

CFDA Issues Guidelines for Traceability Systems

In April, the China FDA published Provisions for Establishment of Food Safety Traceability Systems by Food Production and Trading Companies (the Provisions). There are detailed information recording requirements and high-level principles for setting up and improving traceability systems across a wide range of business categories. Roles and responsibilities are clarified for the China FDA, provincial FDAs and local governments.

The Provisions state that food production and trading companies bear primary responsibility for food safety traceability systems and their establishment. The foundation and core of these systems is the recording of food safety information for the entire process; and that information should be factual, effective and preserved so that it is not easily changed or lost.

What does it mean for companies?

The Provisions contain many specific requirements for food safety traceability systems and for the recording and preservation of information; but these should be viewed as merely the minimum requirements for records, documentation, systems and procedures related to traceability.

Companies also must fulfill separately issued requirements for specific products (e.g. infant milk formula) and channels (e.g. e-commerce platforms); and must work closely with provincial FDAs and local governments in order to fulfill additional local requirements (e.g. the Shanghai Food Safety Information Traceability Measure).

The Provisions make clear that traceability systems and requirements will continue to evolve and become more comprehensive and technologically sophisticated. Companies must not only meet today's requirements, but should plan on making continuous improvements and adjustments to meet future requirements.

Companies will need a sophisticated and flexible approach that makes full use of information technology (e.g. ERP) and can be updated to fulfill new requirements. They must be able to efficiently record and manage massive amounts of information, ensure accuracy and rapid access for emergency responses, and provide regular and timely information transfer to local regulators' traceability platforms.

In the future, companies will need to go beyond one-up, one-down traceability requirements and integrate systems for their entire supply chain. Executives should have a strategy in place to continuously improve their supply chain visibility and integrity, utilize new technologies and anticipate future regulatory requirements.

Traceability in China

Traceability in China is extremely difficult due to the highly fragmented agriculture and food sectors, the variety of food and agricultural products, the uneven technical capabilities of businesses and farms, and the growing complexity of supply chains.

The government has long recognized the importance of food traceability. During the past 15 years there have been many traceability initiatives focused on various types of food and agricultural products, certain information technology standards, and specific municipalities and provinces.

Article 42 of China's 2015 amended Food Safety Law assigns traceability responsibilities:

Food producers and traders shall establish food safety traceability systems pursuant to provisions of this Law to guarantee traceability of foods. China

encourages food producers and traders to use information technology to collect and retain production and trading information and establish food safety traceability systems.

The China FDA will work with the Ministry of Agriculture and relevant departments to establish the coordinated traceability system for food safety that covers the whole process.

The CFDA's Provisions for Establishment of Food Safety Traceability Systems by Food Production and Trading Companies

The Provisions include requirements for recording and documenting specific information by companies involved in food production, trading of food and agricultural products, food service, as well as transportation, storage and distribution of food. (Appendix I contains details for some key requirements.) The Provisions do not apply to producers and traders of special foods, as defined in the National Food Safety Law (ch. 1).

Objectives of production and trading companies' traceability systems include factual recording and preservation of food product quality and safety information, risk management, and upstream and downstream traceability. In the event of a food safety problem, the systems must ensure root cause investigation and identification, recall capability, ascertainment of responsibility, etc. (ch. 2). Companies are expected to continuously improve and gradually enhance their traceability systems (ch. 6.3).



Food production and trading companies have the primary responsibility to set up food safety traceability systems, while the FDA provides guidance and oversight for the establishment of food safety traceability systems (ch. 3.1-2).

Local FDAs are responsible for guiding and supervising companies in establishing food safety traceability systems and fulfilling their food safety and quality responsibilities, and for establishing a communication and coordination mechanism with the departments of agriculture and customs, inspection and quarantine (ch. 7.1).

Implementation by category and localized approaches

Because of the challenges posed by the diversity of companies' scale and technological capabilities, the Provisions set principles of "implement by category" and "avoid a one-size-fits-all approach" (ch. 3.3). Provincial FDAs should formulate measures and conduct pilot projects tailored for local conditions (ch. 7.1-2).

Several provincial and municipal governments have implemented their own traceability measures. One example is the Shanghai Food Safety Information Traceability Management Measure, issued in 2015. Companies in Shanghai must upload information to a municipal platform that gathers information and enables the government to rapidly investigate food safety problems. Consumers can access the platform online by using information from product labels. The 2015 work plan covered rice, pork, mutton, chicken, pigeon, cowpeas, potatoes, tomatoes, chili peppers, winter melons, apples, bananas, hairtail,

yellow croaker, butterflyfish, lactone tofu, infant milk formula and soybean oil. By March 2017 the platform covered 25 types of food and agricultural products.¹

The Shanghai measure applies to companies that produce or trade food and edible agricultural products, agricultural cooperatives, slaughterhouses, wholesale markets, standardized food markets, medium and large stores, meal delivery services, central kitchens, school cafeterias, medium and large restaurants, restaurant chains, and transportation, storage, and distribution businesses (art. 3). These parties must upload traceability information to the platform within 24 hours of production or transfer (art. 18). Companies are encouraged to use information technology to upload the information (art. 10). The measure contains detailed information requirements for each type of business (art. 12-17).

Aligned with the "implement by category" principle, many product-specific traceability initiatives have been launched during the past 15 years, often focusing on vegetables, meat or dairy products sold within a municipality.

The government's treatment of infant milk formula is among the strictest product-specific approaches. The CFDA's Standards for Infant Milk Formula Powder Production Company Food Safety Traceability Records, also issued in 2015, contains very detailed recordkeeping requirements, including product R&D and formulation, raw and supplementary materials management, production and processing, finished product management, sales management, risk information collection, and product recalls (art. 3-9).

Examples of channel-specific traceability measures include the CFDA's Measure to Handle Online Food Safety Violations (2016), and Draft Measure for Oversight of Online Food Services (2017). Although these measures do not include the word "traceability" in their titles, they include extensive requirements for recordkeeping and verification for companies that sell food products or restaurant delivery services online, as well as for 3rd party e-commerce platforms.

How PwC can help

PwC can help companies integrate traceability with their ERP to enable rapid tracing of root causes and execution of targeted recalls. We can help integrate capabilities needed to comply with regulatory requirements for recording, documentation, storage, query and transmission of food safety, quality and transaction information. We can help formulate a long term strategy and design an organisation to facilitate compliance with future traceability regulations that apply to specific locations, products and sales channels.

Using these systems, we can help companies to more efficiently manage their suppliers and supply chain. We can help companies leverage their traceability capabilities to provide consumers with transparency, and build trusted premium brands.

For more information, please visit our websites:

www.tiangandpartners.com

www.pwccn.com/fsis

This article was written by Brian Marterer of PwC China.

¹ "Food safety expert explains the municipal food safety regulation, and related improvements to Shanghai's meat, dairy, liquor, etc. traceability system", Shanghai Morning Post, 14 March 2017, http://newspaper.jfdaily.com/xwcb/html/2017-03/14/content_14515.htm (accessed on 29 May 2017)

Contact us



Samie Wan

PwC Hong Kong
Food Supply & Integrity Services Partner

+852 2289 2019
samie.sm.wan@hk.pwc.com



David Tiang

Tiang & Partners¹
Partner

+852 2833 4928
david.wp.tiang@tiangandpartners.com

¹Tiang & Partners is associated with PwC Legal International Pte. Ltd. (a licensed Foreign Law Practice) in Singapore. Tiang & Partners is an independent law firm. Neither Tiang & Partners nor PwC Legal International Pte. Ltd. has any control over, or acts as an agent of, or assumes any liability for the acts or omissions of, the other.

The following are some key requirements for companies' traceability systems as described in the CFDA's Provisions for Establishment of Food Safety Traceability Systems by Food Production and Trading Companies, published in April 2017.

Requirements for recording, preservation and connectivity

Information recording must be effective, complete and must accurately reflect the food safety and quality controls throughout the production and trading process.

Based on their individual circumstances, companies must determine which specific information to record, and the appropriate data collection points, methods and frequency to ensure that the root cause of any food safety problem can be investigated and identified.

Whenever possible information should be collected automatically and in real time. Hand recorded information must be checked for correctness. For information collected on paper, original copies must be preserved. For information collected electronically, the original raw data must be kept. All records must be signed by both the recording person and the verifying person.

Paper records must be preserved and have clear methods for safekeeping; electronic records must have a backup system. The technology, scope and system all must ensure that traceability information cannot be changed after it is collected (ch. 5.1).

Systems, procedures, information and documentation requirements

A. Production companies (e.g. processors, manufacturers)

Production companies must have the following systems and procedures:

- (1) **Raw and supplementary materials:** Systems for receiving, inspecting and recording food product raw material, food additives and food packaging materials (ch. 4.1.2).
- (2) **Products leaving factory:** Inspection and recording systems, inspection of compliance testing certificates and safety status (ch. 4.1.4).
- (3) **Recall and destruction:** Systems for managing recall records and the handling of recalled products (ch. 4.1.8-9).

(4) **Complaints:** System for managing and handling customer complaints, communications with customers and recording of relevant information (ch. 4.1.10).

(5) **Preservation of proof:** Preservation of proof for information from materials receiving, sales, recalls, destruction, and complaint handling; filing of actual labels for finished products (ch. 4.1).

Production companies must record the following information:

(1) **Finished product and sales information:** Name, standards, ingredients, production method, labels, etc. (ch. 4.1.1); information related to the finished products departure from the factory, including product name, specifications, quantity, production date, batch number, testing compliance certificate number, etc. ; storage information, including entrance to warehouse, exit from warehouse and relevant information for items that require special conditions, e.g. cold storage or freezing; date of sale, purchaser's name, address, responsible person, contact info, etc. (ch. 4.1.3-4). In principle, records should include the first direct post production recipient, and companies are encouraged to extend traceability towards downstream retail sales (ch. 4.1.2).

(2) **Raw and supplementary materials, food additives, packaging materials, etc.:** Name, specifications, quantity, production date or batch number, shelf life, date received, supplier's name and address, supplier responsible person's name and contact information, etc. (ch. 4.1.2); information related to entrance and departure from storage, use in production, etc. relevant information for items that require special conditions, e.g. cold storage or freezing, etc. (ch. 4.1.3). In principle, records should include the first direct upstream source. Companies are encouraged to extend traceability towards upstream raw material sources (ch. 4.1.2)

(3) **Production process:** Information related to production process, including technical parameters, environmental testing, etc.; information related to production process testing, mainly the test batch number, test date, test method, test results, staff conducting tests, raw test data, test reports, etc.; partially finished products' entrance to warehouse, exit from warehouse and relevant information for items that require special storage conditions, e.g. cold storage or freezing. In addition, companies must determine the specific information to record according to their specific categories, production techniques, product characteristics, etc. (ch. 4.1.3).

(4) **Production equipment:** Information relevant to the following: material, procurement, installation, use, monitoring, control, cleaning, disinfection, maintenance, etc.; this information must be linked to the relevant production processes (ch. 4.1.5).

(5) **Production facilities:** Relevant basic information for facilities related to production, including raw and supplementary material storage, pre-processing workshops, production workshops, packaging workshops, finished product storage, testing laboratories, water supply and drainage, cleaning and disinfection, waste material storage, ventilation, lighting, storage, temperature control, etc. including information on management, use, repairs and changes (ch. 4.1.6).

(6) **Production staff:** Training, qualifications, date of employment, group, shift, health status, etc., as well as information about their production-related duties (ch. 4.1.7).

(7) **Recall and destruction:** Name of product, batch, specifications, quantity, origin, reason for recall, recall status, rectification measures, risk control and harm control (ch. 4.1.8); recalled product destruction's time, place, staff, method and, if destruction is supervised by FDA, basic information about the supervisor (ch. 4.1.9).

(8) **Complaint information:** Relevant food safety and handling information for complaints and advice communicated in writing or verbally (ch. 4.1.10).

B. Sales companies (e.g. retail, wholesale)

Sales companies must have the following systems and procedures:

(1) **Product receiving:** Inspection of received food products permit and food product factory departure compliance testing certificate or other proof of compliance; system for recording the inspection of received products; system for recording inspection of received edible agricultural products (if applicable) (ch. 4.2.1).

(2) **Storage:** Periodic inspection of stored food products; prompt destruction of food products that have spoiled or passed shelf life (ch. 4.2.2).

(3) **Sales:** Systems to record relevant information (ch. 4.2.2).

(4) **Preservation of proof:** Preservation of proof for information from product receiving and sales (ch. 4.2.1-3).

Sales companies are required to record the following information:

(1) **Product receiving:** Name, production place, production date or batch number, specifications, quantity, shelf life, date received, and supplier's name, address, responsible person, contact information, etc. (ch. 4.2.1).

(2) **Storage:** Information related to storage processes, e.g. periodic inspection of food products, disposal of products that have spoiled or passed their shelf life, information related to storage processes for products that require cold storage, freezing or other special conditions; for bulk food storage, the production site, name, production date or batch number, producers' name and contact information, etc. must be clearly indicated at the place of storage (ch. 4.2.2).

(3) **Sales information:** Wholesale sellers must record product name, production site, name, specifications, quantity, production date or batch number, shelf life, sales date, and purchaser's name, address, responsible person's name, contact information, etc.; bulk sellers must indicate on the product's outer packaging the product name, production site, production date or batch number, shelf life, producer's name, contact information etc. For bulk food that has come from different initial packages and mixed together, the product variety and composition must be recorded (ch. 4.2.3).

(4) **Other information:** Relevant information about equipment, facilities, staff, recall, destruction, complaints, etc. must be recorded as described above for production companies (ch. 4.4.4).

C. Restaurant/catering companies

Restaurant/sales companies must have the following systems and procedures:

(1) **Product receiving:** Systems to record inspection of received products, inspect supplier's permits and food products' factory departure compliance testing certificate or other proof of compliance; other required raw material controls (ch. 4.3.1).

(2) **Preservation of proof:** Preservation of proof for information from product receiving (ch. 4.3.1).

Restaurant/catering companies are required to record the following information:

(1) **Product receiving:** Product inspection information; raw material production site, name, specifications, quantity, production date or batch number, shelf life, date of product arrival, and supplier's name, address, responsible person, contact info, etc. (ch. 4.3.1).

(2) **Storage:** Information relevant to maintenance of food processing, storage and display equipment, as well as the cleaning and checking of warming, cold storage and freezing facilities, etc. (ch. 4.3.2).

(3) **Other information:** Relevant information about equipment, facilities, staff, recall, destruction, complaints, etc. must be recorded as described above for production companies (ch. 4.4.4).

D. Transportation, storage and transfer information requirements for companies that produce, trade, ship or store food products and edible agricultural products

Companies must have the following systems for food transportation, storage and transfer:

Com(1) **Shipping and storage:** Systems to manage the recording of shipping information (ch. 4.4.1).

(2) **Edible agricultural products:** Traceability systems established by traders or producers with producers of for edible agricultural products must ensure effective connection with the planting and cultivating stages (ch. 4.4.3).

(3) **Preservation of proof:** Preservation of proof for shipping, storage, and transfer information (ch. 4.4)

Companies must record the following transportation, storage and transfer information:

(1) **Shipping:** Relevant shipping information, including products' production site, name, quantity, batch number, vehicle, time of shipment, shipping employee and responsible person's name and contact information, information about the transfer from one party to the other, etc.; information relevant to the shipping process for products that require cold storage, freezing or other special shipping conditions (ch. 4.4.1).

(2) **Storage:** Stored products production site, name, quantity, batch number, time of entering storage, time of leaving storage; warehouse management, delivery and receiving parties' employee name, contact information, etc.; relevant storage information for food that requires freezing or other special storage conditions (ch. 4.4.2).

(3) **Transfer:** Companies must record the information for one delivery and one reception, including the transfer's time, place, employees, shipping method, vehicle, etc. (ch. 4.4.3).

(4) **Other information:** Relevant information about equipment, facilities, staff, recall, destruction, complaints, etc. must be recorded as described above for production companies (ch. 4.4.4).

This content is for general information purposes only, and should not be used as a substitute for consultation with professional advisors.