

Chinese Medicinal Herbs Case Study

New Markets Lab
November 2017

I. Executive Summary

Over the past several years, China has pursued ambitious legal and institutional reforms to boost food safety, with an amended Food Safety Law (2015) (FSL) as the centerpiece. This case study assesses the reform of China's food safety regime as it pertains to the Chinese medicinal herbs (CMH) industry. It presents a snapshot of China's rapidly evolving food safety system, highlights obstacles to the ongoing implementation of the FSL, and offers recommendations for improving implementation of China's legal system related to food safety. Several areas of legal and regulatory reform are assessed, all of which are central to food safety and part of ongoing implementation efforts: inspection, certification, traceability, and e-commerce.¹ This case study on CMH is part of an ongoing series of work on China's legal and regulatory system for food safety done in partnership by the Syngenta Foundation for Sustainable Agriculture (SFSA) and New Markets Lab (NML), which includes additional case studies on important value chains and an assessment of global best practices in food safety.

Among horticultural crops, CMH hold unique cultural, health, and economic significance. Indeed, in China, CMH underpin Chinese people's daily diet, healthcare system, and economy. Moreover, the development of the CHM industry has become a national strategy, enshrined in China's Outline of the Strategic Plan on the Development of Traditional Chinese Medicine (2015 - 2030) released by the State Council. In this case study, several CMH are assessed – fritillaria cirrhosa (beimu), American ginseng (ginseng), and Sichuan lovage rhizome (chuanxiong) – which have highly varied supply chains and climatic conditions.

The action-oriented recommendations at the conclusion of the case study (summarized in Table 1) were developed in the context of global best practices and are designed to address the challenges identified in the legal and regulatory assessment. Overall, two overarching themes emerge. First, stakeholders are widely divergent in terms of size and capacity, which has given rise to varying levels of compliance and necessitates policy responses to balance food safety management and

¹ Importantly, China's food safety is rapidly evolving; this paper is a snapshot of the developments in November 2017. Future development should be closely monitored.

inclusive growth (particularly with respect to e-commerce and certification). Second, China's existing institutional structure has led to inefficiencies (e.g. inspection) and overlapping mandates (e.g. multiple traceability systems). Hence, institutional overhaul should be a priority, and inter-agency cooperation should be enhanced.

Table 1: Summary of Current Status of Food Safety Regulation in Chinese CMH Context

Regulatory Issue	Current Status	Recommendations
Inspection	<ul style="list-style-type: none"> • Institutional restructuring mandated to create China Food and Drug Administration (CFDA) by merging existing ministries at all levels (e.g. province, city, district, and county) in order to centrally manage food safety; restructuring has occurred at different paces across different levels and has resulted in supervision gaps/unclear obligations during the restructuring • Inter-agency cooperation ineffective as government affiliated consumer associations minimize food safety inspections to avoid calling into question the effectiveness of CFDA • Innovations in the public sector to enable more streamlined and targeted inspection include establishment of the Pesticide Supervision Bureau (PSB) and branch office of CFDA in a wholesale market that routinely inspects sulfur dioxide • Increased inspection by private actors, particularly through frequent self-inspection (including inspection of farmers by company employees in integrated supply chains) and growing use of third-party testing 	<ul style="list-style-type: none"> • Completion of institutional restructuring at all levels with clear deadlines and clarification of responsibilities before the completion of restructuring • Outsourcing, partially or fully, of food inspection to independent third parties to address the challenges facing government affiliated consumer associations, a process that could be initiated by consumer associations, branch Administration for Industry and Commerce (AICs) that fund consumer associations, or a more top down policy change
Certification	<ul style="list-style-type: none"> • Proposed cancelation of mandatory Good Manufacturing Practice (GMP) and Good Storage Practice (GSP) certifications due to financial and technological infeasibility for a large portion of processors and distributors 	<ul style="list-style-type: none"> • Finalization of the proposed cancelation of mandatory certifications • Partnership between ministries to encourage the voluntary uptake of certifications to promote high standards and spur exports, a practice in line with global trends
Traceability	<ul style="list-style-type: none"> • Three overlapping and gradually converging traceability systems (food, drug, and CMH-specific) resulting 	<ul style="list-style-type: none"> • Collaboration among stakeholders administering overlapping traceability systems to ensure interoperability and

	<p>from different legal mandates and institutional initiatives</p> <ul style="list-style-type: none"> • Guidelines, opinions, and standards continuously released (formulated in collaboration with private actors and academic institutions) and pilot projects undertaken in 18 provinces • Private traceability systems highly heterogeneous, depending on their capabilities and supply chain structures • Forthcoming industry standards with differential and phased-in implementation with market leaders as standard setters, 2nd tier companies as market followers, and SMEs in need of training and resources to comply with traceability requirements 	<p>reduce duplication and fragmentation</p> <ul style="list-style-type: none"> • Rigorous analysis, institutionalization, and scaling up of pilot projects • SMEs assisted through structural reforms (e.g. equitable contract farming) and specialized market services (e.g. Farmforce) • Development and diffusion of information technology (e.g. blockchain technology)
E-commerce	<ul style="list-style-type: none"> • Traders, third-party platforms, and healthcare food subject to stringent regulation, which could be heightened with the forthcoming E-Commerce Law • Ambiguity and complexity in legal regulation raise entry barriers and favor more sophisticated and specialized actors • Divergent level of compliance between retail and wholesale e-commerce markets 	<ul style="list-style-type: none"> • Construction of an inclusive legal and regulatory framework with clearly defined legal obligations (e.g. resolution of legal ambiguities such as license waivers and responsibilities for WeChat stores) • SMEs assisted through training of operation of e-commerce and marketing by local officials or third parties (e.g. “senior universities”)

Source: *New Markets Lab (2017)*

II. Overview of the Chinese Medicinal Herbs Industry

CMH are integral to the daily diet, healthcare system, and economic activities in China. Within households, CMH are consumed as dishes (e.g. leaves of chuanxiong and Chinese yam), beverages (e.g. dried chrysanthemum and honeysuckle), and seasonings (e.g. dried ginger and prickly ash).² As a pillar of China’s health care system, CMH function as a relatively affordable and easily accessible alternative to or supplement of Western hospitals and medicine. By 2015, there were 3,966 Chinese medicine hospitals and 42,528 Chinese medicine clinics, providing an annual average of 910 million consultations.³ Further, CMH are also key drivers of the economy at both the micro and macro levels: farmers of CMH have generally earned a higher income than farmers cultivating other crops, CMH hospitals and clinics employed around 452,000

² Greenpeace, *Chinese Herbs: Elixir of Health or Pesticide Cocktail?* 2013. Web. November 17 2017.

³ China.org.cn, *China issues first white paper on TCM*, December 6 2016. Web. November 17 2017.

practitioners in 2015,⁴ and CMH products accounted for roughly 32 percent of wholesale revenue of China's total pharmaceutical market in 2015.⁵

There are around 11,146 different varieties of CMH, both wild and cultivated, scattered across China.⁶ The government has promoted cultivation of CMH; over 200 species of CMH have become highly commercialized with demand over one thousand tons.⁷ The production and processing of CMH can be summarized in 3 main steps, as illustrated by Diagram 1 below.

Diagram 1: Production and Processing of CMH



Source: *New Markets Lab (2017)*

The cultivation of CMH can take longer periods of time than other crops. For example, while chuanxiong is harvested annually, it can take four years to cultivate ginseng and five years to cultivate beimu. Once CMH are harvested, farmers undertake preliminary processing manually or with machines (e.g. specialized cleansing or drying machines). Preliminarily processed CMH are regulated as edible agricultural products and can be sold by farmers without a license. CMH can be further processed by licensed entities to produce three main products: Chinese patent medicine (中成药), decoction pieces (中药饮片), and health food. Health food derived from CMH is predominately made through extraction.⁸ Some CMH, such as beimu, tend to be primary ingredients of health food, while others, such as ginseng, tend to be subsidiary ingredients.

The industry structure of CMH is highly heterogeneous, even with respect to the same CMH. For instance, ginseng is mostly grown in three provinces: Beijing, Shandong, and Jilin. The supply chains in Beijing and Shandong have become highly integrated. Leading pharmaceutical companies in these two provinces have established cultivation bases, deployed long-term contract farming, or worked closely with agricultural cooperatives. In contrast, the ginseng industry in Jilin is fragmented, and ginseng cultivated in Jilin are more likely to end up in

⁴ China.org.cn, *China issues first white paper on TCM*, December 6 2016. Web. November 17 2017.

⁵ GF Securities (Hong Kong) Brokerage Limited, *Traditional Chinese Medicine Industry*, October 31 2016. Web. November 17 2017.

⁶ Greenpeace, *Chinese Herbs: Exlir of Health or Pesticide Cocktail?* 2013. Web.

⁷ The Wildlife Trade Monitoring Network (TRAFFIC), *Engaging China's Private Sector in Sustainable Management of Medicinal Plants—The Multiplier Effect*, July 2015. Web.

⁸ Sa Yi and Yu Chao, *Analysis of approved health food containing Chinese materia medica and advice for supervision and management*, *Chinese Traditional and Herbal Drugs*, 45 (10), May 2014.

wholesale markets and eventually in Chinese medicine clinics, retail stores, and local residents' tea pots. Akin to the ginseng industry, the beimu industry also witnesses a high degree of heterogeneity. Chuanxiong, found only in two cities in Sichuan, is predominantly grown on small family farms that do not belong to any agricultural cooperatives or closed supply chains.

III. Legal and Regulatory Assessment

A. Standards, Inspection, and Certification

Food safety standards associated with CMH are contained in the Pharmacopoeia of the People's Republic of China (the Pharmacopoeia; edited by the Chinese Pharmacopoeia Commission and updated in 2015). The Pharmacopoeia sets out various product and production standards, such as maximum residue levels (MRLs) of pesticides, heavy metals, and sulfur dioxide. The standards were formulated in collaboration with private actors, academic institutions, and hospitals. The coverage of CMH has expanded, and a new edition of the Pharmacopoeia will be released in 2020, with a growing list of CMH.

A number of standards are applicable to CMH, such as MRLs for pesticides, heavy metals, or sulfur dioxide (a chemical commonly used during storage). Pesticide residues in particular have received sustained public attention due to a Greenpeace report (2013) that documented the use of illegal or highly or extremely hazardous pesticides among several dozens of CMH.⁹

Inspection

The FSL requires regular self-inspection for food producers, distributors, and wholesale market operators and obligates governmental agencies to redouble their efforts in inspection through random and regular inspections.¹⁰ Since the passage of the FSL, both public and private initiatives have improved inspection in China.

Public initiatives include institutional reforms to bring about more streamlined and targeted supervision of inspection. One recent reform is the establishment of Pesticide Supervision Bureau (PSB), within the Ministry of Agriculture, in June 2017. PSB was created by merging the relevant functions of the Administration for Industry and Commerce (AIC) and Administration of Quality Supervision, Inspection and Quarantine (AQSIQ).¹¹ PSB was designed to avoid regulatory overlap and gaps that hampered pesticide supervision and monitoring in the past. Additionally, a branch office of the municipal China Food and Drug Administration (CFDA) was installed in a wholesale market with over 2000 stores in Sichuan. The CFDA branch office has an on-site testing lab that routinely inspects for sulfur dioxide, frequently applied in excess of the MRL across different CMH.

⁹ Greenpeace, *Chinese Herbs: Exlir of Health or Pesticide Cocktail?* 2013. Web. November 17 2017.

¹⁰ The Amended Food Safety Law (2015), Articles 47,64, and 87.

¹¹ Xinhuanet, *农业部成立农药管理局 农药管理体制作出新调整*. October 10 2017. Web. November 17 2017.

Private initiatives include increased supply chain integration, frequent self-inspection, and growing use of third-party testing. With respect to supply chain integration, actors with market power, such as major pharmaceutical companies, have instituted mechanisms to ensure standard compliance along the supply chain. For instance, ginseng pharmaceutical companies in Beijing and Shandong form long-term contracts with farmers or work closely with cooperatives; under these models, company send employees to perform on-site supervision, monitoring, and inspection.

Some companies have also engaged in frequent self-inspection through purchasing of testing equipment or outsourcing to third party testing agencies. For these companies, inspection could have two objectives. The first is to ensure compliance with relevant standards. The second, for companies that produce both health food and drugs, is to distinguish raw materials destined for the two types of products. Due to stringent requirements, high penalties, and high rates of government inspection of health food (a special category under the FSL), companies sometimes allocate batches with lower levels of pesticide residue for health food to minimize the possibility of non-compliance with standards. Further, third-party testing agencies have become more prominent in the market. Large upstream actors (including wholesalers) routinely obtain inspection results indicating standard compliance before selling to downstream actors (such as pharmaceutical companies). In response, downstream actors regularly engage other inspection agencies to carry out additional rounds of inspection to guard against skewed results or collusion between downstream actors and their inspection agencies. Such has waned in recent years; the growing market has fostered the expansion of reputable inspection agencies, and frequent inspection by downstream actors renders collusion less profitable in the long run.

Two issues potentially impair the overall efficacy of CMH inspection. The first issue is ineffective inter-agency cooperation, shaped by existing institutional structures. One example is the functioning of consumer associations, an arm of AIC, that have the mandate and funding to inspect food. In practice, consumers associations inspect food much less frequently than other products such as electronic devices. This is because the AIC has operated with the implicit understanding that it should refrain from activities that could call into question the effectiveness of CFDA, given the role of CFDA as the primary guardian of food safety and the attention and sensitivity around CMH. Another example is the uneven pace of institutional restructuring. Local CFDA offices are being created by merging provincial, municipal, district, and country Food and Drug Administrations (FDAs), AICs, and AQSIQs. These mergers started in 2013 with disparate levels of completion. This means that the officials in institutions with an incomplete merger often lacked clarification of their roles during transition periods. For instance, AIC officials from the district level (where institutional mergers have not been completed) who work at the wholesale market with a municipal CFDA branch either do not have clear mandate to inspect or often show a preference for deferring to the more specialized municipal CFDA.

Another issue concerns small and medium-sized enterprises (SMEs). While actors with market power are working to ensure compliance with standards among SMEs that fall within their supply chains, SMEs outside of these closed or quasi-closed systems appear unaware of relevant standards and tend to channel their products into segments of the market where inspections occur rarely. For instance, the production of Chuanxiong is not monitored or inspected by any public or private institution. For ginseng, wholesalers sometimes deliberately purchase products from

SMEs from regions that are known to have high pesticide residues and distribute them to buyers that are unlikely to conduct further inspection (e.g. small pharmacies, clinics, and local residents).

Certification

In food safety systems, certification is typically a verification process, usually done by a third-party, that a product, process, or system conforms to a given standard.¹² Certification can be voluntary or mandatory. In China, the Certification and Accreditation Administration (CNCA) oversees a wide range of certification and accreditation activities, including managing eleven certification systems aligned with international standards such as Hazard Analysis and Critical Control Point (HACCP) and Good Agricultural Practices (GAP).¹³

With respect to CMH, two existing certifications are particularly relevant: Good Manufacturing Practice (GMP) and Good Manufacturing Practice (GSP). Under the Drug Administration Law, GMP and GSP are mandatory for the processing and distribution of CMH products and are certified by CFDA. As a major policy shift, on October 23 2017, CFDA rolled out the draft amended Drug Administration Law, which proposes the cancelation of GMP and GSP certification requirements.¹⁴ The proposed cancelation stems partly from the financial and technological infeasibility of GMP and GSP certification for a large share of CMH processors and distributors. Limited access to finance was cited as a critical challenge by stakeholders. As a result, some CMH processors and distributors were pushed to operate under illegal conditions. Additionally, GMP and GSP are not suited to the market condition in China: processors and distributors do not perceive a clear market advantage for GMP or GSP certified products. Consequently, enterprises that have invested in certification and incurred large operational costs might become less competitive vis-à-vis those that operated without certifications.¹⁵

B. Traceability

“Traceability systems use information and communication technologies (ICTs) for product identification, information capture, analysis, storage, and transmission, as well as integration of overall systems.”¹⁶ Effective traceability systems capture product, locational, and stakeholder attributes throughout the value chain – production, processing, distribution, import, and retail – and help minimize the occurrence and extent of foodborne illness, especially during recalls.

Traceability lies at the heart of China’s food safety reform and has been identified as an area where implementation challenges have persisted.¹⁷ Currently, three overlapping traceability

¹² Global Food Safety Resource, *The Importance of Food Safety Certification*. Web. 1 October 2017.

¹³ Certification and Accreditation Administration of the People’s Republic of China, *The Certification of Food and Agricultural Products*, 28 December 2015. Web. 1 October 2017.

¹⁴ China Food and Drug Administration, 总局办公厅公开征求《〈中华人民共和国药品管理法〉修正案（草案征求意见稿）》意见, October 23 2017. Web.

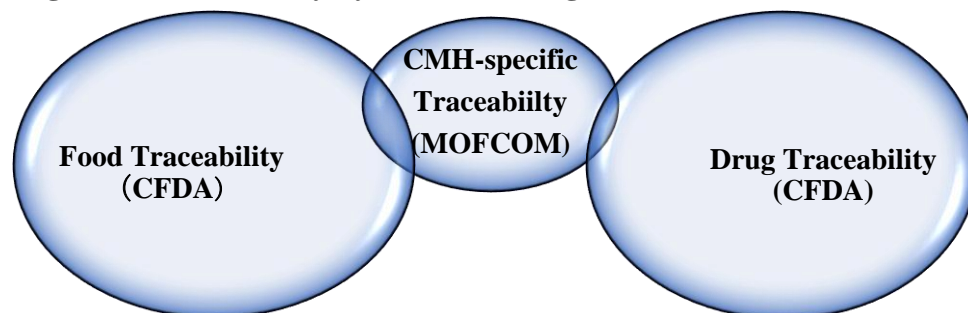
¹⁵ Sohu, *中药饮片GMP认证之困境：“死结”究竟在哪里?*, January 8 2008. Web. November 17 2017.

¹⁶ Yanqing Duan, Meiyin Miao, Ruimei Wang, Zetian Fu & Mark Xu *A framework for the successful implementation of food traceability systems in China*, *The Information Society*, 33:4, 226-242. (2017).

¹⁷ Yanqing Duan, Meiyin Miao, Ruimei Wang, Zetian Fu, and Mark Xu, *A framework for the successful implementation of food traceability systems in China*, *The Information Society*, 33:4, 226-242. (2017); Katrin Kuhlmann, Mengyi Wang, and Yuan Zhou. *China Food Safety Legal and Regulatory Assessment*. Syngenta Foundation for Sustainable Agriculture, publication forthcoming.

systems cover CMH products: food, drug, and CMH. Of the three, the most long-standing system is the CMH-specific traceability system, launched by Ministry of Commerce (MOFCOM) in 2012 as part of a broader initiative to establish traceability systems for key commodities.¹⁸ The second traceability system covers food, which is mandated by the FSL. The third traceability system covers drugs, which is mandated by the amended Drug Quality Management Standards (traceability-related requirements were added in July 2016¹⁹). While the three systems are rooted in different initiatives and legal instruments, relevant ministries are starting to align their practices. The alignment is exemplified by the Guideline on Carrying out Traceability Standardization of Important Products (Guideline 2017) issued by 10 ministries, including MOFCOM and CFDA, on October 24 2017. The Guideline emphasizes standardization and centralized planning of important products. Diagram 3 depicts the relationship of the 3 overlapping traceability systems.

Diagram 2: Traceability Systems Covering CMH



Source: New Markets Lab (2017)

Institutionally, CFDA oversees food and drug traceability systems. Legally, with respect to the traceability of food, key policies, laws, regulations, and guidelines include the FSL, Regulations on the Implementation of the Food Safety Law of the People's Republic of China (Draft Implementation Regulation (2017)),²⁰ Opinion of the State Council's General Office for Accelerating the Construction of the Traceability System for Key Commodities (State Opinion), opinions promulgated by subnational governments (Subnational Opinions), Opinion to Further Improve the Food and Drug Traceability System (CFDA Opinion 2016), Guiding Opinions for Food Producers and Traders to Establish the Food Safety Traceability System (CFDA Opinion 2017), and product specific guidelines released by CFDA (e.g. edible oil and infant formula powder).²¹ Among these legal instruments, FSL, the Draft Implementation Regulation, and State Opinion set out broad requirements and guidance for two tracks of traceability: private and public.²² For the private track, producers and traders of edible agricultural products, food

¹⁸ CFDA, *Opinion to Further Improve the Food and Drug Traceability System (CFDA Opinion 2016)*. Web. November 17 2017.

¹⁹ Finance.huanqiu, *将药品电子监管系统调整为药品追溯体系*, February 25 2016. Web; China Food and Drug Administration, *《国家食品药品监督管理总局关于修改〈药品经营质量管理规范〉的决定*, July 20 2016. Web. November 17 2017.

²⁰ Since the passage of the FSL, several versions of draft implementation regulation have been published for comments. On August 14, 2017, China notified the World Trade Organization of its latest draft implementation regulation but did not specify proposed date of adoption.

²¹ United States Department of Agriculture Foreign Agricultural Service, *Food and Agricultural Import Regulations and Standards – Narrative*, February 3 2017. Web. November 17 2017.

²² The Amended Food Safety Law (2015), Article 42; Draft Implementation Regulation, Articles 20 and 21.

products, and agricultural inputs are obligated to construct traceability systems; they are also encouraged to use ICT and participate in the national platform. For the public track, the state pledges to establish a preliminary national platform to enable nation-wide data sharing by 2020.

With respect to traceability of drugs, GSP and State Opinion are the core legal instruments. Together, they require pharmaceutical companies to develop and implement systems to trace the procurement, production, and distribution of pharmaceutical products.²³ The electronic national drug traceability system, supported by Alihealth (a subsidiary of Alibaba), was abolished, although thousands of pharmaceutical companies have continued to rely on Alihealth as their third-party platform provider.

MOFCOM, supported by Ministry of Finance (MOF) and National Development and Reform Commission (NDRC, a macroeconomic management agency under the State Council), oversees the CMH-specific project. MOFCOM's traceability system is being developed through pilot projects; it designs, runs, and scales up CMH pilot projects that have so far reached 18 provinces.²⁴ MOFCOM and NDRC have jointly designated over 100 types of CHM as pilot products whose demonstration projects will be completed in the next several years. These pilots and relevant standardization are conducted in collaboration with leading CHM companies, third-party technology providers (e.g. Geo Herbal), and academic institutions. In July 2017, MOFCOM released the Standard Governing the Construction of the National Chinese Herbs Circulation and Traceability System and announced in September that detailed industry standards would be completed for review by the end of the year.²⁵

Two aspects of MOFCOM's forthcoming traceability system are noteworthy. The first is the envisioned platform and information architecture, which will consist of three layers: 1) the top layer is the central, national platform; 2) the middle layer consists of platforms operated by local governments, industry associations, and third-party platform providers (the second tier platforms inform the first tier platform); and 3) the bottom layer is made up of enterprise traceability systems that feed information to platforms in the middle layer. Moreover, within the third layer (enterprise system), information will be grouped into two categories: basic information that must be made publicly available and additional information that is encouraged to be made publicly available. The categorization of information could mitigate concerns around the disclosure of sensitive business information. The second noteworthy aspect of the forthcoming system is that the standard is deemed an industry standard (voluntary) rather than a national standard (mandatory); this approach exemplifies a differential and phased implementation method that can be better keyed to market circumstances. Under this method, enterprise commitments, in terms of substance and timing, are based on their capabilities: first tier enterprises, which are generally large state-owned enterprises or other market leaders, participate in pilots and standard setting; second tier enterprises are expected to gradually adopt the industry standards (estimated to be 3 to 5 years); and SMEs need to receive policy and private support to be able to eventually

²³ China Food and Drug Administration, *对十二届全国人大四次会议第6807号建议的答复（关于尽快建立完善药品追溯管理制度的建议*, August 29 2016. Web. November 17 2017.

²⁴ Business.China., *商务部明年向全国推广重要产品追溯体系建设*, June 29 2017. Web. November 17 2017.

²⁵ National Important Product Traceability System, *中药材追溯标准年内有望制定完成并报批*, September 1 2017. Web. November 17 2017.

catch up. Table 2 below summarizes the legal and institutional framework governing the traceability system.

Table 2: Institutional and Legal Frameworks Governing CMH Traceability

Covered Product	Institution	Key Legal Instruments	Public Platform
Food	<ul style="list-style-type: none"> CFDA 	<ul style="list-style-type: none"> FSL Draft Implementation Regulation (2017) State Opinion (2015) CFDA Opinion (2016) CFDA Opinion (2017) Guideline (2017) Subnational Opinions 	<ul style="list-style-type: none"> National platform to be developed by 2020
Drug	<ul style="list-style-type: none"> CFDA 	<ul style="list-style-type: none"> GSP State Opinion (2015) CFDA Opinion (2016) 	<ul style="list-style-type: none"> National platform abolished
CMH-specific	<ul style="list-style-type: none"> MOFCOM MOF NDRC 	<ul style="list-style-type: none"> State Opinion (2015) Guideline (2017) Detailed industry standard could be formulated by the end of 2017, which envisions a three-layered platform approach 	<ul style="list-style-type: none"> National platform to be developed by 2020

Source: *New Markets Lab (2017)*

Industry experience is highly heterogeneous and differentiated principally by stakeholder capabilities and their supply chain structures. As mentioned, first tier enterprises have been actively involved in pilot projects and standard setting. They proactively embrace traceability as a potent tool for increasing quality control over the entire supply chain and for shaping and accommodating consumer preferences. For instance, for some ginseng products from Shandong, Quick Response Code (QR Code) has become available for end consumers. Scanning the QR code allows end consumers to access information of the life cycle of the ginseng products; the availability of QR Code serves a useful marketing tool that helps distinguish between ginseng products from different companies.²⁶ Some first tier enterprises have also engaged specialized third-party providers with advanced hardware and (sometimes proprietary) software to maximally automate traceability. For instance, a particular set of hardware is installed at the production base (for greenhouse-grown CMH) to track and record information such as location, humidity, and temperature; tracking and recording then follow the full cycle of supply chain. For these market leaders with sophisticated internal traceability systems, navigating traceability requirements under different initiatives is not difficult and chiefly entails sharing a particular subset of well-stored data. Large enterprises have also collaborated among themselves in a way that could lead and guide other market participants. For instance, more than 10 pharmaceutical

²⁶Xinhuanet, 培育新型经营主体让食药材可追溯到田间地头, June 19 2017. Web. November 17 2017.

companies have set up the China Drug Safety Traceability Alliance in collaboration with third-party platform provider Alihealth.²⁷

Second tier enterprises are also developing their traceability systems. Compared to their first tier counterparts, they generally lack dedicated hardware, trained personnel, and information technology; information collected and recorded tends to be more generalized. However, their typically vertically integrated supply chains facilitate traceability. For instance, an enterprise specializing in beimu products has both production bases and long-term contract farming arrangements (at least 10 years) in multiple provinces and supplies most of its products to several pharmaceutical companies. Given the small number of upstream and downstream actors involved, the enterprise could trace the locational attributes of products with relative ease. It does not, however, track or record information such as agricultural inputs.

SMEs, particularly those falling outside of closed supply chains, remain largely unaware of traceability requirements or are reactively implementing them when requested by companies that they transact with. The abundance of middlemen in the primary and wholesale secondary markets exacerbates this trend. For instance, middlemen generally purchase Chuanxiong from a number of farms (all ranging from 4-6 Chinese acres) as one batch and rarely undertake record-keeping.

C. E-Commerce

China surpassed the United States as the world's largest e-commerce market in 2013.²⁸ The retail sector in particular has experienced exponential growth, starting at less than 1 billion dollars in 2005 and growing to 812 billion dollars in 2016.²⁹ A confluence of factors precipitated the explosive expansion, including a trusted and ubiquitous digital payment system, an efficient shipping logistics infrastructure, and the rising purchasing power of 415 million millennial consumers.³⁰ Food is digitally distributed via a number of business models: Business-to-Consumer (B2C), Consumer-to-Consumer (C2C), digital platforms (e.g. JD.com and Tmall), specialty online stores, hybrid retail stores with both traditional and online components (e.g. Alibaba's grocery store chain Hema Supermarket³¹), and cross-border C2C and B2C platforms.³² Diagram 3 illustrates the growth and magnitude of retail e-commerce in China vis-à-vis the rest of the world.

²⁷ YiCaiGlobal, *Alihealth Sets Up China Drug Safety Traceability Alliance with Over 10 Pharmaceutical Companies*, August 29 2017. Web. November 17 2017.

²⁸ United States Department of Agriculture Foreign Agricultural Service, *China's Cross-border E-Commerce Opportunities for U.S. Exports*. August 17 2015.

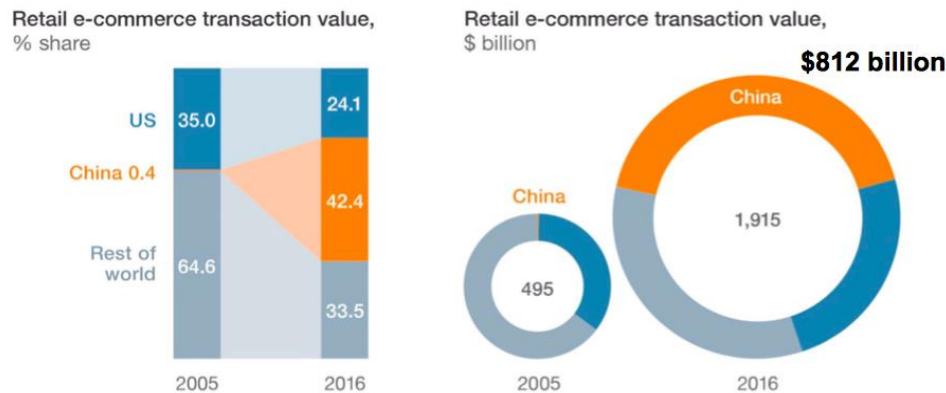
²⁹ Tingyi Chen, WalktheChat, *China Digital Ecosystem & WeChat Marketing*. October 28 2017.

³⁰ PricewaterhouseCoopers, *Total Retail 2017, E-Commerce in China – The Future Is Already Here* (2017). Web. November 17 2017.

³¹ CNBC, *Jack Ma's Alibaba Is Doubling Down on Its Supermarket Strategy*, July 18 2017. Web.

³² United States Department of Agriculture Foreign Agricultural Service, *Annual Retail Foods Report – China*, January 2017. Web. 1 October 2017.

Diagram 3: Growth and Magnitude of Retail E-commerce in China



Source: Dealogic; eMarketer; iResearch; PitchBook; TechCrunch's CrunchBase Unicorn Leaderboard; McKinsey Global Institute analysis

Source: Tingyi Chen, *WalktheChat* (2017)

Two existing legal instruments primarily govern the food safety aspect of China's e-commerce market: the FSL and the Measures of the Investigation and Punishment of Illegal Conducts Concerning Online Food Safety.³³ Three elements of this combined legal framework are noteworthy. First, third-party platforms, as the preeminent distribution mechanism, must install multi-functional food safety management systems performed by a dedicated food safety management unit or person.³⁴ The system encompasses a variety of functions, such as information verification (e.g. relevant licenses of traders), food safety surveillance (e.g. monitoring traders' operations), management of food safety complaints, reporting violations of FSL to law enforcement, record keeping (this requirement is extended to company owned-and-run websites; e.g. real-name registration of admitted food traders and preservation of transaction data for at least 6 months past the expiration of the transacted product or for at least 2 years for products with unspecified expiration dates).³⁵ Second, relevant licensing requirements for traders are replicated in the digital world: traders must first obtain food production or operation license from CFDA, conduct business within the scope of their licenses, and display licenses on their online stores.³⁶ Third, for health food, to protect consumers against unfounded health claims, on-line traders must display their product registration or filing certificates online, prominently stating that the health product cannot substitute medicines, and health claims cannot be made for non-health foods.³⁷

Forthcoming legislation, the E-Commerce Law, is expected to intersect with the existing online food safety framework. The current draft and its legislative history indicate that the new law could ultimately strengthen responsibilities of digital platforms and clarify legal obligations of businesses operating through WeChat (the primary social media application with an e-commerce

³³ China Food and Drug Administration, Measures of the Investigation and Punishment of Illegal Conducts Concerning Online Food Safety (CFDA Order 27). July 19 2017. Web; the Amended Food Safety Law (2015), Article 62; PricewaterhouseCoopers China, *China's New E-commerce Food Safety Measures* - PwC China. 2017. Web; King & Wood Mallesons, *China's e-commerce regulatory tsunami continues: New advertising and food safety regulations*, July 29 2016. Web; Baker McKenzie, *China: Food Traders to Comply with New Measures Governing Online Food Safety*, October 11 2016. Web.

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

component that could impact farmers who may wish to set up WeChat stores).³⁸ The State Council solicited public comments on the draft until November 26, 2017;³⁹ future developments should be closely watched, and it is not clear when the drafting phase will be completed.

In practice, relatively tepid digital trading of CMH products stands in contrast with the enormity and dynamism of China's e-commerce ecosystem. Indeed, digital trading of CMH products as food or health food are limited in scope and volume and largely confined to more resourceful actors such as wholesalers and leading pharmaceutical companies. Several factors may have inhibited the e-market penetration of CMH products: complexity and ambiguity of the legal and regulatory framework, low digital demand, and supply side constraints.

For CMH, legal complexity and ambiguity are significant factors affecting e-commerce. Complex and stringent compliance obligations could unduly restrict activities, raise entry barriers, and favor more specialized and established entities over SMEs. Commentators and stakeholders have flagged that the existing monitoring, information verification, and data storage obligations incur additional cost and favor sophisticated businesses with robust information and communication technologies (ICT) systems.⁴⁰ This observation is bolstered numerically by the existence of a small number of prominent third-party platforms and company owned-and-run websites as well as qualitatively by the degree of compliance by more specialized platforms. Indeed, platform oversight and awareness of food safety regulations seem to be more pronounced for more specialized platforms (e.g. Zycst.com, a CMH wholesale platform) than general platforms (e.g. JD.com and Tmall). This trend will likely be amplified by the forthcoming E-Commerce Law, which may intensify platform obligations. Legal ambiguity is another stumbling block for setting up digital stores. Some wholesale store owners hesitate to open up digital stores due to the perceived ambiguity around licensing. This ambiguity stems from a gap between traditional and digital markets: while distribution licenses are waived for stores in nationally-accredited wholesale markets, the waiver is not explicitly authorized for digital markets.

On the demand side, there is a demographic disconnect between consumers of CMH products and digital shoppers. Indeed, middle-aged or senior citizens have traditionally been the primary consumers of CMH products, while the majority of digital shoppers are between the ages of 20 and 29. However, this paradigm is poised to shift, as the demand for CMH products is forecasted to grow across demographic groups and particularly among the young generation, emblematic of the rising middle class that increasingly emphasizes healthy eating. On the supply side, a large segment of CMH producers and processors are not familiar with the operation of e-commerce and, partly due to the low digital demand, have not had financial incentives to investigate e-commerce.

³⁸ 163.com, *电子商务法草案二审稿审议 委员:微商应纳入监管*, November 5 2017. Web. November 17 2017.

³⁹ National People's Congress, Portal for Public Comment, http://www.npc.gov.cn/COBRS_LFYJNEW/user/UserIndex.jsp?ID=8429025.

⁴⁰ See, e.g. PricewaterhouseCoopers China, *China's New E-commerce Food Safety Measures* - PwC China. 2017. Web.

Recommendations

The preceding section identified key implementation gaps in China's legal and regulatory reform related to CMH, and the recommendations below are tailored to respond to these gaps. Overall, a number of diverse regulatory options exist with respect to different aspects of food safety governance which could contribute to the progressive refinement of China's food safety regime.

Inspection

Overall, China's existing institutional framework should be modified in order to improve the effectiveness of inspection. In particular:

- Institutional restructuring is needed at all levels (i.e., provincial, municipal, district, and country) and should be accelerated to implement the FSL. This could be done by setting clear deadlines and clarifying official duties in the interim.
- Consumer associations could consider, partially or fully, outsourcing food safety inspection (potentially along with inspection of other products) to independent third parties such as international organizations. This shift to engaging independent third parties instead of AIC-affiliated consumer associations could help insulate AIC from perceived criticism of CFDA when inspection results differ. The outsourcing could be initiated by consumer associations, branch AICs that fund consumer associations, or more top-down policy change (a process akin to the separation of public food testing agencies from their affiliated inspection authorities).⁴¹

Certification

In order to leverage certification to promote high standards and spur exports, China could take the following steps to enhance the current capabilities of industry actors:

- China should finalize the amended Drug Administration Law and cancel mandatory GMP and GSP certification requirements, since the capacity does not exist to follow these certification schemes.
- Once mandatory certification requirements are canceled, CFDA could continue to encourage voluntary certifications, including GMP and GSP, as practicable and partner with CNCA to raise awareness and uphold the quality of certifications.

Traceability

As China moves towards a more detailed national CMH traceability framework to meet its 2020 target, several steps could be explored.

⁴¹ Katrin Kuhlmann, Mengyi Wang, and Yuan Zhou. *China Food Safety Legal and Regulatory Assessment*. Syngenta Foundation for Sustainable Agriculture, publication forthcoming.

- First and foremost, relevant ministries operating under overlapping mandates to work together to promote compatibility and avoid duplication and fragmentation of the three existing traceability systems. Unified standards and methodologies could help private actors navigate the web of traceability requirements.
- Pilot projects should be closely studied in order to fine tune and scale up existing traceability systems. As MOFCOM is due to complete the CMH pilot projects, detailed reports based on rigorous analysis and action-oriented recommendations are necessary for pinpointing deficiencies to tweak and optimize the system. The reports should be composed after consulting a wide range of stakeholders, including those who are not actively participating in the pilots such as various government agencies, industry and consumer groups, international organizations, and non-profit organizations. Notably, the execution of pilot projects could be delegated to specialists with more abundant time, resources, and possibly expertise. For instance, the U.S. Food and Drug Administration designated the Institute of Food Technologists (IFT) to execute traceability pilots.⁴² IFT then collaborated with representatives from over 100 organizations, including various government agencies, industry and consumer groups, and non-profit organizations, to produce an extensive final report with thorough recommendations.⁴³
- Technology could significantly enhance the quality, consistency, and comprehensiveness of data collected and subsequently turn the data into useful analytical tools. Important technological advancement includes information tracking using DNA, molecules, or radioisotopes (chemical elements in radioactive form) and blockchain technology.⁴⁴ Blockchain technology is particularly noteworthy given its relative technological maturity, its ability to reliably and transparently record data throughout the supply chain, and existing efforts to expand its application by private actors (six leading retail and food companies introduced blockchain platforms to expedite the expansion of blockchain ecosystems across academia and the start-up community).⁴⁵
- Private innovations should also be encouraged, and successful private initiatives could be institutionalized by the public sector. The GrapeNet Initiative, for instance, is a monitoring software developed by the private company Logicsoft with a centralized web-based database to help ensure that international standards are met for Indian table grapes,⁴⁶ covering “all stakeholders in the grapes export supply chain.”⁴⁷ The traceability

⁴² *Id.*

⁴³ Jennifer McEntire, Tejas Bhatt, *Pilot Projects for Improving Product Tracing along the Food Supply System – Final Report*. Institute of Food Technologists, 2012.

⁴⁴ The Future of Food Traceability, Food Safety Magazine, Web. 1 October 2017. For instance, in 2016, Sample6 and Safe Traces, two prominent start-ups, raised 12.7 million \$1.5 million respectively. See The Challenges 9 Traceability and Food Safety Technology Startups Face in Disrupting the Industry, AgFunder. Web. 1 October 2017; The food industry gets an upgrade with blockchain, IBM, Web. 1 October 2017; IBM Forges Blockchain Collaboration with Nestlé & Walmart In Global Food Safety, Forbes, Web. 1 October 2017.

⁴⁵ New Markets Lab, *Assessment of Good Regulatory Practices for Food Safety and Implications for China’s New Legal Regime*, Publication forthcoming.

⁴⁶ Shukla, Danashree and Elisa Sabbion. *Electronic Traceability of Agricultural Products in India: The Case of GrapeNet*. Brief No. 15. United Nations Network of Experts for Paperless Trade and Transport in Asia and the Pacific, Aug. 2015. Web. 13 May 2017.

⁴⁷ *GrapeNet: Traceability Solution for Fresh Grapes Exported from India*. Logicsoft International Private Limited, n.d. Web. 12 May 2017.

system under GrapeNet was later replicated by the government through *HortiNet*, which includes mangoes and vegetables.⁴⁸ Similarly, private innovations are also occurring in China (e.g. CHIC Group attaches QR Code to their end products and accelerates supply chain integration to facilitate traceability) and could be studied by the public sector.⁴⁹

- As a cross-cutting issue, the government and private sector should address the capacity constraints of SMEs that prolong legal implementation challenges, particularly in areas that require financial investment such as traceability and those with untapped market potential such as e-commerce. For traceability, possible mechanisms could include promoting equitable contract farming arrangements that incorporate training and resource support for SMEs, tax benefits for enterprises that integrate SMEs into their supply chains, or measures that increase capacity of cooperatives. In addition, some services are geared towards helping SMEs. For example, Farmforce is a mobile traceability platform initiative created by SFSA that focuses on information storage, data input, and information retrieval of business outputs. The platform interface is simple to navigate and facilitates the switch from traditional data recording, usually done on paper, to a technological approach that is simple and straightforward for farmers and agents.⁵⁰

E-Commerce

There is ample room for government to tailor policy responses to allow CMH stakeholders, particularly SMEs, to exploit China's vast e-commerce market, with the following as priorities:

- Construct an inclusive legal and regulatory environment with clearly defined legal responsibilities. Balancing food safety and ease of operating third party platforms or company owned-and-run websites and laying down clear legal obligations (e.g. WeChat stores) will be essential to inducing market participation and competition. One approach that could help balance food safety needs while promoting inclusive participation and competition is differential and phased implementation – staging commitments based on priority and capability. This approach is epitomized by the U.S. Food Safety Modernization Act, which follows such a model and sets out different requirements with staggered compliance dates based on the size of the facilities/businesses.⁵¹
- Supply side solutions could be formulated to position producers and processors to take advantage of the emerging demand of CMH products. There are different modes of business that could be considered, including through existing or new third-party platforms, enterprise websites, establishing WeChat stores, or a combination of these venues. Local governments could help train or engage third parties to provide training of e-commerce and marketing for SMEs. For instance, service could be provided by “senior universities” that charge a small fee for different skill trainings. In some cities, there are

⁴⁸ APEDA has GrapeNet for grapes and AnarNet for pomegranate, while mango and vegetables exporters are registered with State Horticulture Department.

⁴⁹ 熙可：安全逼上全供应链 《商界评论》，CHIC GROUP, 3 August 2017, Web. 1 October 2017.

⁵⁰ E-agriculture.org, *The Farmforce Platform*, October 5 2013. Web. November 25 2017.

⁵¹ Grocery Manufacturers Association, *Reference Sheet for FSMA Compliance Dates*. Web. October 1 2017.

already courses that teach the basics of smartphones, which could be incorporated as the first step of e-commerce training.