USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Voluntary _ Public

Date: 12/23/2015
GAIN Report Number: CH15067

China - Peoples Republic of

Post: Beijing

Draft Implementing Rules for the 2015 Food Safety Law

Report Categories:
Policy and Program Announcements

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Report Highlights:
On December 9, 2015, China Food and Drug Administration (CFDA) released the "Draft Implementing Rules for the 2015 Food Safety Law" for public comment. Interested parties can submit their comments via mail or email directly to CFDA before January 9, 2016. This report provides an unofficial translation of the Draft Implementing Rules and ways to submit comments.

Executive Summary:

On December 9, 2015, China Food and Drug Administration (CFDA) released the "Draft Implementing Rules for the Food Safety Law" for public comments. Interested parties could submit their comments via mail or email to CFDA before January 9, 2016. This report provides unofficial translation of the Draft Implementing Rules and ways to submit comments.

Comments can be sent directly to CFDA in two ways:

- Mail: Enclose the comments in an envelope and mail it to:

The Legislative Affairs Department, China Food and Drug Administration
No.2 Compound, No.26, Xuan Wu Men Xidajie, Xicheng District, Beijing 100053
北京市西城区宣武门西大街26号院2号楼 邮编100053
国家食品药品监督管理总局法制司
*Please mark "Comments on the Implementing Rules for the 2015 Food Safety Law" (对食品安全法实施细则的评论)" on the envelope.

- Email: rendp@cfda.gov.cn.

BEGIN TRANSLATION

Implementing Rules of the Food Safety Law (Draft for Comments)
China Food and Drug Administration
December 9, 2015

Chapter 1: General Provisions

Article 1 The Implementing Rules were developed pursuant to the Food Safety Law of China.

Article 2 Food producers or traders shall produce and distribute food in accordance with relevant laws, regulations, and food safety standards. They shall ensure food safety by taking effective measures to prevent and control food safety risks, prevent and mitigate food safety harms.

Article 3 The Food Safety Commission of the State Council is responsible for making plans for and guide the food safety work nationwide; it develops China's food safety strategies, proposes major food safety policies and measures, analyze and solve critical food safety problems, and supervise the fulfillment of food safety responsibilities.
The Food Safety Commission Office (FSCO) undertakes daily operation of the Commission. It organizes the development of the national food safety plans, coordinates and solves critical issues in law making and standard development/implementation; as well as supervises and inspects the fulfillment of

major food safety decisions; FSCO reviews the food safety work by the provincial governments and relevant ministries under the State Council, and guides for the settlement of critical food safety incidents.

Article 4 County and above level municipal governments are in charge of food safety in their respective regions; they shall improve the food safety oversight mechanism, strengthen enforcement, and guarantee personnel, fund and technical supports are in place; they are accountable for regional food safety risks and severe incidents.
The local municipal government determines responsibilities of the county and above level food safety commission and its office shall be determined by the l pursuant to the jurisdiction of the Food Safety Commission and the FSCO.

Article 5 County level FDAs may set up dispatched offices in towns or specific regions pursuant to size of the area under their jurisdiction, population, and the supervised entities.

Article 6 Town/village governments and sub-district offices of the municipal government are responsible for food safety risk screening check, reporting, enforcement assistance, public education, etc.; they shall take effective measures to strengthen food safety administration.
Town/village governments and sub-district offices of the municipal government shall support the FDA dispatched offices for its oversight work.
Town/village governments and sub-district offices of the municipal government shall establish the team of food safety warden or information officers to assist the local FDA for food safety work.

Article 7 China will include food safety knowledge into the national essential quality-oriented education and primary/middle school courses; (the government) intends to enhance the food safety awareness through popularizing food safety sciences and legal knowledge.

Article 8 County and above level municipal government shall establish the special programs and funds to award entities and individuals who make significant contributions to risk surveillance, assessment, standard development, inspection, major event safeguarding, emergency response, case investigation, public education, and social governance.

Chapter 2: Food Safety Risk Surveillance and Assessment

Article 9 The National Health and Family Planning Commission (NHFPC) works with the China Food and Drug Administration (CFDA), the General Administration of Quarantine and Quality Inspection (AQSIQ) and the Ministry of Agriculture (MOA) to develop and announce the national food safety risk surveillance plans.
Provincial health departments shall file the local food safety surveillance plans to NHFPC for record; NHFPC will notify the CFDA, AQSIQ and MOA such plans.

Article 10 The national food safety risk surveillance plans will take the following foods lacking food

safety standards and hazardous factors as the key surveillance targets:
(1) Products of high risks, wide area of circulation, large volume of consumption;
(2) Easy to affect health of infants/young children and other specific populations;
(3) More consumer complaints;
(4) Caused food safety incidents abroad.
CFDA, AQSIQ and MOA will conduct sampling test of foods that have food safety standards. With the risk surveillance and testing results, NHFPC will track, evaluate and revise the existing national foods safety standards.

Article 11 NHFPC, CFDA, AQSIQ and MOA follow the national food safety risk surveillance plans and conduct food safety surveillance within their jurisdiction.
NHFPC is in charge of risk surveillance of food-borne disease, food contamination, and harmful factors in foods; CFDA is in charge of risk surveillance over harmful factors in food production/distribution and catering services; AQSIQ is in charge of risk surveillance on harmful factors in food-related products and import/export foods; MOA conducts risk surveillance over growing of edible agricultural products, pesticides/vet drug residue/other contaminants in the breeding link; the Grains Bureau is in charge of risk surveillance of heavy metals and other contaminants in raw grains.
Relevant ministry/administration shall hold consultations to address problems revealed in the risk surveillance under their respective jurisdictions, take effective measures to prevent and control food safety risks.

Article 12 NHFPC, CFDA, AQSIQ and MOA could entrust eligible technical institutes and/or third-party institutes to conduct food safety surveillance.
Such technical institutes shall following the surveillance plans and working procedures in food safety surveillance work, and shall guarantee truthfulness, accuracy and completeness of the surveillance data.

Article 13 Provincial health departments and the same level FDA, quality supervising authorities, and agricultural authorities will establish the food safety risk surveillance data notification and consultation mechanism; through which, they could collect and analyze the risk surveillance data, assess the risks, and form the monthly/quarterly/semi-annual/annual reports. The reports shall be submitted to the provincial government and the NHFPC, CFDA, AQSIQ, MOA within seven working days; the report shall be submitted within two working days upon detection of significant risks.

Article 14 The local health departments shall conduct risk assessment in a timely manner upon detecting food safety risks in food safety risk surveillances; they shall notify the local FDA upon discovering food production/trading that violate laws and regulations.
Finding issues need food safety risk assessment in its food safety investigations, local FDA shall notify the local health department; the local health department shall conduct the risk assessment and notify the assessment results to the local FDA.

Article 15 When the risk surveillance results reveal existence of food safety risks, the local FDA shall, based on necessity of risk control, inform relevant food producers or traders; the latter shall take immediate action to screening check risks, terminate production/trading/use of the problematic products, recall the food products of potential risks, and report the situation to the county and above level FDA.

Article 16 Risk surveillance and assessment of edible agricultural products shall be carried out by county and above level agricultural authorities with the health departments and FDA of the same level.

Article 17 NHFPC, CFDA and other ministries jointly formulate the food safety risk assessment plans, establish and manage the risk assessment database; they organize the collection of basic data and conduct method analysis, etc.
NHFPC, CFDA, AQSIQ and MOA establish the communication mechanism for food safety risk assessment, and share the data/materials.
It is encouraged that the National Food Safety Assessment Center (CFSA) entrusts eligible technical institutes to undertake food safety assessment tasks.

Article 18 NHFPC, CFDA, AQSIQ and MOA jointly establish and supervise the National Food Safety Risk Assessment Expert Committee.
The Expert Committee is in charge of developing methods and requirements for food safety risk assessments, review the assessment result reports, explain and communicate the assessment results.

Article 19 CFDA, AQSIQ and MOA, discovering issues that need safety assessments (such as pesticides, fertilizer, vet drugs, feed and feed additives), shall propose to the Expert Committee to conduct risk assessment. The latter shall follow the suggestions in a timely manner, and notify the assessment results to relevant ministries under the State Council.
Relevant review committees shall work with the National Food Safety Risk Assessment Expert Committee in safety assessments of pesticides, fertilizers, veg drugs, feed and feed additives.

Article 20 NHFPC, based on need of risk assessment work, conducts basic data researches, such as food consumption, environmental factors affecting food safety, total dietary researches, and public awareness, etc.

Article 21 Provincial FDA shall work with other departments of the same level to evaluate the information obtained in oversight work (i.e. from risk surveillance, assessment, routine oversight, sampling test, case investigation, special rectification programs, etc.) and the public opinion; they shall publish food safety alerts for products that present higher safety risks in assessments.

Article 22 China establishes the food safety risk communication mechanism. Food safety risk communication shall be science-based, transparent, open, timely, effective, participated by a broad range of stakeholders, and communication/coordination-oriented.
China encourages the food producers or traders, food safety technical institutes, industry associations, consumer association and media to participate in food safety risk communication work, which is conducive to the social governance of food safety.

Article 23 CFDA and other ministries establish the working procedures for food safety risk communication, establish the risk communication mechanism, and guide the local government in the risk communication work.

Article 24 CFDA and other relevant ministries shall establish the risk communication consulting committee, which is composed of experts in food, public health, clinical medicine, news and media; the committee will provide advisory suggestions to the government, and participate in risk communication.

If necessary, the consulting committee could solicit comments from social organizations, food producers or traders, consumers, media; they can also invite stakeholders to participate in risk communication work.

Chapter 3: Food Safety Standards

Article 25 NHFPC shall work with CFDA, AQSIQ and MOA in developing national food safety standard plans and the annual work plans. The plans shall be published for comments.

Article 26 NHFPC and CFDA set up the national food safety standard review committee; they jointly develop administrative measures for food safety standards, and organize the standard proposing, drafting, review and publishing of the national food safety standards.
NHFPC and CFDA would select eligible entities to develop the draft national food safety standards.
It is encouraged that the research institutes, technical institutes, academies, industry associations jointly develop the draft national food safety standards.

Article 27 NHFPC and CFDA shall expedite the development of national food safety standards for food additive category/scope/limits for the catering service industry, as well as national food safety standards urgently needed in food safety law enforcement.

Article 28 Provincial health departments and FDA of the same level shall develop local food safety standard plans and implementing plans thereof; they shall work together for the standard proposal, drafting, review and publishing of local food safety standards.
It is prohibited to develop local food safety standards for health foods, foods for special medical purposes, infant formula foods, food additives, food-related products and new food materials.

Article 29 Provincial health departments shall file the local food safety standards to NHFPC for records within 30 working days after its publication.
NHFPC shall correct the local food safety standards that violate laws, regulations and national food safety standards in a timely manner.
After release of national food safety standards, relevant local food safety standards shall be annulled. Provincial health departments shall timely announce annulling of the local food safety standards.

Article 30 Company standards shall be implemented after approval by the legal representative or person in charge; food producing firms shall be accountable for the company standards filed for records.

Chapter 4: Food Safety Standards

Section 1: General Rules

Article 31 CFDA shall formulate regulations for food production and trading licensing pursuant to social and economic development, size of business, technical conditions, and food safety requirements. Food producers or traders shall follow the regulations for food production and trading licensing in its

production and trading activities.

Article 32 Food producers or traders and food transportation entities are prohibited to purchase, use, store, and transport non-food-use products that are prohibited by relevant authorities; they shall not use recycled food additives to produce foods or food additives.
It is prohibited to add medicine, chemicals other than food additives, or substances that may harm human health in food additives.

Article 33 Companies producing half-finished food products or extracts shall obtain food producing license; companies that sell foods via telephone, conferences, workshops shall also obtain food trading license.
Food producers having food production license do not need to apply for food trading licensing for selling self-made foods in its production venue; catering service providers do not need to apply for food production license for selling its self-made foods at its service venue.

Article 34 Companies entrusted by food producers or traders to produce foods and food additives shall obtain food production license; the trustor undertakes legal liabilities for safety of the produced foods, the trustee shall be accountable for its production activities.
The two sides shall sign written commission contract for food production, which shall clearly identify the two parties' rights and obligations in terms of food safety.

Article 35 NHFPC and relevant ministries publish the catalogues of new food materials, new food additive varieties, new food-related products, and national food safety standards thereof on a regular bases; they shall also track and evaluate safety of such products.

Article 36 Filing safety review applications to the NHFPC for new food materials, new food additive varieties and new food-related products, the applicant shall submit materials proving the product's technical necessity issued by relevant industry organizations, the safety assessment opinions by the special technical institute, relevant standards and development of relevant standards.

Article 37 Substances listed in the Catalog of the Substances Traditionally Considered as Both Foods and Chinese medicines shall meet the following requirements:
(1) Have history of human consumption in China; have not had cases of acute, subacute, chronic, or other potential harms to human health;
(2) Ancient books have records about consumption of the substance, and no record showing the substance is toxic;
(3) The substance is listed in the national drug standards;
(4) Using of the substance will not impact sustainability of relevant plant variety development, and will not cause negative impact to the wild medicinal resources and the ecological environment; such substances are not produced from wild animals or plants in the "Catalogue of Specially Protected Wild Animals" or the "Catalogue of Specially Protected Wild Plants";
(5) Comply with provisions of relevant laws and regulations.
Article 38 Food producers or traders shall keep good records of information concerning material purchase, production, processing, packaging, transportation, storage, distribution, testing, recall and termination of business. The records shall be truthful, accurate and complete for traceability purposes.

Section 2: Process Control of Production and Distribution

Article 39 Legal representative or person-in-charge of the food producers or traders shall be accountable for food safety of the company; they shall establish and ensure functioning of the food safety accountability system of the company.

Article 40 The food safety managers (of the food producers or traders) shall assist the legal representative or person-in-charge food safety management.
Legal representative or person-in-charge of the food producers could authorize the food safety managers to undertake the following food safety management responsibilities:
(1) Select suppliers;
(2) Inspection of purchased materials and finished products; they shall be accountable for truthfulness of records;
(3) Organize self-inspection; they shall be accountable for truthfulness of the inspection reports;
(4) Supervise the food safety process control in food production or distribution;
(5) Organize and conduct food recall;
(6) Report food safety incidents;
(7) Other obligations provided by laws and regulations. ‘

Article 41 Food safety managers shall have professional knowledge about food safety laws, regulations, standards, and technical background, etc., as well as the capacity for food safety management.
CFDA shall develop the evaluation measures for food safety managers of producers or traders.

Article 42 Food producers or traders could conduct self-inspection, or entrust the third-party institutes/individuals to conduct food safety inspections.

Article 43 In case irradiation is necessary for production or trading of a product, the food producers or traders shall entrust qualified entities for the treatment, and conduct inspection according to relevant standards for irradiated food.
Food producers or traders shall report to county level FDA about the treatment of foods, and use of irradiated food materials.

Article 44 Food producers or traders shall establish the food safety information disclosure mechanism; through which, they will disclose information to the public, such as food production license, company food standards, risk grading labels, inspection/testing results, food recall and termination of operation, disposal of unqualified foods, etc.

Article 45 Pursuant to the food safety risk situation and food safety oversight need, provincial FDAs shall promote the GMP and HACCP to food producers or traders of larger size and to meat/dairy producers.

Article 46 Producers of foods, food additives and food-related products shall conduct self-inspection or entrust other institutes to conduct inspections over its food, food additive and food-related products

pursuant to food safety standards.
If the time for regular inspection is longer than the food's shelf life, fast testing could be adopted.

Article 47 Food traders selling health foods, foods for special medical purposes and infant formula that require registration shall verify the product registration certificates, confirm the certificate and food label indicate consistent information; they shall keep a copy of the registration certificate for file.

Article 48 Food producers or traders shall record expired/rotten/recalled foods, food additives, or food-related products. Such products shall be kept separately in a venue with clear signs, they shall be timely disposed or treated with harmless measures, with good record keeping.

Article 49 Food producers or traders shall investigate into the storage or logistics companies' food safety safeguard capacity before entrusting the company for food storage or transportation services; also, the food producer or trader shall strengthen its supervision over food safety management by the company.
The companies providing food storage or transportation services shall strengthen the process control to guarantee that their storage and transportation conditions meet food safety requirements.
The companies providing food storage or transportation services shall check and keep a copy of the trustor's ID, food production/trading license, business license, compliance certificates, inspection/quarantine certificates; they shall be accountable for food safety during food storage and transportation.

Article 50 The food storage and transportation company that do not produce foods shall file records with the county level FDA within 30 working days upon obtaining its business license.
When complaints or case investigation reveal that the food storage and transportation company may violate food safety laws/regulations/national food safety standards in food storage or transportation, the FDA shall take timely actions to address the issue.

Article 51 (The companies providing food storage or transportation services) shall install equipment/facilities for thermal insulation or cold storage to meet temperature and humidity conditions for food storage and transportation; they shall keep the equipment in proper operation.
County and above level municipal government shall take effective measures to support cold chain transportation.
In storage and transportation of edible agricultural products, it is prohibited to add non-food-use chemical substances or other substances that may harm human health; it is also prohibited to use food additive in excessive amount and scope.

Article 52 Food storage and transportation shall have good records for traceability of the process.
The trustor and trustee of food storage and transportation shall sign written contract in advance, which shall clearly identify the two parties' rights and obligations.

Article 53 Catering service providers, using food additives in its self-made products, shall disclose name and amount of the food additives.

Article 54 Catering service providers procuring tableware cleansing and sterilizing services shall sign contract with the service provider; the trustor shall check and keep copies of the trustee business license

and cleansing/sterilization compliance certificate.

Article 55 Tableware cleansing companies shall have full-time/part-time health managers, establish the health management mechanism and keep records of hygienic management; they shall follow the hygienic regulations in business operation.

Article 56 Schools, kindergartens, nursing houses, hospitals and construction sites that have cafeterias shall conduct self-inspection to screening check risks; they shall submit the self-inspection reports to the county level FDA on a regular basis.
Entities that out-source cafeteria, strictly following laws, regulations and rule, shall strengthen inspection to the contractors and urge the contractors to fulfill food safety rules. The two sides shall sign written contract in advance, which shall clearly identify the two sides' rights and obligations.
The entities outsourcing cafeteria services shall strictly follow relevant laws and regulation in inspecting the cafeteria, supervise and urge the contractors to comply with relevant food safety management requirements. The two parties shall sign written contract in advance, which shall clearly identify the two parties' rights and obligations.

Article 57 County and above level municipal governments shall strengthen food safety oversight in the rural areas; they shall clarify the food safety rules and requirements for rural group dining to prevent food safety incidents.
The organizers and catering service providers of the rural group dining activities shall be accountable for food safety of the activities; they shall procure, store and process foods in accordance with relevant food safety requirements, and shall report the activities (to competent authority).

Article 58 Catering service providers and the hired catering service management companies shall sign contracts, which shall clearly identify the two sides' rights and obligations. The catering service providers shall be responsible for legal liabilities of the catered foods.

Article 59 Food additive traders shall establish the accounting records of the food additive transactions, which shall record such information as name, specification, quantity, production date or batch number, shelf life, sale date, buyer (name, address and contact), and properly keep relevant credentials. Terms of keeping such records and credentials shall be subject to the provisions set forth in Article 50.2 of the Food Safety Law
The food additive traders shall file records with the county level FDA within 30 working days upon obtaining its business license.

Article 60 Third-party platform providers for online food transactions shall file records with the county and above level FDA within 30 days upon obtaining its business license; information filed for records shall include website, IP, IP certificate, company name, legal representative and copy of his/her ID, contact information, etc.
Third-party platform providers shall publish its food safety management system in the platform for access of on-line food producers, traders and consumers.
Third-party platform providers shall publish information of food safety violations by food producers and traders using the platform at the conspicuous place of the webpage.

Article 61 On-line food producers or traders shall obtain food production/trading license unless

otherwise provided in laws and regulations. On-line food producers or traders shall engage in businesses that are permitted for their physical transactions.

Article 62 On-line food producers or traders shall file records to the FDA office that issues its production/trading license within 30 days after it joins the on-line platform; the filed information shall include website and IP. At the same time, they shall publish their business licenses, production/trading licenses and other information at the front page of its website or the webpage; the on-line food producers or traders shall update such information if there is any change.

Article 63 Pursuant to local situation, provincial municipal government could gradually launch the food safety e-traceability system in high-risk food categories and large-size food producers or traders. Food producers or traders are encouraged to use the informatization methods to collect and record production/trading data.

Article 64 Food producers or traders and wholesale market shall report to county and above level FDA data and information related to food safety.
Third-party platform providers shall properly keep the registration and trading data of the producers and traders of food, food additive, and edible agricultural products that operate in the platform; they shall faithfully report such information to the county and above level FDA as requested by the CFDA.

Article 65 In accordance with the national food recall regulations, food producers or traders shall terminate production/trading of unsafety foods, recall and dispose the unsafety foods.
Based on seriousness and emergency grade of food safety risks, food recalls could be categorized to the following grades:

Grade I recall: consuming the food caused serious harm to human health, or even death; the food producers or traders of such foods shall initiate food recall within 24 hours upon knowing the food safety risks;
Grade II recall: consuming the food caused general harm to human health; the food producers or traders of such foods shall initiate food recall within 48 hours upon knowing the food safety risks;
Grade III recall: label or description of the product fail to comply with food safety standards, but in normal situation the incompliance is not causing harm to human health; the food producers or traders of such foods shall initiate food recall within 72 hours upon knowing the food safety risks.
Initiating food recall, the food producers or traders shall report to the county and above level FDA within the set time limit for the food recall grade.

Article 66 The food producers or traders shall properly dispose the foods withdrawn from the market due to termination of production/distribution or recall; such disposal measures may include harmless treatment, destroy the product, or remedial measures.
The food producers or traders shall immediately destroy the unsafety products that cause serious harm to human health and life; such as illegally adding non-food-use substances, rotten foods, poultry/livestock die from diseases, pesticide/vet drug residue exceed the limits, etc.
The food producers or traders could take remedial measures to foods recalled for label or marks not complying with food safety standards, and sell the products again if the food safety is guaranteed. The food producers shall inform consumers of the remedial measures taken when the products are launched in market again.

County and above level municipal government will set up special fund for storage, harmless disposal and destruction of the unsafe foods involved in criminal investigations.

Section 3 Trading of Edible Agricultural Products

Article 67 Operators of the edible agricultural product wholesale market shall file records with the county level FDA within 30 working days upon obtaining its business license; the filed information include market name, type, address, legal representatives or person in charge, food safety manager, food safety management system, categories of edible agricultural products sold in the market, number of shops, etc.

Article 68 Operators of the edible agricultural product wholesale market shall set up information bulletin boards at conspicuous spots in the market, which publishes food safety management system, product testing results, handling of unqualified edible agricultural products, and oversight authorities' telephone number for reports and complaints.

Article 69 Operators of the edible agricultural product wholesale market undertakes the following management responsibilities for quality and safety of edible agricultural products that are sold in the market:
(1) Set up the edible agricultural product safety management system, equipped with safety managers and technical staffs; they shall carry out food safety trainings, and strengthen testing work of edible agricultural products;
(2) Set up files of traders selling edible agricultural products in the market; record traders' name, contact information, social credit code or ID, home address, procurement sources, categories of edible agricultural products, origin of the products, etc.; the files shall be kept for no less than six months after the trader stopped business.
(3) set up the market access system for edible agricultural products; check and keep copies of the traders' social credit code or ID, procurement credentials, or quality certificates;
(4) Set up the routine inspection system; regularly or irregular inspects the environment, condition and behavior of the traders operating in the market; keep a file of trader's operation management;
(5) Upon detection of illegal behavior or existence of risks, the market operator shall timely take actions to stop the behavior/risks, and immediately report to the county and above level FDA; they shall cooperate with the authority's investigation work;
(6) Set up food safety incident respond plans; regularly inspect the traders for their fulfillment of food safety incident preventative measures to eliminate incident risks.

Article 70 The operator of the edible agricultural product wholesale market shall take the following responsibilities in addition to the responsibilities listed in Article 69 of the Implementing Rules:
(1) Sign quality and safety agreements with traders operating in the market; the agreement shall clearly identify each side's rights and obligations; traders who have not yet signed the quality and safety agreements are not permitted to sell products in the wholesale market;
(2) The market operator make available testing equipment and technical staffs, or entrust qualified food testing institutes to conduct sampling testing or fast testing; frequency of the testing shall be determined according to categories of the edible agricultural products and risk grades; the sampling test results shall

be published in a timely manner.
(3) Print sales credentials of the unified format, which shall provide information such as product name, place of production, dates of transactions, trader's name, address and contact information.

Article 71 Traders of shall provide the place of production credentials, purchase credentials and quality certificates to get permission to sell edible agricultural products in the market. If the trader could not provide such documents, the market shall conduct fast testing or sampling testing; the trader could enter the market only when its products pass the testing.
Traders shall provide the quarantine compliance certificates to the market for meat that are quarantined; traders shall provide inspection compliance certificate for meat products.
Traders selling imported edible agricultural products shall provide the entry inspection and quarantine certificate issued by the China Inspection and Quarantine (CIQ).

Article 72 Traders selling unpackaged edible agricultural products in wholesale/retail markets shall publish name/production place/name of the producer or trader at the conspicuous spot of the booth/counter.

Article 73 Traders of edible agricultural products shall establish the incoming raw material verification record; the record shall indicating such information as name, production place, quantity, purchase date, and contact information of suppliers, and keep relevant credentials. Traders purchasing imported edible agricultural products shall also record the country of origin, name/address and contact information of the product's Chinese domestic agents. Records and credentials shall be kept for at least six months. Companies that adopt a centralized logistics model could have their headquarters set up the inspection record for incoming food products.

Section 4: Labels, Descriptions, and Advertisements

Article 74 Food producers shall be accountable for content of the food and food additives' label and descriptions.
Food producers or traders shall not change the production dates and shelf life on label and descriptions, which is in violation of relevant regulations.

Article 75 Production dates and shelf life marked for unpackaged foods shall be truthful, clear and easy to read; such information shall be the same as in the bulk package labels marked by the food producers.
Food producers or traders, when mixing unpackaged foods of different production dates, shall mark on the label the earliest production date and the shortest shelf-life of the mixed products.
Foods repackaged by food producers or traders shall not change the original production dates or extend the original shelf-life.

Article 76 Edible agricultural products that are packaged after cleaning or cutting shall mark shelf-life, and shall be sold within the shelf-life. Unprocessed edible agricultural products are not required to mark shelf-life.
CFDA will work with relevant ministries to decide shelf-life of preliminarily processed and packaged edible agricultural products based on product category.

Article 77 Prepackaged foods produced of GMO materials shall be clearly labeled pursuant to relevant provisions.
Labeling of GMO foods shall comply with provisions of the Administrative rules for Agricultural Biotech Safety Management.

Article 78 Food labels and descriptions shall not mark phrases such as "Specially Supply to", "Solo Supply to" or "Produced with the Supervision of". For materials that shall not be used or contained (in foods) as provided by food safety standards, food labels shall not contain the phrase "not added", or "not containing". For GMO foods and materials China has not yet approved, the labels shall not contain the phrases such as "non-GMO".
Any foods other than health foods shall not mark or hint the healthcare function in any form in any form on the package.
Content of labels for health foods, foods for special medical purposes, and infant formula foods shall be the same as the registered/filed information. Foods other than health foods/foods for special medical purposes/infant formula foods shall not mark fixed amount consumption or daily consumption volume.
Irradiated foods shall indicate "Irradiated Food" on the label and descriptions; ingredients that have been irradiated shall be marked in the ingredient list.

Section 5: Special Foods

Article 79 Health foods, foods for special medical purposes, formula of infant formula powder products that are subject to registration requirements shall obtain the registration certificate issued by CFDA.

Article 80 CFDA, NHFPC and the State Administration of Chinese Medicine shall develop, adjust and announce the catalogue of health food materials and the catalogue of health foods that are allowed to have health function claims..
The catalogue of health food materials and the catalogue of health function claims aim to protect the public health, and shall follow the principles of science-based, open and fairness, and shall be under dynamic management. CFDA, NHFPC and the State Administration of Chinese Medicine shall timely adjust the two catalogues pursuant to science advancement and health food registration.

Article 81 While publishing the catalogue of health food materials, the material name, dosage, production techniques, corresponding effects and testing methods shall be published at the same time.
Materials listed in the catalogue of health food materials, experiencing substantial change after reprocessing extraction, purification, are materials not in the catalogue of health food materials.
The health function materials that are not intended for nutrient materials shall be administered as health food materials, and shall not apply for permission as new food materials. Foods other than health foods shall not use materials that are solely for production of health foods.

Article 82 The on-site inspection to applicants for health foods production license shall inspect the dynamic production process, and take sample products that rolled out of the production line for testing purposes.
Health foods producers must have the finished product testing capacity that matches the product varieties and size of production.

Article 83 To apply for health food registration, the producer shall conduct R&D, produce samples in a company that follows the GMP in health food production, and submit the testing reports issued by eligible testing institutes.

Article 84 For health foods and infant formula foods that are subject to record filing requirements, food and drug administrations shall complete information entry, document filing and verification before issuing the record filing number according nature of the application.
After obtaining the record filing number, the applications for domestic production shall apply for food production license within three months; the product formula and production techniques shall meet requirements for issuing food production license.
After obtaining the record filing number, the applications for importing health foods shall import relevant products within three months; the customs clearance documents and inspection reports shall be submitted to the provincial FDA at the same time.

Article 85 With the occurrence of one of the following circumstances, CFDA will organize the re-evaluation of the health food; based on the re-evaluation results, CFDA could take measures including revoking the registration certificate and adjusting the catalogue of health food materials, and publish the measures taken.
(1) Change of recognition for safety or health function of a health food or a category of health foods with the science research advancement;
(2) Risk surveillance and risk assessment reveal a health food or a category of health foods may have safety risks;
(3) Other situations that need re-assessment of the health foods

Article 86 CFDA entrusts qualified food testing institutes to undertake formula registration testing and verification work for health foods, foods for special medical purposes, and infant formula powder products; the list of the testing institutes will be published by CFDA.
Companies applying for formula registration for foods for special medical purposes or infant formula powder products shall have R&D capacity, production conditions, and whole-range testing capacity as required by relevant standards; they shall comply with GMP requirements, and adopt the HACCP system.

Article 87 Producers of health foods, foods for special medical purposes and infant formula food shall use the registered/filed formula and techniques in production.
The producer of infant formula foods shall file the materials, food additives, product formula and labels for records before launching its products in the market; such filed records shall be published.
Health food producers must have proper material pre-processing capacity that matches the product categories and product scope to process raw material that needs extraction or purification

Article 88 Name of a health food shall not include words that directly mention or hint function of the product.
The health function claim of the health food shall be labeled pursuant to the catalogue of health function claims; it is not allowed to add/remove words or recombine descriptions.

Article 89 Health foods, foods for special medical purposes and infant formula food shall be sold at the

specific counters or areas, which shall clearly mark “special area/counter for health foods”, “special area/counter for foods for special medical purposes” and “special area/counter for infant formula food”. Health foods, foods for special medical purposes and infant formula food shall not be displayed together with medicines or other food products.
The health foods area or counter shall clearly mark “this product may not replace medicine”.
The special whole-nutrient formula foods of the foods for special medical purposes shall be sold in hospitals or medicine retailers; other foods for special medical purposes could be sold in food distribution locations.

Article 90 Formula of the imported foods for special medical purposes and infant formula powder products shall be registered as provided by laws.

Article 91 Advertisements of the special whole-nutrient formula foods shall be regulated as prescription drug advertisements; Advertisements of other foods for special medical purposes shall be regulated as OTC medicines.

Article 92 Producers shall not sell in China infant formula powder that only have label/company name/address registered abroad; it is prohibited to use milk or milk products of animals other than cow or goat to produce infant formula powder.
The product formula applying for registration shall be researched and developed pursuant to relevant laws, regulations, and national food safety standards, and shall have science bases. Different formulas by one company for same age infants/kids shall present obvious difference, and have science basis. In principle, each company could register at the maximum nine formulas of three series.
Name of infant formula foods shall not include substances that are optional substances, as required by the national food safety standards.
Infant formula powder producers shall not set distribution region restrictions; producers shall not tailor products for specific traders.
Article 93 The same producers shall not use the same formula to produce foods for special medical purposes and health foods under different brands.
Health foods holding the same registration certificate or record filing number shall use the same trademark.

Chapter 5: Food Inspection

Article 94 The food and drug authorities and the quality authorizes shall conduct random sampling test to foods, food additives and food-related products according to their jurisdictions.
The sampling testing for food safety shall be conducted according to the testing items/methods provided in relevant food safety standards. In responsive works, such as case investigation, incident investigation, and emergency response, inspectors could adopt testing items or methods not provided in food safety standards to find reasons of food safety problems. Taking the testing method not provided by the food safety standards, the inspectors shall follow the principle of using the “advanced technical measures”, and obtain consent from provincial FDA.

Article 95 The food and drug authorities and the quality authorities could take the samples themselves,

or entrust qualified food testing institutes to take samples. There should be at least two inspectors in presence when the samples are taken.
The law enforcement investigators shall take samples for purposes of case investigations and incident investigations; sample taking is not subject to requirements such as quantity of samples, location, and whether the sampled company has the legal qualifications.

Article 96 For on-line e-commerce, the food and drug authorities will follow the on-line food sampling test plans in determining sample buyers, payment account, registered account, product delivery address, contact information, and keep bills of purchase; they shall also record name/kind/quantity of the sampled product.
Upon receiving the samples, the sample buyer, the sampling person, and the FDA enforcement officials shall open the parcel together, examine the samples, seal the samples and the back-up samples, and notify the on-line food producers or traders; if the samples are purchased through the third-party platform providers, the platform provider could notify the on-line food producers or traders.

Article 97 The food and drug administration shall inform the on-line food producers or traders about the sampling test results. If the samples are purchased through the third-party platform providers, the testing results shall be notified to the on-line platform provider at the same time.
When the on-line food producers or traders do not have valid contact information, the testing results could be forwarded to them through the platform provider. Unable to reach on-line food producers or traders that have unqualified testing results, (the food and drug administration) could demand the third-party platform provider to remove the producer/trader's product information from the platform, and suspend the transaction service by the platform.
Unable to pass the testing results to on-line food producers or traders that provided invalid addresses, the food and drug administration could publish relevant information through its official website.
Article 98 Getting acceptable testing results, the testing institute shall send the testing reports to the food and drug administration that requested the sample testing within ten working days; getting unacceptable results, the institute shall immediately inform the food and drug administration.
Receiving unacceptable testing results, the food and drug administration shall immediately deliver the result to the local food and drug bureau where the sampled food producer or trader locates; another option is checking product package/label for address of the producer or importer, and send the result to the food and drug administration in the region.
The food and drug administration, upon receiving the testing results the present potential harm to public health and life, shall immediately inform the involved food producers or trader to terminate production/distribution of the product and recall unsafe foods; such measures are taken to mitigate and control food safety risks; the FDA shall also investigate into the issue in a timely manner. The food and drug administration could instruct the food producer or trader to fulfill its obligations if it fails to do so.

Article 99 Obtaining official seals and signing accreditation by qualified third-party service provider, the testing institute could issue electronic testing report, which has the same legal power as the hardcopy testing reports do.

Article 100 With the occurrence of one of the following circumstances, it is not allowed to re-test the samples:
(1) Testing results show excessive microbiological count;
(2) The back-up samples for re-testing has passed their shelf-life;

(3) The application for re-testing was submitted after deadline;
(4) Other reasons that prevent the back-up sample to be used for re-testing purpose.

Article 101 Food producers or traders opposing the testing results could submit applications for re-testing pursuant to the food safety laws and regulations; the applicant shall not entrust testing institute in interest to conduct the re-testing.
Unless otherwise agreed by the FDA, the re-testing applicant and the re-testing institute, the re-testing institute shall deliver the re-testing report to the FDA that requested the re-testing within 20 days upon receipt of the samples.
During re-testing, the food producer or trader shall continue fulfilling its obligations, such as terminating production/distribution of the product, or recalling the product.

Article 102 The re-testing institute shall follow the arbitration method provided in relevant standards in re-testing; lacking the arbitration method, the institute shall use the same testing methods used in the first testing. The re-testing sample shall be the reserved sample in the first testing. After re-testing, the institute shall make the conclusion whether the tested sample show acceptable result.

Article 103 The applicant shall pay the re-testing fee first; if the re-testing has the same conclusion as the first testing, the re-testing cost will be paid by the applicant; if the re-testing show different conclusion from the first testing, the re-testing fee will be paid by the first testing institute.

Chapter 6: Food Import and Export

Article 104 China Inspection and Quarantine Services (CIQ), following the Food Safety Law and its Implementing Rules, oversights import and export of foods, food additives and food-related products, as well as foods entering the border/ports.
AQSIQ shall publish the inspection and quarantine certificates of imported foods and food additive, which shall be available to the public.

Article 105 AQSIQ, pursuant to its jurisdiction, grades the imported food categories based on safety risks, company's risk control capacity, exporting country/region's food safety conditions, etc.

Article 106 Importers or their agents, while importing foods, food additive and food-related products, shall present relevant documents and approving certificates (such as contracts, invoice, packing list and bill of lading) to CIQ for clearance. Relevant compliance certificates shall be provided according to AQSIQ requirements.
Imported edible animals and animal products shall come along with quarantine compliance certificates, such as entry inspection and quarantine certificates, animal quarantine certificates, and CIQ's "Notification of Inspection and Quarantine Treatment", etc.
Customs clears products based on the CIQ issued "Certificate of Customs Clearance", and publish the certificates at the customs official websites.

Article 107 For special foods that need registration or record filing, the importer or its agent shall present the registration or record filing documents to the CIQ. The CIQ shall conduct sampling test of the imports based on requirements indicated in the registration or record filing documents.

Article 108 CIQs oversight and conduct sampling tests on products for export; if the international treaties or protocols have specific provisions, the CIQs would follow such treaties and protocols in its inspections.

Article 109 CIQ conducts sampling tests to imported foods, food additives and food-related products in the importation link; once the products enter the Chinese domestic market, it is the food and drug administration that implements inspection and sampling tests.
For food products, food additive and food-related products of high risks, CIQs would detain the products for inspection; for products of common risks, CIQs would adopt sampling tests; for products of low risks, CIQ would conduct on-site inspections.

Article 110 Foreign food exporters and producers shall guarantee that the food exports to China comply with the Chinese Food Safety Law, relevant Chinese laws, regulations, rules and national food safety standards. The Chinese importers shall establish the system for reviewing foreign food exporter/foreign food producers.

Article 111 When an importer is recalling imported food products, the CIQs shall notify the issue to the food and drug administration.

Article 112 Foreign food producers, foreign exporters or agents that export foods products to China shall take effective measures to prevent intended chemical/biological/physical harm to the edible agricultural products and foods in the planting, raw material/auxiliary materials control, production, packaging, storage and transportation links.

Article 113 The Certification and Accreditation Administration (CNCA) will track the foreign food producers that have obtained the Chinese GMP, HACCP accreditation; for companies that no longer meet the accreditation requirements, CNCA will cancel their accreditations, and make timely notifications to other ministries and publish the list to the public.

Article 114 Imported prepackaged foods shall have Chinese labels, which shall be directly printed on the product package before importation; it is not allowed to stick Chinese label over the foreign language label.

Article 115 CFDA could organize on-site inspections to foreign producers of health foods, foods for special medical purposes and infant formula powder; the inspection will focus on their quality management system, and the GMP/record filing of health foods.
Food producers or traders shall not import foods that contain materials only used in health foods and declare it non-health foods.
Article 116 Noticing foreign food incidents or public health incidents that might affect Chinese domestic market, or discovering serious food safety problems in imported foods/food additives/ food-related products, AQSIQ shall timely publish import food safety alerts and take the following control measures:
(1) Mandatory inspection, detain the products for testing;
(2) Reject or destroy the problematic products;
(3) Limited imports with conditions;

(4) Terminate or ban imports;
(5) Initiate the emergency response plan for imported foods.

Article 117 Foods imported and exported via cross-border e-commerce shall comply with relevant provisions of the Food Safety Law and its Implementing Rules.
The administrative measures for foods, food additives, food-related products imported via cross-border e-commerce shall be developed by AQSIQ and relevant ministries.

Chapter 7: Settlement of Food Safety Incidents

Article 118 Food safety incidents shall be graded for handling purposes.
The extremely severe food safety incidents shall be handled by CFDA and relevant other ministries with the supervision of the State Council.
Severe, large and general food safety incidents shall be handled and investigated by the provincial, city and county level FDAs and other departments of the same level under supervision of the same level municipal government.

Article 119 Provincial governments shall formulate emergency response plans for food safety incidents; the plans shall be revised or improved based on the real circumstances.
County and above level municipal governments shall properly manage the food safety emergency response plans; they shall conduct an emergency response drill at least once every three years.
County and above level municipal governments shall include the food safety emergency response plans into the government leader training programs, civil servants trainings, and emergency response officials' routine training programs.

Article 120 Provincial municipal governments shall develop plans to develop their food safety emergency response systems.
County and above level municipal government shall establish the offices for food safety emergency management, improve the management mechanism, secure fund, upgrade equipment/facilities, store needed materials, and set up an emergency respond team; the emergency response trainings, drills and assessments of emergency responses shall be strengthened.
County and above level municipal government shall conduct surveillance of and issue alert for food safety incidents; they shall strengthen information collection, analysis and judgment of food safety-related information; based on degree of emergency, development, and possible harm, the county and above level municipal government shall timely issue alerts.

Article 121 County and above level FDA and health departments shall establish the food safety incident surveillance and reporting mechanism; establish the direct food safety reporting network that cover above-scale enterprises [1] food producers or traders, third-party on-line trading platform providers, hospitals, CDC, etc.

Article 122 Food producers or traders shall establish the food safety emergency management mechanism; develop plans for incident handling and emergency reporting.
Above-scale food producers or traders shall conduct emergency response drills regularly for different

types of incidents.

Article 123 With the occurrence of one of the following circumstances, the food and drug administrations will conduct investigations in a timely manner:
(1) Food poisoning caused by foods provided by food producers or traders;
(2) Food producers or traders caused food contamination in production, processing, storage and transportation, distribution because of staffs' action or other reasons, which caused harm to public health or even injury;

Article 124 The entity that have food safety incident shall take control measures to food and materials/tools/equipment that might have caused the food safety incidents, and report the incident to the county level FDA in the region within two hours of the incident.
Hospitals and CDC, discovering hospitalized patients or public health incidents might be related to food safety incidents, shall report to the county level FDA and local health departments within two hours. Local health departments shall immediately organize CDC to treat the incident site, and conduct epidemiological investigations on factors related to the food safety incident; such investigation shall be assisted by other government agencies; county and above level CDC shall submit the preliminary epidemiological investigation reports to the local health departments and the food and drug administration of the same level within 24 hours. The final investigation report shall be submitted within seven working days after conclusion of the investigation.
CDC and food testing institutes, discovering food safety incident information, shall report to the county and above level FDA in a timely manner.

Article 125 County and above level health departments and the food and drug administration of the same level shall establish the food-borne disease and food safety incident surveillance and reporting system; instruct the local CDC to verify reported disease information. If the reports involve food safety issues, the local health departments shall report to the higher level health department and the same level municipal government within two hours; they shall at the same time inform the FDA of the same level.

Article 126 County and above level health departments, quality authorities, agricultural authorities, public security authorities and relevant departments shall report the discovered food safety incident information to the same level FDA; discovering food safety incidents that may relate to jurisdictions of other departments, the local FDA shall notify such departments of the food safety incident information.

Article 127 County and above level municipal government, receiving food safety incident reports, shall immediately organize relevant departments, including FDA, health department, ag authority, quality authority, and public security departments to conduct investigation to verify the information. For confirmed food safety incidents, the food and drug administration, the health department, the ag authority, quality authority and the public security department shall conduct investigation and take actions.
After the investigation is concluded, the food and drug administration shall report the investigation results to the municipal government of the same level and higher level FDA.
Once the food safety incident triggers the emergency response plan, the county and above level municipal government shall immediately set up the incident commanding organization and start responding to the incident following the emergency response plan.

Article 128 Development of emergency response plans and investigation of food safety accidents other than food safety incidents could refer to provisions of this chapter.

Chapter 8: Supervision and Administration or Oversight and Law Enforcement?

Article 129 CFDA is responsible for registration and record filing of relevant special foods; it organizes the national food safety sampling check, the system-wide inspections and unannounced inspections. CFDA establishes the unified food safety information release platform, which announces significant information related to food safety; CFDA conducts investigations into serious food safety violation cases, handling extremely severe food safety incidents, and prevent systematic food safety risks.
Provincial FDAs oversight food production licenses for special foods; their responsibilities include province-wide food safety sampling inspections, system-wide inspections and unannounced inspection, releasing food safety information within the region, conducting investigations into food safety-related law violation cases, and handling of extremely severe food safety incidents, as well as regional food safety risk control.
City and county level FDAs oversight food production license; their responsibilities include routine food safety inspections and sampling inspections, releasing food safety information within the region, supervising company's food recall, and conducting investigations into food safety-related law violation activities. Their primary responsibilities are routine inspections and sampling tests on pesticide/vet drug residues of food materials sold/purchased in food and agricultural wholesale/retail markets, supermarkets, and catering service providers, as well as oversight on operation of small food workshops and food vendors.

Article 130 When necessary, CFDA could set up dispatched offices to supervise the local government's food safety work.

Article 131 County and above level FDA, quality supervision authorities and agricultural authorities shall grade the food safety risks in the region based on food safety risk surveillance, risk assessment, inspections, sampling inspections, incident handling, case investigations, etc.

Article 132 China establishes the food safety inspector system. Provincial FDAs will set up the full-time food safety inspector teams, which will conduct on-site inspections to above-scale food producers or traders in terms of GMP and HACCP. The specific administrative measures for food safety inspectors will be developed by the CFDA.

Article 133 Local FDA and the quality authorities, discovering foods that are rotten or spoiled, contain mold or insects, contain foreign matter/adulterated, or display abnormal sensory indication, could take pictures of the foods as evidence.
If the persons involved refuses to sign his/her name (on the investigation report) or could not sign name due to special reasons, the inspectors shall indicate the reasons on the report, with signatures of at least two inspections on the site.

Article 134 Loosing evidence or unlikely to obtain evidence in the future, the enforcement officials

from local FDA, the quality authority, the ag authority could adopt the advanced registration and preservation rules to preserve relevant documents, such as contacts, bills, accounting books, sales records, and storage devices of electronica data, etc.

Article 135 For a food producer or a trader being investigated due to food safety violation activities, the local FDA could suspend its application for relevant administrative licenses while the investigation is in process; for the accepted applications, the local FDA could suspend processing the applications, and the suspension is not counted in the administrative licensing time limit.

Article 136 When the higher level FDA deems necessary, it could investigate into food safety violation activities that fall into jurisdiction of lower level FDA; it could also designate FDA from other regions to conduct the investigation, and the local FDA shall cooperate with/assist the investigation.

Article 137 Based on food-borne disease information, risk surveillance, risk assessment and other oversight information, the NHFPC and other relevant ministries shall timely publish the lists of non-food-use chemical substances and other substances added/possibly added to foods; the testing methods for such substances shall also be published in a timely manner.

Article 138 For pathogenic microorganisms, pesticide residues, vet drug residues, heavy metals, biotoxins, contaminants, and other harmful substances that lack residue limits and/or testing methods, NHFPC, MOA, CFDA will develop temporary limits and testing methods; they will release the limits/methods for public comments. Such standards shall be referred to in production and food safety oversight.

Article 139 CFDA, AQSIQ and MOA approve the use of fast testing methods necessary for their oversight work that have passed their evaluation.

County and above level FDA, quality supervision authorities and agricultural authorities could adopt the national food safety standards or CFDA/AQSIQ/MOA recognized fast testing methods in sampling inspections.

Finding products not complying with food safety standards in the sampling inspections, the food and drug administrator shall investigate into the issue, and instruct the food producers or traders to take control measures (such as suspending sales); the food and drug administration could use the sampling inspection results that confirm the product's incompliance as evidence for administrative punishment.

Article 140 The CFDA develops fast testing evaluation regulations; CFDA could entrust provincial FDA, industry associations and technical institutes to review the fast testing methods proposed by the industry and research institutes; the fast testing methods passed review will be published (and adopted).

CFDA could entrust provincial FDA and relevant technical institutes to conduct on-site inspections to companies that apply for approval of fast testing methods; the inspectors will review the applicant's production and the application files, and take samples.

Provincial FDA shall develop working rules for fast testing work, regulate the check/acceptance and use of the fast testing methods, and supervise the use of fast testing methods in the region.

Article 141 For fast testing methods that have not yet been evaluated by CFDA, provincial FDA could develop administrative rules and review regulations pursuant to oversight needs, and organize fast testing method review by technical institutes. Fast testing methods passing the reviews could be used in

preliminary food safety screening check in the region.

Article 142 CFDA and other ministries shall establish the food producers and traders credit reporting systems, establish/improve the negative safety record information disclosure system and the positive safety credit awarding system; CFDA shall promote the integration of food safety credit scores with the credit system (such as industry accession, financing/credit loans, and stock issuance), aiming to restrain the credit dishonesty in food safety.

Article 143 The food and drug administrations shall timely publish information such as issuance of licenses, results of routine inspections, and investigations into food safety violation activities.
Information of license issuance shall include the producer/trader's name, social credit code (or ID of self-employed), legal representative (person in charge), residence address, production/trading venue, food categories or other items, license number, valid period, oversight authority, oversight officials, telephone numbers for complains/reporting, license issuance authority and officials, date of the issuance, etc.
Routine inspection results shall include producer/trader's name, social credit code (ID of self-employed), legal representative (person in charge), residence address, licensing number, date of inspection, content of the inspection and results of the inspection.
The investigation information shall include case name, name or title of the punished individual/entity, facts of the violation, type/basis/results of the punitive measures. If the investigation involves revoking license, name and ID number of the food producers or trader's legal representative, person in charge and other persons accountable will also be disclosed.

Article 144 County level health departments carry out inspections to centralized tableware sterilization service providers; finding incompliances to food safety laws/regulations/hygienic requirements, the health department shall conduct investigations and disclose the inspection results to the public.

Article 145 With the occurrence of one of the following circumstances, the food and drug authorities could arrange meetings with food producers or trader's legal representative or person in charge:
(1) Food safety-related issues draw intensive social attention;
(2) The food producers or traders fail to properly and timely handle the complained/reported food safety problems, causing broad social consequences;
(3) The food producers or traders fail to fulfill food safety responsibilities, and fail to take effective measures to eliminate food safety risks;
(4) County and above level FDA deems necessary to accountability conversation *(Yue Tan)* with the company;
For food producers or traders violating laws, the accountability conversation will not affect the administrative punishment to them; information of the accountability conversation and follow-up measures shall be disclosed to the public.
The food producer or trader fail to take corrective actions after the accountability conversation without valid reasons will be recorded in the food safety credibility records (by the food and drug administration), and shall be subject to more frequent inspections.

Article 146 County and above level municipal government shall be accountable for food safety in major events; they shall develop food safety protection plans for major events, which will clarify responsibility (of stakeholders) and secure funds/ resources for food safety work.

Major event organizers shall identify the agency in charge of food safety management work; it selects food producers or traders that have the capacity to safeguard food safety of the event, and urge the producer/trader to fulfill their food safety obligations.
The producers or traders supplying foods for major events shall be the primary responsible person for food safety; it shall formulate food safety protection plans and emergency response plans, fulfill the requirements for whole-process food safety control.
County level FDA, health departments, agricultural authority, and quality authority shall follow the food safety protection plans to safeguard food safety of major events, strengthen food supplier review and food testing. If necessary, they could hire professionals to conduct the evaluation/testing.
Organizers of major events are encouraged to hire specialized organizations to protect food safety of major events.

Article 147 With the occurrence of one of the following circumstances, the higher level FDA could conduct unannounced inspections, and inspects work by the lower level FDAs:
(1) Food producers or traders are suspected of violating food safety laws and regulations, and may cause severe harm or serious social consequences;
(2) Food producers or traders have food safety risks, which may cause regional food safety risks, or may cause severe harm or serious social consequences;
(3) Receiving report or complaints by insiders about severe law violation or serious food safety risks by the food producers or traders;
(4) Other circumstances that are necessary to conduct unannounced inspection.
The unannounced inspections shall be conducted following random inspection principles and the procedure of on-site inspections.

Article 148 County and above level FDAs shall set up an agency to take food safety complaints, and publish the agency's telephone number for complaint/reporting; the county and above level FDAs shall establish the on-line complain/reporting information management system.
The agency shall collect and analyze the complaints/reports it receives, and put forward proposals to improve food safety oversight.

Article 149 CFDA and other relevant ministries shall develop the standards for food safety oversight capacity building; the standard shall clearly set goals/requirements for capacity building by FDA of various levels, enforcement officials, facilities and equipment.
County and above level municipal government shall include food safety inspections, sampling inspections, risk surveillance, administrative licensing, public education, and capacity building into its financial expenditure budget; they shall also secure special funds for emergency response, case investigation, awards for reporting, and safeguarding food safety for major events.

Article 150 CFDA and other ministries shall develop training outlines, while the provincial FDA are in charge of (training effect) appraisal.
Each year, each enforcement officials of FDA (and involving agencies) shall take food safety trainings for no less than 40 class hours, and pass examinations thereof; those fail in the examination shall not engage in food safety law enforcement work.

Article 151 County and above level FDA shall develop the annual food safety inspection plans, and determine frequency of investigation pursuant to grade of risks.

Food safety inspectors shall handle the violations pursuant to laws/regulations; they shall record the facts of investigation and the results. The inspection forms will be filed for records after the inspectors and the food producers or traders signing their names.
The inspection results will be posted at the inspected site, and published on-line.

Article 152 Entrusted by the municipal government, FDA could arrange accountability conversation with official-in-charge of the lower level municipal government that fail to perform its duty, or fail to eliminate severe food safety risks in the region.

Article 153 CFDA, NHFPC, MOA, and the AQSIQ shall strengthen food safety information system; they shall establish the unified food safety information platform, which would consolidate the food safety information resources for use of all stakeholders.

Article 154 CFDA shall formulate and publish national food safety situation report each year.

Article 155 China establishes food safety statistical research mechanism; CFDA and the National Bureau of Statistics will create the food safety statistics index system, and will jointly conduct food safety related statistical work.
County and above level FDA shall work with statistics bureau of the same level to establish the regional food safety statistical working system and index system; they shall jointly conduct food safety related statistical work in the region.
Food producers, traders and industry associations shall assist the food safety statistical work by the food and drug administration.

Article 156 Investigating agency directly under the county and above level FDA could take enforcement measures (such as on-site inspection, sampling inspections, close the facility and detain products, as well as case investigation) in its own name.

Article 157 County and above level CFDA and the quality authority, upon noticing one of the following circumstances, shall transfer the clues and evidences to the public security bureau within three working days:

1. Producing foods with non-food-use raw material, adding chemical substances other than food additives or other substances which may harm human health, or using recycled foods to produce food products;

(2) Producing staple and supplementary foods for babies and other specific populations, but the product's nutritional ingredients fail to comply with food safety standards;
(3) Selling meat or meat products from poultry, livestock, animals, or aquatic animals that die from disease, poison, or any unidentified causes;
(4) Selling meat or meat products that have not been inspected and quarantined, or fail to pass such inspections and quarantines;
(5) Producing or selling foods that are prohibited to be produced or traded for special purposes, such as disease prevention;
(6) Producing or distributing food containing medicine.
(7) Producing or distributing food or food additives which exceed that contain excessive amount of

contaminants (pathogenic microorganisms, pesticide residues, vet drug residues, biotoxins, heavy metals) and other substances that may harm health;
(8) Other activities that are suspected to violate the food safety law.
The public security bureau shall conduct preliminary investigation by taking such measures including inquiry, appraisal, requesting the delivery of evidence and materials.
For the suspected crimes, the public security bureau shall file the case for prosecutor investigation pursuant to laws; activities not constituting crimes shall be punished by the administrative authorities pursuant to relevant laws and regulations.

Article 158 County and above level municipal governments shall establish and improve the convergence mechanism between the administrative law enforcement and the criminal investigations, which shall responsibility of the administrative authority and the public security bureau in clue notification, case transfer, case consultation, information sharing, information release, etc.; the mechanism will facilitate coordinated work in food safety crime investigation.

Article 159 CFDA and the Ministry of Justice shall formulate measures for food safety judicial authentication, which will clarify qualifications of the judicial authentication institutes; the two ministries will formulate the lists of food safety judicial authentication institutes and authenticators. The institutes or authenticators entrusted to conduct food safety judicial authentication shall be selected from the lists.

Article 160 In law enforcement, with the occurrence of one of the following circumstances, the food and drug administration and the quality authority could ask the public security bureau to provide necessary assistance, the latter shall follow the request:
(1) Violent confrontation against food safety law enforcement or causing mass disturbances;
(2) The person concerned refuse to cooperate in investigation; he/she obstruct, or harass food safety law enforcement;
(3) The person concerned destroys/hides evidence, or escapes;
(4) The enforcement officials need assistance to obtain evidence for hard and complicated cases;
(5) Other circumstances provided by laws and/or regulations.

Article 161 In criminal case investigations involving food safety, the public security bureau could ask the food safety administration and the quality authority to provide necessary technical support and information verification, the latter shall provide such assistance.

Article 162 For cases transferred by the food and drug administration, the quality authority, or the agricultural authority, the public security bureau shall review the case within three working days.
The public security bureau shall immediately start reviewing the transferred cases if the violation activity involves serious harm to human health, such as illegal adding non-food-use substances, illegal adding medicine to foods, producing/selling poultry/livestock die from diseases;

Article 163 The food and drug administration, the quality authority, or the agricultural authority shall strengthen communication and coordination with the public security bureaus, and establish the convergence mechanism between administrative evidence and criminal evidences.
Before transferring evidences to the public security bureau, the food and drug administration, the quality authority, or the agricultural authority could keep electronic data, copy of the paper evidences (with the

FDA's official stamp); the kept evidences could be used as evidence for administrative punishment. After verification, the public security bureau could use the evidence transferred by the food and drug administration, the quality authority, or the agricultural authority in criminal investigation. .

Article 164 Finding no *corpus delicti*, or minor *corpus delicti* in food safety violation activities that only deserve administrative liabilities, the public security bureau could transfer the cases to the food and drug administration, the quality authority, or the agricultural authority in a timely manner.
Along with the case, the public security bureau shall transfer copy of the evidences (with official stamp) to the food and drug administration, the quality authority, or the agricultural authority. The latter, after reviewing the case, could use the transferred evidence as evidence in their law enforcement.

Article 165 For cases that have already been ruled by the people's court but are pending for administrative punishment by the food and drug administration/the quality authority/ the agricultural authority, the latter shall verify the case and make administrative punishments (such as revoking license) pursuant to the facts and evidence in the court's verdict.

Article 166 The dispatched food safety offices could conduct inspections and give administrative guide in its own name in its administrative area.
The dispatched food safety offices could make warnings and impose fines of less than 5,000 Yuan in its own name.
With approval of the county and above level FDA, the dispatched food safety offices could take compulsory administrative measures (such as closing business and detaining goods) to food producers or traders that violate the laws/regulations to control food safety risks.

Chapter 9: Legal Liabilities

Article 167 Discovering food producers or traders that continue operation after their production licensing is revoked/nullified/expired, or their administrative license is revoked or withdrawn, the county and above level FDA could impose administrative punishment pursuant to Article 122.1 of the Food Safety Law.

Article 168 With the occurrence of one of the following circumstances that has not yet constitute crime, the county and above level FDA could impose administrative punishment pursuant to the "serious cases" as provided in Article 123.1 of the Food Safety Law:
(1) Producing food with non-food-use raw material, adding in foods chemicals other than food additives, or adding other substances which may possibly harm human health, or producing food produced from recycled food as raw material, or selling these products; total value of the products exceeds 1,000 Yuan, or the company had administrative punishment for food safety violation in the past one year;
(2) Producing or distributing staple and supplementary food for infants or other specific populations and the product's nutritional ingredients fail to comply with food safety standards; total value of the products exceeds 1000 Yuan, or the company had administrative punishment for food safety violation in the past one year;
(3) Distributing meat or meat products of poultry, livestock, animals, or aquatic animals that die from

disease, poison, or any unidentified causes, or producing or distributing products derived from them; total value of the products exceeds 1000 Yuan, or the company had administrative punishment for food safety violation in the past one year;
(4) Distributing meat which have not been quarantined or inspected, or producing or distributing meat or meat products which fail to pass such quarantine or inspection; total value of the products exceeds 1000 Yuan, or the company had administrative punishment for food safety violation in the past one year;
(5) Producing or distributing food expressly prohibited from being produced or traded by the State for disease prevention and control purposes; total value of the products exceeds 1000 Yuan, or the company had administrative punishment for food safety violation in the past one year;
(6) Producing or distributing food containing added medicine; total value of the products exceeds 1000 Yuan, or the company had administrative punishment for food safety violation in the past one year;
(7) Other circumstances provided by laws and regulations.
Article 169 With the occurrence of one of the following circumstances that has not yet constitute crime, the county and above level FDA could impose administrative punishment pursuant to Article 123.1 of the Food Safety Law:
(1) Using non-food-use substances in food producing/trading/storage and transportation;
(2) Producing food and food additives with waste/recycled food additive;
(3) Using substances that may cause harm to human health in product treatment, such as immersion or fumigation;
(4) Procuring and storing non-food-use chemical substances in food producing/trading, procurement, or storage, which are clearly prohibited by the relevant government agencies;
(5) Using non-food-use chemical substances to substitute food additives;
(6) Illegally adding medicine, chemicals other than food additives, or other substances that may possibly harm human health in food additives;
(7) Using non-food-use detergent or disinfectants to clean and sterilize containers and tools for food producing/trading;
(8) Other circumstances provided by laws and regulations.
Pursuant to Section 1 of this article, the county and above level agricultural authority will would impose administrative punishments to producers that use banned pesticides or vet drugs in edible agricultural products growing or breeding.
Article 170 With the occurrence of one of the following circumstances, CFDA will revoke the special food registration certificate:
(1) Producing special foods with non-food-use raw material, adding chemicals other than food additives or other substances which may possibly harm human health in the special foods;
(2) Adding medicine in special foods production;
(3) Producing special foods not following the registered product formula or production techniques; total value between 10,000 and 20,000 Yuan;
(4) Producing infant formula milk powder through sub-packaging, or the same enterprise using the same formula to produce health foods/ foods for special medical purposes/infant formula powder under different brands; total value between 10,000 and 20,000 Yuan;
(5) Other circumstances provided by laws and regulations.
Article 171 with the occurrence of one of the following circumstances that has not yet constitute crime, county and above level FDA could impose administrative punishment pursuant to the “serious cases” as provided in Article 124.1 of the Food Safety Law:
(1) Producing or distributing food or food additives two times the food safety standard limits in content

of pathogenic microorganisms, pesticide residues, vet drug residues, biotoxins, heavy metal contaminants, and other substances which may possibly harm human health, or total value of the product exceeds 30,000 Yuan;
(2) Producing or distributing food or food additives produced with expired raw materials or food additives, or trading such foods or food additives; total value of the product exceeds 30,000 Yuan;
(3) Producing or distributing food with excessive use of food additives (in scope or in amount), total value of the product exceeds 30,000 Yuan;
(4) Producing or distributing foods or food additives which is rotten or spoiled, has rancid fat, mold or insects, is dirty or contaminated, contains foreign matters, has been adulterated, or displays abnormal sensory indication; total value of the product exceeds 30,000 Yuan;
(5) Producing or distributing food or food additives with a false production date or shelf life, or exceeding the shelf life; total value of the product exceeds 30,000 Yuan;
(6) Producing or distributing health foods, foods for special medical purposes, infant formula powder that have not been registered or fail to organize their production according to the registered formula and production techniques; total value of the product exceeds 20,000 Yuan;
(7) Producing infant formula milk powder through sub-packaging, or the same enterprise using the same formula to produce infant formula powder under different brands; total value of the product exceeds 20,000 Yuan;
(8) Producing foods with new raw materials or new food additives that have not passed safety assessment; total value of the product exceeds 30,000 Yuan;
(9) Food producers or traders refuse to recall or stop operations when the food and drug administration orders a recall or cease of operation;
(10) Causing consequences such as serious food poisoning and food-borne diseases;
(11) Food producers or traders continue production or trading after the food and drug administration demands it take corrective measures and suspend operation;
(12) Target at special groups of persons, such as disabled people, senior-aged people, pregnant women, children, or at patients covered by the social medical insurance who suffer from serious diseases.

Article 172 With the occurrence of one of the following circumstances that has not yet constitute crime, the county and above level FDA could impose administrative punishment pursuant to Article 124.1 of the Food Safety Law:
(1) Food producers or traders fail to suspend production/trading or recall problematic foods as required when risk surveillance results show potential food safety risks during re-testing or verification of truthfulness;
(2) Fail to fulfill obligations provided in the Food Safety Law and relevant regulations, causing food safety incidents;
(3) Infant formula powder producers violating provisions of the Article 92 of the Implementing Rules;
(4) Food producers or traders fail to recall unsafety foods within set deadline;
(5) Import food traders cannot provide phytosanitary certificate or quarantine certificates, Chinese label, and inspection mark;
(6) Producers of special food fail to update registration or production license when its production condition/production techniques change;
(7) Producing general foods with materials that could only be used for health food production;
(8) Other circumstances provided by laws and regulations.

Article 173 With the occurrence of one of the following circumstances, the county and above level

FDA could impose administrative punishment pursuant to the "serious cases" as provided in Article 125.1 of the Food Safety Law:
(1) Producing or distributing food or food additives contaminated by the packaging materials, container, or transport means; total value of the product exceeds 20,000 Yuan;
(2) Producing or distributing pre-packaged food or food additives without a label, or food or food additive's labels or instructions are not in compliance with the food safety law and regulations; total value of the product exceeds 30,000 Yuan;
(3) Producing or distributing genetically modified foods that have not been labelled as required; total value of the product exceeds 30,000 Yuan;
(4) Food producers or traders purchasing or using food materials, food additives, or food related products which are not in compliance with food safety standards; total value of the product exceeds 20,000 Yuan;
(5) Other circumstances provided by laws and regulations.

Article 174 With the occurrence of one of the following circumstances, the county and above level FDA could impose administrative punishment pursuant to Article 125.1 of the Food Safety Law:
(1) Using fake, exaggerating, misleading language or pictures in product label and descriptions;
(2) Label medicines as food products, or label foods as health foods, or claim the food has medicine or health food functions;
(3) Fake product execution standard, ingredient table, and other mandatory contents on product labels;
(4) Fail to label food additive that shall be labeled, or the labeling method is incompliance with food safety laws/regulations/standards.

Article 175 With the occurrence of one of the following circumstances, the county and above level FDA could impose administrative punishment pursuant to the "serious cases" as provided in Article 126.1 of the Food Safety Law:
(1) Producers of food or food additives fail to test the purchased food materials, produced food and food additives; total value of the products that fail to comply with food safety standards exceeds 30,000 Yuan;
(2) Food producers or traders fail to establish the food safety management system as required, or fail to properly equip, train, or assess food safety managers, and causing food safety incident that involves 10 to 30 people;
(3) Food or food additive producers or traders fail to inspect the license and relevant certificate upon purchasing, or fail to establish and abide by purchasing inspection records, ex-factory inspection records and sales record systems as required; total value of the products that fail to comply with food safety standards exceeds 30,000 Yuan;
(4) Food producers or distributors fail to formulate an emergency food safety incident plan, and causing food safety incident that involves 10 to 30 people;
(5) Tableware and containers which contain food for direct consumption are not cleaned, sterilized before use, or the cleaning or sterilization is not qualified, or catering service facilities or equipment are not regularly maintained, cleaned, and checked; causing food safety incident that involves 10 to 30 people;
(6) Food producers or traders contract any person who has not obtained a health certificate or has developed diseases which endanger food safety as prescribed by the NHFPC for any operation that requires contact with food for direct consumption, and causing food safety incident that involves 10 to 30 people;

(7) Food distributors fail to distribute food as required, and causing food safety incident that involves 10 to 30 people;
(8) Producers of health food fail to file with the CFDA for record, or fail to produce products according to the filed technical requirements, such as product formula or production process; total value of the products exceeds 30,000 Yuan;
(9) Producers of infant formula fail to file the food raw materials, food additives, product formula, and labels with the CFDA; total value of the products exceeds 20,000 Yuan;
(10) Producers of special food fail to establish the production quality management system and maintain its effective operation as required, total value of the products exceeds 30,000 Yuan; or fail to regularly submit a self-inspection report;
(11) Food producers or distributors fail to carry out self-inspection assessments of food safety, or fail to deal with any change in production or distribution conditions; total value of the products exceeds 30,000 Yuan;
(12) Schools, kindergartens, nursing homes and construction fields that have a centralized cafeteria fail to perform their management responsibilities of food safety, and causing food safety incident;
(13) Food producers and catering service providers fail to formulate and implement process control over production and distribution, and causing food safety incident that involves 10 to 30 people;
(14) Other circumstances provided by laws and regulations.

Article 176 With the occurrence of one of the following circumstances, the county and above level FDA could impose administrative punishment pursuant to Article 126.1 of the Food Safety Law:
(1) Staffs of food producers or traders fail to wear clean working outfit and cap; or fail to use sterilized and clean containers, vending tools, and equipment to take unpackaged foods for direct consumption;
(2) Food producers or traders fail to establish the mechanism and records for food additive use;
(3) Catering service providers use tableware that are not cleaned or sterilized; or fail to request for sterilization compliance certificate from the centralized sterilization service providers;

Article 177 With the occurrence of one of the following circumstances, the centralized tableware sterilization service providers will be punished by the county and above level health departments pursuant to provisions of the Article 126.1 of the Food Safety Law:
(1) Fail to establish the position of hygienic manager, the hygienic management system, or the hygienic management files;
(2) fail to follow relevant hygienic regulations in production;
(3) Sampling inspection results show the tableware are not properly cleaned/sterilized;

Article 178 With the occurrence of one of the following circumstances, the county and above level FDA will issue warnings and instruct food producers or traders to take corrective measures; rejection to take corrective measures will result in fines between 5,000 to 50,000 Yuan:
(1) Food traders fail to set up protective facilities (such as dust-prevision or fly control tools); product package and label do not comply with food safety requirements;
(2) Food traders and edible agricultural product traders fail to separately display fresh and cooked foods, which may cause cross contamination of foods;
(3) The food storage service providers fail to keep copies of the client's ID, license, and business license;
(4) Food producers or traders fail to establish the food traceability system, unable to trace problematic foods;

(5) Third-party on-line platform providers, operators of the wholesale market, food counter leasers and food exhibition organizers fail to establish the food safety incident handling plan;
(6) Food materials, half finished products, containers holding finished products, or packaging materials are placed directly on floor or directly contact dirty stuffs;
(7) Quality of self-supplied water do not comply with national hygienic standard for drinking water;
(8) Catering service providers do not have equipment for cleaning/sterilization tableware;
(9) Detergents and disinfectants used in food producing and trading do not comply with relevant requirements;

Article 179 Finding food products comply with food safety standards but do not comply with company standards marked on product labels, the food and drug administration could instruct the food producers or traders to take corrective measures. The food producers or traders shall perform relevant civil responsibilities when consumers request to return the product and demand compensation.

Article 180 With the occurrence of one of the following circumstances, the county and above level FDA could impose punishment to the third-party platform providers pursuant to Article 131.1 of the Food Safety Law:
(1) The third party platform provider of online food trader fails to provide information, such as registration information of the food/food additive trader and their trading data;
(2) Without authorization, the third party platform provider transfer, change, fake, or remove the trading data of the admitted food and food additive distributors.

Article 181 Food producers or traders illegally dispose the FDA sealed or detained products in forms of hiding/moving/using/selling/destroying the products, the county level FDA could confiscate their illegal gains, and concurrently impose a fine of 10 to 20 times the value of the hidden/moved/sold/destroyed products, revoke their licensing; the behavior is subject to criminal prosecution if it constitutes crime.

Article 182 "Refuses, impedes, or intervenes" mentioned in Article 133.1 of the Food Safety Law include the following circumstances:
(1) Delay and evade on-site inspection and investigation by enforcement officials;
(2) Refusing the enforcement officials to enter the production/trading/storage venue for over an hour;
(3) Refuse to provide contract, bills, accounting books and electronic data as required;
(4) Other circumstances provided by laws and regulations.

Article 183 With the occurrence of one of the following circumstances, the competent authority could impose punishment pursuant to their jurisdictions and according to provisions of the "serious cases" as provided in Article 133.1 of the Food Safety Law:
(1) Refuses, impedes, or intervenes food safety enforcement in forms of beating, harassing, cursing, and threatening enforcement officials;
(2) Destroy or hide evidence, or escape of the persons involve;
(3) Take revenge actions to the reporter or witness;

Article 184 While imposing punitive measures pursuant to Article 135.1 and 135.2, Article 137, Article 138.2, Article 139.1, CFDA and AQSIQ shall compose the list of the direct principal in charge and other direct principals, and publish the lists (including such person's name and ID number) on its official website.

For an applications concealing or providing fake materials in applying for an administrative license, the competent administrative authority will not accept the application or reject the application after accepting it; the authority will issue a warning to the applicant, and the latter is not allowed to file application for the administrative license within a year;
For food producers or traders who obtained the administrative license by cheating or bribing, the competent authority shall impose administrative punishments; the applicant is not allowed to apply for the same administrative license in three years; the behavior is subject to criminal prosecution if it constitutes crime.

Article 185 Finding food producers or traders faking, changing the Food production license, product registration certificate, label and descriptions, inspection report, quarantine certificate, accreditation certificate, and providing fake materials in inspections, the county and above level FDA will confiscate the illegal benefits and impose the fine between 50,000 and 100,000; the food producers or traders, if holding the Food production license, will be revoked of their licensing; the behavior is subject to criminal prosecution if it constitutes crime.

Article 186 With the occurrence of one of the following circumstances, food producers or traders are subject to more severe punishment:
(1) The law violation behavior causes serious damages or causes serious social consequences;
(2) The law violation behavior causes systematic, regional food safety risks;
(3) Illegally produce and trade special foods;
(4) Had two food safety incidents of the general grade within one year; or had one incident higher than the "large" grade within one year;
(5) The food producer or trade is subjectively intentional or negligent;
(6) Other circumstances that shall subject to more severe punishment according to the law.
One behavior violating several terms of relevant laws and regulations are subject to more severe punishments.

Article 187 With the occurrence of one of the following circumstances, the food producers or traders are subject to lighter or mitigated punishment:
(1) The food producer or trader could provide evidence to prove it is not subjectively intentional or negligent, with minor violation, low product value and caused no harmful consequences;
(2) Proactively report to the food and drug administration, and did not cause harmful consequences;
(3) The food producer or trader proactively recalls unsafe food, causing no harmful consequences; and they have taken effective measures to mitigate or remove food safety risks;
(4) The food producer or trader report to the oversight authority other undiscovered violations, and cooperate in the investigation, and have meritorious performances;
(5) Other conditions that are subject to lighter or mitigated punishment
The authority will not impose administrative punishment if the violation is minor and corrected timely, causing no harmful consequences.

Article 188 Finding hospitals and their staffs fail to report food safety incident or CDC fail to make epidemiological investigation report as required or within given time, the county level health department shall instruct the hospital or CDC to take corrective measures; refuse to do so, the hospital/CDC is subject to a fine between 5000 Yuan to 50,000 Yuan.

Article 189 With the occurrence of one of the following circumstances, the county level advertisement authority will instruct the advertiser, advertisement operator and publisher to stop publishing the ad, make public correction, confiscate the revenue; if the revenue is lower than 10,000 Yuan, a fine of 50,000 will be imposed; if the advertisement revenue is over 10,000 Yuan, a fine of five times the revenue will be imposed; in addition, the provincial FDA could remove the products from the market temporarily, and make announcements. Finding the product is still available in market, the county and above level FDA will confiscate the illegal gains and the food/food additive, concurrently impose a fine between 20,000 Yuan to 50,000 Yuan:
(1) The ad has not yet been approved;
(2) The advertisement approval certificate has been revoked or cancelled;
(3) Relevant government authority has instructed termination of the product production or distribution;
(4) The ad fail to pass review of the provincial FDA where it is launched;
(5) Without authorization, change the ad that has been approved;;
(6) The ad contains content that is prohibited by laws or regulations.

Article 190 The county and above level FDA will confiscate illegal gains from selling health foods/foods for special medical purposes/food additive via fake, exaggerated and deceiving instructions in forms of telephone sale, workshops, conferences or organized tours, and imposes a fine between 50,000 Yuan to 200,000 Yuan; the act is subject to criminal prosecution if it constitutes crime.
Finding entities or individual person knowing the aforementioned illegal act but still providing venue or other conditions for those engaging in the illegal acts, the county and above level FDA will instruct the entity or individual person to stop such illegal acts, confiscate the illegal gains, and concurrently impose a fine of RMB 50,000 to RMB 100,000; if the lawful rights and interests of consumers are damaged, such person shall, together with the producers and traders of food and food additives, be held jointly and severally liable.

Article 191 Anyone who produce, import or sell special dosage food products with fixed amount consumption that have health function claim on product label or description, but do not register the product as health food are subject to investigation by the county and above level FDA pursuant to Article 124.1 of the Food Safety Law; suspected of crime, the case will be transferred to the public security bureau.

Article 192 Officials of the county level FDA, quality authority, agricultural authority, and health department who violate the law with intention or culpable negligence are subject to administrative liabilities by the supervisory authority or the personnel appointment and removal organization of the same level. The behavior is subject to criminal prosecution if it constitutes crime.
For food safety violations and food safety incidents caused by food producers or traders, relevant officials of the food and drug administration, the quality authority, the agricultural authority, and the health department shall be exempted of the administrative liability if evidence proves they have properly performed food safety oversight responsibilities.

Article 193 After issuing food recall notices, the food producers or traders are not subject to punitive compensation or the minimum compensation for the same foods purchased during the recall period as provided in the recall notice.
Food traders do not stop selling relevant products after receiving recall notices are subject to punishments pursuant to Article 124.1 of the Food Safety Law.

Article 194 For food producers or traders suspected of food safety crimes, the food and drug administration could impose administrative punishments to the food producer or trader (such as instructing the food producers or traders to stop production/trade, or revoking the company's license) while the crime investigation is in progress (during filing the case for investigation and prosecution, review and prosecution, and during trial).

Chapter 10: Supplementary Provisions

Article 195 Definition of the terminologies in the Implementing Rule:
Edible agricultural products: plant, animal, microorganisms and their products obtained in agricultural activities (such as growing, breeding, picking, fishing, facility agriculture, biological engineering), and products obtained through preliminary processing (such as sorting, peeling, shelling, smashing, washing, cutting, freezing, waxing, grading and packaging), which do not change the natural characteristics and chemical properties of the products.
Catering service: service activity that directly provide foods to consumers by real-time food producing or processing.
Food safety risk assessment: the scientific evaluation of potential adverse health effects caused by the biological, chemical and physical hazards in foods, food additives and food-related products; it include hazard identification, hazard characterization, exposure assessment, and risk characterization.
Food safety risk communication: the exchange of information and opinions about food safety risks, risk-related factors and risk awareness between interested parties in their work.
Health foods: a food with health function claims, or for supplementing nutrients (such as vitamins/minerals), for regulating body functions, not intend to cure diseases, containing specific functional ingredients, suit for special groups of persons, and with fixed amount consumption.
Unpackaged foods: foods that are not pre-packaged in fixed amount, and are sold after weighing; unpackaged foods include foods without package or foods in non-fixed-amount package.
Special dosage food products with fixed amount consumption: foods in special dosage forms, such as capsule, oral agent, tablet, granules, and pills; such foods shall be consumed at fixed amount, or has daily intake volume.
Sub-packaging: refers to the food producers or traders' act to divide foods in large package to smaller and fixed amount packages through certain technical process, which do not affect safety of the product. In food trading, dividing large package foods to pieces but not processing the foods to pre-packaged products is not categorized as sub-packaging.
Health food imported for the first time: health foods not from the same country, same company, or the same formula.
Fast testing method: the testing methods used in food safety-related items; the methods are fast, simple and sensitive.
Food safety technical staffs: staffs with academic or practical background in food safety related natural sciences, such as food science, biology, chemistry, and has knowledge about the medical science, etc., and understand the food's biological/chemical/physical properties. The staffs knows about the food production techniques and features of the production facilities/equipment; they are clear about sources of food contaminations and requirements for food safety risk control and food safety inspection technologies; they are the professionals who could detect and control relevant food safety risks.

Toxic and harmful non-food-use materials: the substances prohibited by laws and regulations to be added or used in food production and trading; relevant ministries under the State Council would publish the "List of Non-food-use Substances that Maybe Illegally Added in Foods" and the "List of Substances that Maybe Illegally Added in Health Foods"; such materials also include prohibited pesticide, vet drug or other poisonous and harmful and substances that may harm human health.
Flaw of food and food additive label and descriptions: incompliance of food and food additive labels and descriptions that are not related food safety or core content. Such flaws include space between words, size of the font, punctuation, simplified/complex form of the Chinese characters, rounding intervals, etc. such flaws do not have impact on food safety, and would not mislead food consumption.
Product value: total market price value of the foods, food additives and food-related products illegally produced or traded, or total market price value of the edible agricultural products illegally traded. The value of materials and food additives are calculated as the purchase price; the half-finished products are calculated by material price plus other costs; the finished products are calculated at the distribution price. Price of the individual produced product shall be calculated by the quoted price; price of the individual traded product shall be calculated as the price shown on the price tag. Lacking the price quotation/price tag in food production and trading, the product price is the average retail price of the product in the region at the time the investigation is in process.
Illegal gains refer to the total trading income of the violation activities. The purchase price of traded products or materials could be deducted in calculating illegal gains of food producers or traders that have fully performed legal obligations (such as inspection of purchased materials and requested credentials), did violate laws, and have evidence that they are unaware of the purchased foods/traded foods do not comply with relevant foods safety standards, and there is no harmful consequences.

Article 196 "Record filing" in the Implementing Rules refer to the process the Administrative Counterpart submit relevant materials to the competent authority for registration, filing, publishing and keeping on file for reference.
To file the company standard for record, and record filing of health foods, infant formula foods, relevant authorities shall not turn such process to *de facto* administrative licensing process by introducing the process of evaluation, qualification affirmation, approving, etc.

Article 197 If the Implementing rules do not have clear provisions on food additives, the oversight of food additives could refer to the Implementing Rules' provisions for foods.

Article 198 The border/port in the Implementing Rules refer to the international gateways for personnel, luggage, cargoes, containers, transportation vehicles, articles and parcels to enter or exit a country; it is also the entity and area that provides services to personnel, luggage, cargoes, containers, transportation vehicles, articles and parcels.
The food safety oversight in areas other than the border/ports (such as ports, airports, railway/bus stations, land border and border rivers) shall be performed by the food and drug administration.

Article 199 For registration of special foods, the applicants need to pay technical review fee and inspection certificate fee for registration of health foods, foods for special medical purposes, and formula of infant formula powder products; the standard for application fee will be jointly determined by the Ministry of Finance, the National Development and Reform Commission (the pricing authority) and the CFDA.
Article 200 The Implementing Rules will come into force on xxxx (date).

[1] Translator's note: "Above-scale enterprise" is a statistical term, which varies from industry to industry; the "scale" is determined by the enterprise's annual output value and revenue. The National Statistics Bureau only considers the above-scale enterprises in its statistical analysis.

END TRANSLATION