food safety crimes. As an illustration, food safety crimes were put under special case supervision by the Supreme People's Procuratorate from March 2015 until December 2016.[99] Prosecutors in local jurisdictions have also reported more confined prosecutorial discretion with respect to food safety crimes.

Nevertheless, in the eyes of administrative agents, the bar for opening a formal criminal investigation remains too high. When the police are involved in an investigation early on, they frequently deem the available evidence to be insufficient for a formal criminal investigation. However, the accumulation of evidence often entails additional time and overt administrative actions, such as detailed inspection. Without the ability to detain suspects or freeze assets, suspects could destroy available evidence, flee, relocate, or cease their activities until the investigation is over.

The law also encourages individuals to assist with law enforcement.[100] It expressly prohibits retaliation against whistle-blowers, through employment contracts or otherwise, and sanctions are applied to those who retaliate.[101] The Draft Implementation Regulation further authorizes relevant authorities to punish anyone who takes revenge against reporters or witnesses.[102]

Consumer associations in various cities have achieved some successes. Individual consumers, however, face two barriers in their quest to actively report suspected food safety incidents. First, consumer education remains inadequate. They tend to be unaware of relevant standards and the

[96] The National Law Review, China Food Law, Year in Review 2015 Part 1.
[97] *See*, e.g. Xinhuanet, The Establishment of Food http://news.xinhuanet.com/local/2015-03/06/c_127550124.htm
[98] *See*, e.g. 2016 Draft Implementation Regulation, Articles 167, 169, and 171.
[99] The National Law Review, China Food Law, Year in Review 2015 Part 1.
[100] *See* 2016 Draft Implementation Regulation, Article 7.
[101] The Amended Food Safety Law (2015), Articles 115 and 133.
[102] 2016 Draft Implementation Regulation, Article 193.

channels for legal recourse. Moreover, media, when uninformed, could further obstruct the flow of accurate information. Second, even with such awareness, consumers face evidentiary challenges. When a consumer suspects a food safety breach, they would first seek to obtain corroborating evidence, usually testing results from a food testing agency.

Two hurdles are pervasive. The first is financial. While the amended Food Safety Law allows consumer associations and consumers to entrust a food testing agency with food testing,[103] the market for food testing generally is not open to individuals. Indeed, due to the limited quantity and sporadic nature of individual food testing requests, food testing agencies tend to prioritize business relations with government agencies, food companies, or consumer associations. The second relates to a lack of information and knowledge. Even in circumstances where local governments have set aside a budget and contracted with testing agencies to allow individual consumers to test samples free of charge, consumers generally fail to take advantage of it. After all, consumers generally lack the technical background to pinpoint the exact substance that should be tested. For instance, a consumer suspecting that she has purchased fake honey is unlikely to be able to specify which the difference in chemicals between fake and authentic honey and subsequently request the testing of those chemicals.

Overall, within the formal legal framework, several cross-cutting challenges arise. First, most stakeholders, public and private, lack awareness of food safety requirements.[104] Knowledge of relevant legal liabilities is limited, as is knowledge of the means through which the public could proactively participate in food safety management. Social media campaigns, orchestrated by the government with accurate information, has not reached the general public.

Second, oversight cohesion and government coordination, while substantially addressed, is a recurrent stumbling block. Overlapping responsibilities and ambiguous delineation of authority are still present. For instance, MOA and MOFCOM have both launched traceability mechanisms for pork without express cooperation with respect to uniform standards, technological interoperability, and division of labor. Similarly, heterogeneous paces of reform at different levels of governance have slowed down cross-fertilization of expertise and institutional integration. Officials in local CFDAs, previously in three different agencies, sometimes continue to work in clinical isolation. For instance, in some provinces, the CFDA is established by merging the FDA, the AQSIQ, and the AIC at the district level but not yet at the city level. As a result, the officials at the newly founded CFDA would continue reporting to and receiving instruction from their former superiors. For instance, a district CFDA official who previously worked at the district FDA would continue working with the city FDA. This phenomenon is commonly dubbed "physical integration, not chemical integration."

Third, weak capacity is prevalent in less affluent regions. Insufficient technological and human capacity cripple inspection and surveillance in particular. The pressing need for food safety training is evident in local jurisdictions.[105]

[103] The Amended Food Safety Law (2015), Article 121.
[104] USDA, The Food Safety Management System in China (2013); Jie-hong Zhou, Kai Li, Qiao Liang, Food Safety Controls In Different Governance Structures In China's Vegetable And Fruit Industry.
[105] USDA, The Food Safety Management System in China (2013).

Fourth, mechanisms to encourage voluntary and proactive compliance with food safety regulation are still insufficient. For food producers and distributors, the imposition of new legal requirements, without flexibility in grace periods or piecemeal capacity building based on the size and sophistication of enterprises, yields reluctant and rushed compliance at best. For consumers, most of them have yet to consolidate and translate their preferences into strong market signals.

Finally, structurally, the dominance of SMEs is a perennial obstacle for effective food safety management. A significant number of SMEs not only lack awareness, financial resources, and incentives to self-regulate in accordance with applicable laws, regulations, and standards; the market composition has also generated a web of first-, second- and third-tier subcontractors and suppliers that complicate monitoring and supervision.[106]

b. Credibility System

Credibility systems, through governmental and private initiatives, complement formal legal sanctions. The government-backed system through the amended Food Safety Law covers various points along the supply chain. For production and distribution, local CFDAs are directed to set up, maintain, update, and publicize food safety credits of producers and distributors.[107] Credits are ratings that correspond to the level of compliance, measured through regular and unannounced inspections. Similarly, for cross-border trade, state entry-exit inspection and quarantine administration are mandated to establish and publish credit records of importers, exporters, and producers of food for export.[108] MOA has also announced that it would set up its own credibility system and blacklist with respect to traceability. In all situations, poor credibility ratings will result in more frequent inspection.[109] Further, the State is committed to giving the credibility system more teeth: the Draft Implementation Regulation seeks to peg food safety credits with other credit systems, such as financing/loan credits and stock issuance.[110]

Similarly, private actors also play a role, most notably through small-scale farmers' markets. These farmers' markets, both in major cities and remote towns, tend to rely upon the same food vendors, who face scrutiny within a relatively small community, thereby substantially increasing the cost of defection or production or distribution of noncompliant products.

[106] Jie-hong Zhou, Kai Li, Qiao Liang, Food Safety Controls in Different Governance Structures In China's Vegetable And Fruit Industry.; Drew Thompson and Hu Ying, Food Safety in China: New Strategies.
[107] The Amended Food Safety Law (2015), Article 113.
[108] The Amended Food Safety Law (2015), Article 100.
[109] The Amended Food Safety Law (2015), Articles 100 and 113; MOA website, http://www.moa.gov.cn/govpublic/ncpzlaq/201606/t20160623_5184476.htm
[110] 2016 Draft Implementation Regulation, Article 147.

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