

**Implementation Rules of Food Safety Law of the People’s Republic of  
China  
(Revised draft for comment)  
China Food and Drug Administrative  
(December 9, 2015)**

**Chapter 1 General Provisions**

Article 1 The Implementation Rules of Food Safety Law of the People’s Republic of China (hereinafter referred to as “the Rules”) are promulgated in accordance with the Food Safety Law of the People’s Republic of China (hereinafter referred to as the “Food Safety Law”).

Article 2 Food producers and traders shall conduct production and trading activities according to laws, regulations and food safety standards, take effective measures to prevent and control food safety risks, and guard against and reduce food safety hazards to ensure food safety.

Article 3 The food safety commission under the State Council shall be responsible for discussing & laying out and planning & directing the national food safety work, formulating national food safety strategies, putting forward major food safety policies and measures, analyzing and solving significant food safety problems and supervising & urging the implementation of food safety responsibilities.

The executive office of the food safety commission under the State Council shall undertake the daily work of the committee, organize the preparation of the national food safety plans, coordinate the addressing of significant problems found in the formulation and implementation of food safety laws, regulations and standards, supervise & urge and inspect the implementation of major decisive arrangements concerning national food safety, evaluate and assess the fulfillment of food safety-related responsibilities by the People’s Governments at province level and the relevant departments under the State Council and direct the handling of major food safety accidents.

Article 4 The local People’s Government at or above the county level shall bear the localized management responsibility for the food safety within its own administrative region, improve the food safety supervision and administration systems and mechanisms, strengthen the construction of food safety governance systems and governance abilities, guarantee the implementation of food safety regulators, funds and technical supports, etc. and shoulder the responsibility for regional food safety risks and major food safety accidents occurred.

The responsibilities of food safety commission and its executive office under local People’s Government at or above the county level shall be determined by local People’s Governments at different levels with reference

to the responsibilities of food safety commission and its executive office under the State Council.

Article 5 The food and drug administrative department under the People's Government at county level can in accordance with the regional area, population size and supervised object, etc., within the region under its administration, establish resident agencies for supervision and administration of food and drug in villages and towns or in specific regions, and perform corresponding responsibilities pursuant to the law.

Article 6 The People's Government and sub-district office at township level shall be responsible for works such as troubleshooting hidden dangers to food safety, reporting information, assisting law enforcement and conducting propaganda & education within its own administrative region, and take effective measures to strengthen the food safety administration.

The People's Government and sub-district office at township level shall support the resident agencies for supervision and administration of food and drug to carry out the supervision and administration works pursuant to the law.

The People's Government and sub-district office at township level shall establish the teams such as food safety coordinators or informers, etc., to assist the food and drug administrative department to effectively perform food safety works.

Article 7 The State has incorporated food safety knowledge into the curriculums of national quality-oriented education and primary and secondary school education, to strengthen the popularization of scientific elementary knowledge and legal knowledge associated with food safety and improve the food safety consciousness of the whole society.

Article 8 The People's Government at or above the county level shall establish special projects and funds for food safety awards to grant commendations and rewards to those entities and individuals that have made conspicuous achievements in the works such as food safety risk monitoring and assessment, standard formulation, supervision and inspection, security ensuring of important activities, emergency handling and case investigation and treatment as well as scientific research, propaganda & education and social co-governance, etc.

## **Chapter 2 Food Safety Risk Monitoring and Assessment**

Article 9 The health administrative department under the State Council shall, in conjunction with food and drug administrative, quality supervisory and agriculture administrative departments, etc., under the State Council, prepare and publish the national food safety risk monitoring plan.

The health administrative departments of provinces, autonomous regions and municipalities shall report the local food safety risk monitoring plan to the health administrative department under the State Council for record-

filing. The health administrative department under the State Council shall notify food and drug administrative, quality supervisory and agriculture administrative departments, etc., under the State Council, of the information on record-filing.

Article 10 The national food safety risk monitoring plan shall take the following foods without available food safety standards currently and their related harmful factors as key monitored objects:

- (1) Those with high level of risks, wide sphere of circulation and large amount of consumption;
- (2) Those liable to affect the health of infants and young children and other specific populations;
- (3) Those with many problems reflected or complained by consumers;
- (4) Those having caused food safety accidents at abroad.

The supervision and sampling inspection of foods with available food safety standards currently shall be performed by food and drug administrative, quality supervisory and agriculture administrative departments, etc. The health administrative department under the State Council shall perform tracking evaluation and revision on the national food safety standards in a timely manner, according to the results of food safety risk monitoring and supervision & sampling inspection.

Article 11 The health administrative, food and drug administrative, quality supervisory and agriculture administrative departments, etc., under the State Council shall carry out the food safety risk monitoring work within the scope of their respective responsibilities, according to the national food safety risk monitoring plan.

The health administrative department under the State Council shall be responsible for organizing and carrying out the risk-based monitoring of foodborne diseases, food contamination and harmful factors in foods; the food and drug administrative department under the State Council shall be responsible for organizing and carrying out the risk-based monitoring of harmful factors in food production and sales, catering services and other links; the quality supervisory department under the State Council shall be responsible for organizing and carrying out the risk-based monitoring of harmful factors in food related products and import and export foods; the agriculture administrative department under the State Council shall be responsible for organizing and carrying out the risk-based monitoring of pesticides, veterinary drug residues and other contaminants in the planting and breeding of edible agricultural products; the grain department under the State Council shall be responsible for organizing and carrying out the risk-based monitoring of heavy metals and other contaminants in unprocessed (raw) grains.

Relevant departments shall organize the consultation of the problems found in the food risk monitoring respectively undertaken by them and take effective measures to prevent and control food safety risks.

Article 12 The health administrative, food and drug administrative, quality supervisory and agriculture administrative departments, etc., shall make full use of the technical institutions and social third-party technical institutions with corresponding abilities to conduct the food safety risk monitoring work.

The technical institutions undertaking the food safety risk monitoring work shall conduct the work according to the food safety risk monitoring plan, monitoring program and work specifications, to ensure the trueness, accuracy and completeness of the monitoring data.

Article 13 The health administrative department under the People's Government at province level shall, in conjunction with food and drug administrative, quality supervisory and agriculture administrative departments etc., at the same level, establish the notification and consultation mechanisms of national food safety risk monitoring data, summarize and analyze the risk monitoring data, study and judge food safety risks, form the monthly, quarterly, half-year and annual analysis reports on food safety risk monitoring and report to the People's Government at province level and health administrative, food and drug administrative, quality supervisory and agriculture administrative departments, etc., under the State Council within 7 working days. In case of finding the possible existence of high food safety risks, they shall be reported within 2 working days.

Article 14 In case that the health administrative departments find the possible existence of the food safety hidden dangers during the food safety risk monitoring work, they shall carry out food safety risk assessment in a timely manner; in case of finding the existence of illegal activities involving food production and trading, they shall notify the food and drug administrative department, etc.

In case of finding that the food safety risk assessment is required to be conducted during the food safety investigation work, food and drug administrative department, etc., shall notify the health administrative department in a timely manner and the health administrative department shall timely conduct food safety risk assessment and notify the assessment results to the food and drug administrative department, etc.

Article 15 In case that the results of food safety risk monitoring show the existence of food safety risks, the food and drug administrative department can inform relevant food producers and traders according to the needs of risk control. Food producers and traders shall immediately take measures to troubleshoot risks, suspend the production, sales and use of products involved, recall the foods with food safety hidden dangers and report to the local food and drug administrative department at or above county level where it is located in a timely manner.

Article 16 The risk monitoring and risk assessment of the quality and safety of edible agricultural products shall be carried out by the agriculture administrative department under the People's Government at or above county level, in conjunction with health administrative and food and drug administrative departments, etc., at the same level.

Article 17 The health administrative department under the State Council shall, in conjunction with food and drug administrative department, etc., under the State Council, prepare the food safety risk assessment work plan, establish and manage the basic database for national food safety risk assessment, and organize and carry out the works such as collection of basic data on food safety risk assessment and method study, etc.

The health administrative, food and drug administrative, quality supervisory and agriculture administrative departments, etc., under the State Council, shall establish an information exchange mechanism of food safety risk assessment and share risk assessment data and information.

The national food safety risk assessment institutions are encouraged to entrust the technical institutions with corresponding abilities to undertake the task of national food safety risk assessment.

Article 18 The committee of experts for national food safety risk assessment shall be set up and managed by the health administrative department under the State Council, in conjunction with food and drug administrative, quality supervisory and agriculture administrative departments, etc., under the State Council.

The committee of experts for national food safety risk assessment shall be responsible for formulating the technical methods and requirements for food safety risk assessment, examining and approving the report of the food safety risk assessment results and explaining and communicating food safety risk assessment results.

Article 19 In case that food and drug administrative, quality supervisory and agriculture administrative departments etc., under the State Council, find that the safety of pesticides, fertilizers, veterinary drugs, feeds and feed additives, etc., is required to be assessed during the supervision and administration work, they shall put forward the suggestion for risk assessment to the committee of experts for national agricultural product safety risk assessment, and the committee of experts for national agricultural product safety risk assessment shall timely conduct risk assessment and in a timely the assessment results to the relevant departments under the State Council.

The safety assessment of pesticides, fertilizers, veterinary drugs, feeds and feed additives, etc., shall be carried out by relevant review committee, in conjunction with committee of experts for national food safety risk assessment.

- Article 20 The health administrative department under the State Council shall according to the needs of food safety risk assessment work, organize and carry out surveys to collect basic data such as status on food consumption, environmental factors affecting food safety, total dietary study and degree of public cognition, etc.
- Article 21 The food and drug administrative department under the People's Government at or above province level shall, in conjunction with relevant departments at the same level, conduct comprehensive evaluation according to the supervision and administration information and public opinion information such as food safety risk monitoring, risk assessment, daily supervision, supervision and sampling inspection, case investigating and handling, and specific rectification, etc. and shall timely publish food safety risk warning information according to their responsibilities, as for foods considered to possibly carry high safety risks upon evaluation.
- Article 22 The State shall establish food safety risk communication system. The food safety risk communication work shall achieve scientificity & objectivity, openness & transparency, promptness & effectiveness, multi-participation and communication & negotiation.
- The State encourages food producers and traders, food safety related technical institutions, food-related industrial associations, consumers' associations and news media, etc., to participate in the food safety risk communication work and promote social co-governance of food safety.
- Article 23 The food and drug administrative department and other relevant departments under the State Council shall formulate the work specifications for food safety risk communication, establish a food safety risk communication mechanism and direct the local departments to conduct food safety risk communication work.
- Article 24 The food and drug administrative department and other relevant departments under the State Council shall establish the advisory committee for food safety risk communication composed of experts from fields such as food, public health, clinical medicine and news communication, etc., to provide consulting advices for food safety risk communication, and participate in risk communication. The advisory committee for food safety risk communication can solicit opinions relating to items concerning risk communication from social organizations, food producers and traders, consumers, news media and other aspects and invite representatives of relevant aspects to participate in risk communication work, as needed.

### **Chapter 3 Food Safety Standard**

- Article 25 The health administrative department under the State Council shall, in conjunction with in conjunction with food and drug administrative, quality supervisory and agriculture administrative departments, etc., under the State Council, make the planning of national food safety standards and the annual

implementation plan thereof, for which the opinions shall be gathered from the public.

Article 26 The health administrative department under the State Council shall, in conjunction with food and drug administrative department under the State Council, organize National Food Safety Standard Evaluation Committee to formulate the measures for administration of food safety standards and organize the project approval, draft, review and promulgation of national food safety standards.

The health administrative department under the State Council shall, in conjunction with food and drug administrative department, select the entities with corresponding technical capabilities to draft the national food safety standards.

It shall encourage the research institutions, technical institutions, academic groups, industrial associations and other entities to jointly draft the national food safety standards.

Article 27 The health administrative department under the State Council shall, in conjunction with food and drug administrative department, speed up the formulation of national food safety standards concerning food additive on its variety, application scope and amount in catering services and national food safety standards urgently needed in food safety supervision and law enforcement.

Article 28 The health administrative departments of the People's Governments of provinces, autonomous regions and municipalities shall, in conjunction with food and drug administrative department at the same level, make the planning of local food safety standards and the implementation plan thereof, and organize the project approval, draft, review and promulgation of local food safety standards.

Such local food safety standards concerning health food, formula food for special medical purpose, formula food for infants and young children, food additives, food-related products and new food raw materials, etc., shall not be formulated.

Article 29 The health administrative departments of the People's Governments of provinces, autonomous regions and municipalities shall, within 30 working days after publishing of local food safety standards, report to the health administrative departments under the State Council for record-filing.

Where the health administrative departments under the State Council find the violations of food safety standards and national laws & regulations, it shall be corrected without delay.

Once a national food safety standard is developed, the corresponding local food safety standard would be eliminated. The health administrative department of the People's Governments of provinces, autonomous regions and municipalities shall timely publish its abolishment.

Article 30 Upon approval of enterprise legal representative or main person in charge, enterprise standards shall be implemented. The food production enterprise shall be responsible for such enterprise standard that has filed for record.

## **Chapter 4 Food Production and Trading**

### Section 1 General Provisions

Article 31 Food and drug administrative department under the State Council shall, according to the economic and social development level, production and trading scale, technical conditions, food safety requirements and other factors, develop management practices for food production and trading.

The food producers and traders shall, according to the management practices for food production and trading, carry out production and trading activities.

Article 32 Any food producer and trader and operator specializing in food transportation shall not, during production and trading process, purchase, use, store and transport such non-edible materials that are strictly forbidden by relevant authorities, and shall not process foods or food additives with the recalled food additives.

It is prohibited to illegally add medicine, chemical substances other than food additive raw materials and other substances that may endanger human health to food additives.

Article 33 Any enterprise specializing in production of semi-finished food products and extracts shall obtain a food production license according to law; while any enterprise specializing in sales of food by means of telephone, meetings and lectures, etc., shall obtain a food trading license according to law.

Any food producer obtaining a food production license shall not be required to obtain a food trading license in the case of sales of their products in its own production sites; any catering service provider obtaining a food trading license shall not be required to obtain a food production license in the case of sales of their self-made products in its own catering service site.

Article 34 In the event that food producers and traders entrust the production of foods and food additives, the entrusted party shall obtain a food production license and be responsible for its production behaviors, while the entrusting party shall undertake legal liabilities for the safety of foods that are entrusted for production.

For entrusted food production, both parties shall sign a written agreement, in which the respective rights and obligations concerning food safety of both sides are clearly defined.

Article 35 The health administrative department under the State Council shall, jointly with relevant departments, regularly collect and publish the new food raw material, new varieties of food additives, catalogue of new varieties for food-related products as well as the executive national food safety standards, and carry out tracking evaluation of safety.

- Article 36 The safety assessment materials concerning new food raw material, new varieties of food additives and food-related products that applicants submit to the health administrative department under the State Council shall include the essential supporting materials in technology of relevant industry organization, safety assessment opinion of specialized technical institutions as well as development of relevant standards and standard text, etc.
- Article 37 Such substances listed in the catalogue of substance traditionally considered as both food and Chinese medicine shall also meet the following requirements:
- (1) Have edible history in our country, and have not found any acute, sub-acute, chronic and other potential danger to human health;
  - (2) Have record of human consumption in ancient books and have not found record of toxicity;
  - (3) Have been listed in National Drug Standards;
  - (4) Maintain the sustainable development of related species resources, do not exert adverse impact on wild medicinal herb resource and ecological environment, and do not belong to wild animals and plants listed in the catalogues of wild animals under national priority protection and wild plants under national priority protection;
  - (5) Comply with requirements of relevant laws and regulations.
- Article 38 The food producers and traders shall record and keep such information as the purchase, production, processing, packaging, transportation, storage, marketing, inspection, recall and suspend operation, etc.; The records shall be true, accurate and complete, so as to realize the traceability of food.

## Section 2 Process Control of Production and Trading

- Article 39 The legal representative or main person in charge of food production and trading enterprises shall be fully responsible for the food safety work in the enterprise, establish and implement the food safety responsibility system.
- Article 40 The food safety management staffs shall assist the legal representative or main person in charge of food production and trading enterprises to undertake the food safety management responsibility.

The legal representative or main person in charge of food production and trading enterprises can authorize food safety management staffs to undertake the following food safety management responsibilities:

- (1) Be responsible for the management of supplier selection;
- (2) Be responsible for the management of incoming product inspection and food shipment inspection and for the truthfulness of record;
- (3) Organize and develop food safety enterprise self-inspection and be responsible for truthfulness of self-inspection report;

- (4) Supervise and implement the process control system for food production and trading;
- (5) Organize and implement the food recall;
- (6) Perform food safety incidents reporting duty;
- (7) Other obligations prescribed by the laws and regulations.

Article 41 The food safety management staffs shall be equipped with food safety laws and regulations, food safety standards, food safety professional knowledge and food safety management ability that are suitable for their positions.

The food and drug administrative department under the State Council shall develop the administrative measures for review of food safety management staffs in food production and trading enterprise.

Article 42 The food producers and traders shall carry out self-inspection and assessment on the food safety situation of their food products or entrust third-party professional organizations or professionals to conduct the testing.

Article 43 For food requiring irradiation, the food producers and traders shall entrust the unit with irradiation qualification to conduct irradiation and inspection in accordance with the relevant food irradiation standards.

The food producers and traders shall timely report the food processing situation of irradiation device unit and usage condition of irradiated food raw materials to the food and drug administrative department of local People's Government at the county level where it is located.

Article 44 The food producers and traders shall establish food safety information publicity system, and timely publish the information including food production and trading license, enterprise food standard, risk ranking identification, examination and inspection results, food recall, suspend operation, handling of unqualified food and other information to society.

Article 45 The food and drug administrative department of the People's Government at or above province level shall, according to food safety risk situation and food safety supervision and management requirements, popularize good manufacturing practice requirements in larger-scale food production and trading enterprise and food production and trading enterprises of meat products and dairy products, and implement the Hazard Analysis and Critical Control Point (HACCP) system.

Article 46 The producers of foods, food additives and food-related products shall, according to the food safety standards, conduct self-inspection or entrusted inspection to their produced foods, food additives and food-related products.

In the event that the food shelf life is less than the required deadline for routine inspection, the rapid detection method can be adopted.

Article 47 The food traders for the sales of health food, formula food for special medical purpose and formula food for infants and young children that are registered shall examine the product registration certificate, check whether

or not the content shown is consistent with the product labeling content, and keep the copy of registration certificate.

Article 48 The food producers and traders shall keep a register of foods, food additives, food-related products that have passed the shelf life and are spoiled or recalled, and store them in an explicitly labeled place for a timely destruction or removal of harm as well as keep relevant records.

Article 49 The food producers and traders who entrust warehousing & logistics enterprises for food storage and transportation shall conduct investigation to the entrusted enterprises' safety guarantee ability and strengthen the management of food safety.

Whoever engages in the food storage and transportation shall strengthen the management of food storage and transportation process, and ensure that conditions for food storage and transportation can meet the requirements of food safety.

Whoever is entrusted for food storage and transportation shall, according to relevant regulations, check and keep the following documents of entrusting party including the proof of identification, food production and trading license, copy of business license, qualified certification and inspection & quarantine certification, etc., and shall undertake the food safety responsibilities in the process of storage and transportation.

Article 50 The producers and traders of non-food products specializing in food storage and transportation shall, within 30 working days after obtaining the business license, report to the local food and drug administrative department at the county level where it is located for record-filing.

In the event that such information as complaints & reports and cases investigation indicates that producers and traders of non-food products have potential violations of food safety laws, regulations and national food safety standards in the food storage & transportation activities, the food and drug administrative department shall timely deal with them according to relevant laws.

Article 51 Where the food storage and transportation require temperature and humidity control, the heat preservation facilities and cold storage and refrigeration facilities shall be equipped and run with high efficiency.

The relevant departments of the People's Governments at or above the county level shall take effective measures to support the cold-chain transportation.

In the process of storage and transportation of edible agricultural products, non-edible chemical substances and other substances with potential harm to human health are not allowed to be added, and the food additive cannot be used beyond its scope and maximum limits.

Article 52 Records of food storage and transportation shall be kept for traceability.

For entrusted food storage and transportation, both parties shall sign a written agreement, in which the respective rights and obligations concerning food safety of both sides are clearly defined.

Article 53 Any catering service unit who adds food additives in their self-made foods shall publish the name, application scope and amount of food additives they use.

Article 54 In the event that catering service providers entrust the tableware and drink-ware disinfection service units for disinfection, both sides shall sign the entrustment contract, check and keep the following documents such as business license and qualified disinfection certificates, etc.

Article 55 The tableware and drink-ware disinfection service units shall set up full-time or part-time sanitary administrators, establish and improve the sanitation management system and documents thereof, and carry on the production and trading activities according to the requirements of hygienic practice.

Article 56 Any unit equipped with canteens such as schools, kindergartens, nursing institutions for the aged, medical institutions and construction sites shall carry on self-inspection to canteen food safety, check the hidden dangers & risks, and regularly submit self-inspection report to the food and drug administrative departments of the People's Government at the county level where it is located.

Any unit who contracts canteen to the other party shall, according to the requirements of laws and regulations, strengthen supervision and inspection, supervise and urge the contractor to implement the food safety management system. Both parties shall sign the written agreement, in which the respective rights and obligations concerning food safety of both sides are clearly defined.

Article 57 Local People's Government at or above the county level shall strengthen the management of food safety in rural areas, specify and publicize the food safety management system and requirements for dinner party activities, so as to avoid the food safety incidents.

The organizers and undertakers of dinner party activities in rural area shall bear the main responsibilities of food safety, and according to food safety requirements, purchase, store and process food as well as submit reports.

Article 58 In the event that catering service providers employ catering service management company for management, both parties shall sign the entrustment contract, in which the respective rights and obligations concerning food safety of both sides are clearly defined. Catering service providers shall bear the legal liability of food safety.

Article 59 The food additives traders shall establish food additive sales account system. They shall truly record information such as name, specification, quantity, production date or batch number, shelf life and sale date of the food additives, as well as name, address and contact information of the purchaser.

The records and documents shall be kept in compliance with provisions in Article 50 (2) of Food Safety Law.

The food additives traders shall, within 30 working days after obtaining the trading license, report to the food and drug administrative department of local People's Government at the county level where it is located for record-filing.

Article 60 Third-party online food trading platform providers shall file such information as website, IP address, approval supporting document proving that IP has been reviewed, company name, legal representative and his/her copy of ID card and contact information for record with the food and drug administrative department of local People's Government at or above the county level at the place where the platform is registered within 30 working days after obtaining business license.

Third-party online food trading platform providers shall make public food safety management system on the platform for query by online food producers and traders and consumers.

Third-party online food trading platform providers shall make public food safety violation information of food producers and traders who use the platform at conspicuous position of the website.

Article 61 Unless otherwise specified by laws and regulations, online food producers and traders shall obtain food production/trading license according to laws. The trading scope of online food producers and traders shall agree with the approval scope for its entity transaction.

Article 62 Online food producers and traders shall file such information as website and IP address for record with the food and drug administrative department by which production/trading license is issued within 30 working days after using the platform, meanwhile, make public its business license, production/trading license and other relevant information at conspicuous position of the front page of its website or main page of its trading activities. In case food production/trading license or other relevant information change, online food producers and traders shall update them timely.

Article 63 The provincial and above level People's Government can gradually implement electronic food safety traceability system among high-risk food varieties and relatively large-scale food production and trading enterprises according to the actual situation of this administrative region, and encourage food producers and traders to collect and record production and trading data information by informatization means.

Article 64 Food producers and traders as well as food wholesale markets shall truly report data information concerning food safety to the food and drug administrative department of local People's Government at or above the county level according to the provisions of the food and drug administrative department under the State Council.

Third-party online food trading platform providers shall properly keep the registration information, transaction data and others of the food, edible agricultural product and food additive producers and traders who use the platform and report them to the food and drug administrative department of local People's Government at or above the county level according to the provisions of the food and drug administrative department under the State Council.

Article 65 Food producers and traders shall stop producing & trading, recall and dispose unsafe food according to relevant provisions of national food recall system.

Based on the seriousness and urgency degree of food safety risks, food recall applies level-by-level administration:

Level I recall: where the food has caused or may cause serious health damage or death after consumption, food producers and traders shall initiate the recall within 24 hours after knowing of the food safety risks;

Level II recall: where the food has caused or may cause ordinary health damage after consumption, food producers and traders shall initiate the recall within 48 hours after knowing of the food safety risks;

Level III recall: where the food label or description dose not conform to food safety standard, and no health damage is caused in generally, food producers and traders shall initiate the recall within 72 hours after knowing of the food safety risks.

Food producers and traders who conduct food recall shall report relevant information to the food and drug administrative department of local People's Government at or above the county level where it is located within the time limit specified by different recall levels.

Article 66 Food producers and traders shall take actions such as removal of harm, destruction or remedy for foods that have exited the market due to cease of production & trading and recall.

Food producers and traders shall destroy unsafe food on the spot due to illegal addition of inedible substances and pesticide and veterinary drug residue exceeding the limit, rotten or spoiled food and diseased or dead livestock and poultry that seriously endanger human health.

Food producers can continue to sell recalled food due to the label and mark not conforming to food safety standard in case remedy has been done and the food safety can be ensured. The remedy shall be expressly notified to customers by posting a notice at conspicuous position of trading place and other means when selling such foods.

The local People's Government at or above the county level shall set up special fund to organize the implementation of storage, removal of harm and destruction, etc. of unsafe food involved.

### Section 3 Edible Agricultural Products Marketing and Sales (Default)

#### Section 4 Label, Description and Advertisement

Article 74 Food producers shall be responsible for the contents in the label and description of food and food additives.

Food producers and traders shall not change food production date, shelf life and other information indicated in the label and description against the provisions.

Article 75 Food traders when selling food in bulk shall indicate the production date and shelf life which shall be true, clear and readily identifiable and consistent with the contents indicated by food producers.

Food producers and traders shall indicate the earliest production date and shortest shelf life among the sold food that are mixed in a package on the label when selling food in bulk with different production date that are mixed in a package.

The original production date of food that is sub-packaged by food producers and traders must not be changed and the original shelf life thereof must not be extended.

Article 76 The packaged edible agricultural products through primary processing such as clean and cut shall be indicated of shelf life and sold within shelf life. Those edible agricultural products unprocessed may not be indicated of shelf life.

The food and drug administrative department under the State Council shall, in conjunction with other relevant departments under the State Council, specify the shelf life of packaged edible agricultural products through primary processing by classification according to practical need.

Article 77 The prepackaged food that are produced directly with GMO materials shall be labeled prominently according to relevant provisions.

Genetically modified food shall be labeled according to relevant provisions in “Administrative regulations on agricultural genetically modified organisms safety”.

Article 78 The label and description of food shall not contain such words as “special supply”, “exclusive supply”, “purpose made” and “supervisory made”, not use such words as “not added” and “not contained” to emphasize that those substances that shall not be contained or used according to food safety standard are not used or contained, and not indicate such words as “Non-GMO” with respect to genetically modified food and materials that are not approved by the State yet.

Other food other than health food shall not express or imply health functions on any carriers by any means.

Relevant contents on the label of health food, formula food for special medical purpose and formula food for infants and young children shall be consistent with the registered or filed contents. The label of other food other than health food, formula food for special medical purpose and formula food for infants and young children shall not indicate quantitative intake and specified intake per day.

Irradiated food shall indicate “Irradiated Food” in the label and description; and the ingredients through irradiation shall be indicated in the list of ingredients.

#### Section 5 Special Foods

Article 79 The formula of health food, formula food for special medical purpose and formula milk powder for infants and young children subject to registration administration shall obtain registration certificate issued by the food and drug administrative department under the State Council.

Article 80 The food and drug administrative department under the State Council shall, in conjunction with the health administrative department under the State Council and national traditional medicine administrative departments, develop, adjust and publish the catalogue of raw materials of health food and catalogue of health functions permitted to be claimed by health food.

The catalogue of raw materials and health functions of health food shall implement dynamic management aiming to safeguard public health and following the principles of science, equity and fairness. The food and drug administrative department under the State Council shall, in conjunction with the health administrative department under the State Council and national traditional medicine administrative departments, adjust the catalogues of health functions and raw materials of health food timely according to the progress of scientific research and health food registration situation.

Article 81 Relevant technical requirements such as raw material name, dosage level, production technologies, functional ingredients and test methods shall be published together with the catalogue of raw materials of health food.

Raw materials in the catalogue of raw materials of health food that have been changed substantially through re-processing such as extraction and

purification shall be excluded from and no longer belong to the catalogue of raw materials of health food.

Functional health raw materials that are not intended to provide nutrients shall be managed as raw materials of health food and shall not be applied for use as new food raw material. Other foods other than health food shall not use raw materials that shall be used only for health food.

Article 82 Dynamic production process with regard to implementation of on-site inspection of health food production licensing applicant's production site shall be inspected, and trial sample produced shall be sampled on site for inspection.

Health food production enterprise shall have corresponding product delivery inspection ability with regard to the production varieties and scale.

Article 83 The applicant who applies for registration of health food, shall organize to conduct relevant research work, complete product production in production enterprise that meets good manufacturing practices for health food, and submit inspection report issued by inspection institution with legal qualification.

Article 84 For health food and formula food for infants and young children subject to record-filing management according to laws, food and drug administrative department shall do well such work as registration, record-filing and future reference of filed information according to provisions, and issue a filing registration number to filing applicant.

The applicant who applies for production of health food in China shall apply for corresponding production licensing within 3 months after obtaining filing registration number. Technical requirements of product formulas and production technologies filed shall meet production licensing requirements.

The applicant who applies for importing of health food shall import relevant products within 3 months after obtaining filing registration number, meanwhile, submit the import declaration supporting document and inspection reports to provincial food and drug administrative department where it is located.

Article 85 In case of any of the following circumstances, the food and drug administrative department under the State Council shall organize to conduct re-assessment of health food, and can take supervision and administration measures such as revocation of health food registration certificate and adjusting of the category of raw materials of health food and make relevant information to the public:

- (1) Where the perception of safety or health functions of certain or certain kind of health food changes as scientific research develops;
- (2) Where monitoring result reveals possible safety risks of certain or certain kind of health food;
- (3) Other situations requiring re-assessment of health food.

Article 86 The food and drug administrative department under the State Council shall entrust qualified food inspection institutions to undertake the inspection and validation tasks for registration of the formula of health food, formula food for special medical purpose or formula milk powder for infants and young children and make the list to the public.

The enterprise that applies for registration of the formula of formula food for special medical purpose or formula milk powder for infants and young children shall have corresponding research and development abilities, production conditions and inspection abilities of all items specified by the standards with regard to the registered formula food for special medical purpose or formula milk powder for infants and young children, meet the requirements of good manufacturing practices and implement hazard analysis and critical control points system.

Article 87 The production enterprises of health food, formula food for special medical purpose and formula food for infants and young children shall organize production according to the technical requirements of product formulas and production technologies registered or filed.

Formula food for infants and young children can be sold in the market only after raw materials, food additives, product formula, label and other items thereof have been filed for record and made public.

In case the production technologies of health food involve such pretreatment processes as extraction and purification of raw materials, the production enterprises must have corresponding raw material pre-treatment ability with regard to the production varieties and scale.

Article 88 The name of health food shall not contain any words expressing or implying product functions.

The health function claim made on health food shall be indicated strictly according to the expressions in the category of health functions, and random addition/deletion or combination of words is forbidden.

Article 89 Sales counter or sales area shall be set up for health food, formula food for special medical purpose and formula food for infants and young children, and “Health Food Sales Areas/Counter”, “Formula Food for Special Medical Purpose Sales Areas/Counter” and “Formula Food for Infants and Young Children Sales Areas/Counter” shall be indicated at conspicuous position of sales counter or sales area. Mixed storage of health food, formula food for special medical purpose and formula food for infants and young children with drugs or common food is forbidden.

In addition, “The product is not drug substitute” shall be indicated at conspicuous position of health food sales counter or sales area.

Among formula food for special medical purpose, special total nutrient formula shall be sold in medical institutions or pharmaceutical retail enterprises, and others can be sold in food trading places.

Article 90 The import formula food for special medical purpose and import formula milk powder for infants and young children shall be registered according to laws.

Article 91 Among formula food for special medical purpose, the advertisement of special total nutrient formula shall be subject to examination and approval administration for prescription medicine advertisement, and the advertisement of others shall be subject to examination and approval administration for over the counter medicine advertisement.

Article 92 Production enterprises of formula milk powder for infants and young children shall not produce and sell formula milk powder for infants and young children, the trademark, enterprise name and address of which are registered in overseas only, and not produce formula milk powder with milk and milk component products of other animals other than cow and goat.

The product formula to be applied for registration shall be developed according to relevant laws and regulations and national food safety standards and on basis of science. The formulas of products for same age group to be applied for registration by same enterprise shall have obvious differences which can be proved by scientific evidence, in principle, each enterprise shall not have over 3 series and 9 product formulas.

Substances that can be optionally added according to national food safety standard shall not be reflected in the name of formula food for infants and young children.

Formula milk powder for infants and young children shall not be limited to, and not

Formula milk powder for infants and young children shall not be sold in limited areas and specially produced for retailers.

Article 93 The same enterprise shall not produce formula food for special medical purpose and health food of different brands by using the same formula.

Health food of same registration certificate or filing number shall use the same trademark.

## **Chapter 5 Food Inspection**

Article 94 The food and drug administrative and quality supervisory department shall perform random sampling inspection on the foods, food additives and food related products according to the division of responsibility.

The food safety supervision and sampling inspection shall be performed according to the inspection items and test methods stipulated in food safety standards. The works such as case inspection, accident investigation and emergency response, etc. can adopt the inspection items and test methods not stipulated in the food safety standards, to analyze and find the reasons for food safety problems. In case of adopting the test methods not stipulated in the food safety standards, it shall follow the principle of advanced

technical means, and get the permission from the food and drug administrative department under the People's Government at or above county level.

Article 95 When carrying out the sampling for food safety supervision and sampling inspection, the food and drug administrative and quality supervisory department can sample by itself, or entrust the food inspection institutions with statutory qualification for sampling, the number of sampling person shall not be less than two.

For case inspection and accident investigation, the sampling shall be organized by law enforcement officer, and shall not be restricted by such factors as sampling amount and site and whether the sampled unit has the legal quantification.

Article 96 The food and drug administrative department shall in accordance with the requirements of network food sampling inspection program, determine the purchaser of sample, payment account, registered account, delivery address, contact information, save the purchasing bill, and record the name, type and quantity, etc. of samples drawn for sampling inspection.

Upon reception of sample, the purchaser of sample, sampling person of the unit undertaking the inspection, and law enforcement officer of food and drug administrative department jointly unpack and check the sample, have the sample and reserved sample respectively sealed, and notify the network food producers and traders; in case of purchasing through the third-party network food platform provider, the third-party platform provider is simultaneously required to assist in notifying the network food producers and traders.

Article 97 The food and drug administrative department organizing and implementing network food supervision and sampling inspection shall timely notify the received inspection result to the sampled food producers and traders; in case of purchasing through the third-party trading platform, the third-party trading platform provider shall be notified simultaneously.

In case the addresses of network food producers and traders are unknown, the inspection result can be notified with the assistance of the third-party platform provider. In case it is disqualified upon inspection, and the network food producers and traders are not available, it can require the third-party platform provider to remove the online food sales information and suspend to provide trading service on third-party platform.

In case the inspection result cannot be notified to food producers and traders due to the incomplete address of network food producers and traders, the food and drug administrative department can publish relevant result information through the government website thereof.

Article 98 In case of being qualified upon food safety supervision and sampling inspection, the institution undertaking the inspection shall submit the inspection report to the food and drug administrative department organizing

and carrying out the supervision and sampling inspection within 10 working days. In case of being unqualified upon inspection, the institution undertaking the inspection shall timely report to the food and drug administrative department organizing and carrying out the supervision and sampling inspection.

In case it may have great harm to public health and life as indicated in the inspection conclusion of disqualification received by food and drug administrative department, the inspection result shall be notified to the local food and drug administrative department of sampled food producers and traders, and the local food and drug administrative department of producers and importers marked on the package or label.

Upon reception of notification, the food and drug administrative department shall immediately notice the relevant food producers and traders to take such measures as halting production and trading and recalling unsafe food, eliminate and control the food safety risk, and conduct investigation and handling in a timely manner. In case food producers and traders fail to fulfill relevant obligations in accordance with relevant provisions, the food and drug administrative department shall order them to fulfill the obligations thereof.

Article 99 In case the inspection institutions obtain the certification on relevant seal and signature from qualified third-party service provider, the electronic edition inspection report issued by them has equal legal effect as that of paper edition.

Article 100 In case of any of the following circumstances, it shall not be re-inspected:

- (1) where the inspection conclusions indicate that the microbiological indicator exceeds the limit;
- (2) where the reserved sample for re-inspection exceeds the expiry date;
- (3) where the re-inspection application is put forward exceeding the time limit;
- (4) where the reserved sample is incapable of achieving re-inspection aim due to other reasons.

Article 101 In case food producers and traders have objection on the inspection conclusion, the re-inspection application shall be put forward according to provisions of Food Safety Law; in case there is benefit relationships such as re-inspection entrusting, etc. between re-inspection applicant and re-inspection institution, it shall not entrust the above-mentioned re-inspection institution for re-inspection.

The re-inspection institution shall submit re-inspection report to food and drug administrative department organizing the sampling inspection work within 20 working days as of the date receiving sample in principle, unless otherwise agreed between food and drug administrative department, re-inspection applicant, and re-inspection institution.

Food producers and traders shall not cease to fulfill relevant obligations such as halting production and trading, and recalling during application of re-inspection.

Article 102 The re-inspection institution shall adopt arbitration method stipulated in relevant standards for re-inspection, and shall adopt the inspection method consistent with that of initial inspection in case of no arbitration method available. The sample used for re-inspection shall be the reserved sample of initial inspection. After completion of re-inspection, the re-inspection institution shall issue the inspection conclusion about whether the inspected sample is qualified.

Article 103 Relevant expense of re-inspection is paid by re-inspection applicant in advance. In case the re-inspection conclusion is consistent with initial inspection conclusion, inspection expense shall be borne by the re-inspection applicant. In case the re-inspection conclusion is inconsistent with initial inspection conclusion, inspection expense shall be borne by the initial inspection institution.

## **Chapter 6 Food Import and Export**

Article 104 The entry-exit inspection and quarantine authorities shall in accordance with provisions of Food Safety Law and the Rules, implement supervision and administration on import & export and frontier port food of foods, food additives and food related products.

The entry-exit inspection and quarantine authorities shall make public to the society the inspection and quarantine supporting document of foods and food additives, for free query by the public.

Article 105 The entry-exit inspection and quarantine authorities shall implement graded and classified administration on import food in accordance with the responsibility, based on the food safety risk, enterprise food safety control ability, food safety condition of exporting country or regions, etc.

Article 106 When importing foods, food additives and food related products, the importer or its agent shall apply for declaration to the entry-exit inspection and quarantine authorities with necessary certificates such as contract, invoice, packing list and bill of lading, etc. and relevant standard documents. As for declaration, the qualified certification materials shall be attached in accordance with the requirements of the quality supervisory, inspection and quarantine department under the State Council.

For imported edible animal and animal products, the inspection and quarantine certification materials, such as Entry Goods Inspection and Quarantine Certificate, Animal Quarantine Certificate, and Inspection and Quarantine Handling Notification etc., shall also be attached in accordance with the requirements of the quality supervisory, inspection and quarantine department under the State Council.

The customs shall release the goods based on the Customs Clearance Certificate issued by entry-exit inspection and quarantine authorities, and publicize on the official website.

Article 107 In case of importing special food requiring registration or record-filing management, the importer or its agent shall submit the supporting documents obtaining registration and record-filing in accordance with provisions of Food Safety Law and the Rules to entry-exit inspection and quarantine authorities. The entry-exit inspection and quarantine authorities shall implement supervision and sampling inspection in accordance with the requirements set out in the registered or filed supporting documents.

Article 108 The supervision and sampling inspection of exported food shall be performed by entry-exit inspection and quarantine authorities. In case there are requirements available in international treaty and protocol, the entry-exit inspection and quarantine authorities shall carry out the supervision and sampling inspection in accordance with requirements of international treaty and protocol.

Article 109 The entry-exit inspection and quarantine authorities shall implement supervision and sampling inspection on import links of foods, food additives and food related products. For those entering the domestic market for sales, the supervision and sampling inspection shall be implemented by food and drug administrative department.

The entry-exit inspection and quarantine authorities shall implement detention and inspection on foods, food additives and food related products with high safety risk; for those with common risk, the sampling inspection shall be implemented; for those with low risk, the on-site inspection shall be implemented.

Article 110 The overseas exporters and overseas food producers exporting food to China shall guarantee that the food exported to China conforms to Food Safety Law, provisions of other relevant laws and regulations, and requirements of national food safety standards. Importers shall establish examination system of overseas food exporters and overseas food producers.

Article 111 In case the importers recall imported foods, the exit-entry inspection and quarantine authorities shall notify the food and drug administrative departments.

Article 112 The overseas food producers, overseas exporters and their agents exporting food to China shall take effective measures to prevent edible agricultural products and food from man-made deliberate destruction of chemical, biological and physical manner during the processes such as planting and breeding, raw and auxiliary materials control, production, package, storage, and transportation.

Article 113 For the overseas production enterprise of imported food which has passed Good Manufacturing Practice and Hazard Analysis and Critical Control Point system certification, the certification authority shall implement

tracking investigation according to law. For enterprises no longer complying with certification requirements, the certification authority shall revoke the certification according to law, timely notify it to relevant departments under the State Council, and make it public to the society.

Article 114 The imported prepackaged food shall have Chinese label, which shall be directly printed on the product package and shall not be attached in the manner of covering the foreign language label.

Article 115 For imported health food, formula food for special medical purpose, and infants and young children formula milk powder, the food and drug administrative departments under the State Council can organize the on-site verification on the quality management system of producers thereof, as well as the implementation and record-filing of good manufacturing practice for health food.

Food producers and traders shall not, in the name of health food, import the food containing raw materials only used for health food.

Article 116 In case food safety accidents or other public health events occurred at abroad may affect China, or serious food safety problems are found in imported foods, food additives, food related products, the national entry-exit inspection and quarantine authorities shall timely release imported food safety risk warning information, and decide to take the following control measures:

- (1) to implement and strengthen supervision and detaining inspection;
- (2) to carry out return or destruction;
- (3) to restrict the import with reservations;
- (4) to suspend or prohibit the import;
- (5) to initiate the emergency response plan for imported food.

Article 117 In case of importing and exporting food in the form of cross-border electronic commerce, it shall comply with relevant provisions on food import and export in Food Safety Law and the Rules.

Measures for supervision and administration of importing foods, food additives and food related products in the form of cross-border electronic commerce shall be separately formulated by the quality supervisory, inspection and quarantine department under the State Council, in conjunction with relevant departments under the State Council.

## **Chapter 7 Handling of Food Safety Accidents**

Article 118 Level-by-level administration shall be applied in handling of food safety accidents.

In case of especially major food safety accidents, the food and drug administrative department under the State Council shall conduct

investigation and handling in conjunction with relevant departments under the State Council, under the unified leadership of the State Council.

In case of major, relatively major and general food safety accidents, the food and drug administrative department under the People's Government at province, city and county levels shall conduct investigation and handling in conjunction with relevant departments at the same levels, under the leadership of the People's Government at the corresponding level.

Article 119 The People's Governments of provinces, autonomous regions and municipalities shall make emergency response plans for food safety accidents, and amend and improve in time according to changes in actual situation.

The local People's Government at or above the county level shall do well in the management of emergency response plan for food safety accidents, and strengthen supervision, inspection and guidance of the management of emergency handling by food production and trading enterprises, and conduct emergency response drills at least once every three years.

The local People's Government at or above the county level shall incorporate the training on emergency response plan for food safety accidents into leaders and cadres training, public servants training, and daily training of emergency response management cadres.

Article 120 The People's Governments of provinces, autonomous regions and municipalities shall make the plans for food safety emergency response system construction.

The local People's Government at or above the county level shall improve the food safety emergency response management authority, perfect the emergency response management system, put the emergency response funds in place, improve the emergency response equipment, do well in emergency response materials storage and emergency response team construction, and strengthen emergency response training, drills and evaluation.

The local People's Government at or above the county level shall carry out the monitoring and early warning of food safety accidents, strengthen the collection, analysis and study and judgment of information related to food safety, and release early warning information in time based on the emergency degree, development trend and the degree of possible hazard of food safety accidents.

Article 121 The food and drug administrative department under the People's Government at or above the county level shall set up the food safety accident information monitoring and reporting system, set up the food safety accident information direct reporting network system covering food producers and traders above the designated size, third-party online food trading platform, medical institutions, disease prevention and control organs, in conjunction with the health administrative department at the same level

and others, thus realizing the unified supervision and management of the food safety accident information reporting.

Article 122 Food production and trading enterprises shall set up the food safety emergency response management system, make the incident handling plan and establish the emergency incident reporting system.

The food production and trading enterprises above the designated size and relevant units shall often organize and carry out emergency response drills pertinently.

Article 123 Under any of the following circumstances, the food safety accident information shall be investigated and handled in time:

- (1) Food poisoning caused by food provided by the food producers and traders;
- (2) Food contamination resulting from human or other factors during production, processing, storage, transportation, and sale by the food producers and traders, which has resulted or is likely to result in personal injury to the public.

Article 124 The unit where the food safety accident has occurred shall take such control measures as sealing up immediately food and raw materials, tools and equipment which has caused or is likely to cause the food safety accident, and report to the food and drug administrative department under the People's Government at the county level where it is located within 2 hours upon discovery of the incident.

In case that the medical institution or the disease prevention and control institution has discovered that the patient treated and the public health emergency incident handled may be related to the food safety accident, it shall report to the food and drug administrative department and the health administrative department under the People's Government at the county level where it is located within 2 hours.

The health administrative department shall immediately organize the disease prevention and control institution to conduct sanitary treatment of the incident site, and conduct an epidemiological investigation into factors related to the food safety accident, and relevant departments shall provide assistance. The disease prevention and control institution at or above the county level shall submit the preliminary epidemiological investigation report to the health administrative department and the food and drug administrative department at the same level within 24 hours, and submit the final investigation report within 7 working days upon the end of the investigation.

In case that the disease prevention and control institution and such technical institution as food inspection have discovered the food safety accident information, they shall report to the food and drug administrative department under the People's Government at or above the county level forthwith.

Article 125 The health administrative department under the People’s Government at or above the county level shall set up the foodborne disease and food safety accident monitoring and reporting work system and organize the disease prevention and control institution to verify the disease information reported, in conjunction with the food and drug administrative department at the same level. In case of involvement of food safety, the health administrative department shall report to the health administrative department at the higher level and the People’s Government at the same level within 2 hours, and at the same time notify the food and drug administrative department at the same level.

Article 126 In case that the health administrative department, quality supervisory, the agriculture administrative, public security and other relevant departments at or above the county level have discovered the food safety accident information, they shall notify the food and drug administrative department at the same level forthwith. In case that the food and drug administrative department has discovered that the food safety accident information involves relevant department, it shall notify relevant department forthwith.

Article 127 The People’s Government at or above the county level shall organize the food and drug administrative, health administrative, agriculture administrative, quality supervisory, public security and other departments to conduct investigation and verification forthwith upon the receipt of the food safety accident information report. In case of food safety accident, the food and drug administrative department will conduct investigation and handling, in conjunction with health administrative, agriculture administrative, quality supervisory, public security and other departments.

Upon the end of the food safety accident investigation, the food and drug administrative department shall submit the final investigation report of food safety accident to the People’s Government at the same level and the food and drug administrative department at the higher level as required.

In case of the need to initiate the emergency response plan due to occurrence of the food safety accident, the People’s Government at or above the county level shall set up an incident handling command body forthwith to initiate the emergency response plan.

Article 128 The emergency response plan and investigation and handling of other food safety incidents other than food safety accidents shall be governed, *mutatis mutandis*, by relevant provisions in this Chapter.

## **Chapter 8          Supervision and Management**

Article 129 The food and drug administrative department under the State Council is mainly responsible for special food registration and filing, organizing and conducting the national food safety supervision and sampling inspection, system inspection and unannounced inspection, setting up the unified food safety information platform, announcing major food safety information under the law, carrying out inspection of major food safety irregularities,

handling especially major food safety accidents under the law and preventing and controlling the systematic food safety risks.

The food and drug administrative departments under the People's Governments of provinces, autonomous regions and municipalities are mainly responsible for relevant special food production license management, organizing and conducting food safety supervision and sampling inspection, system inspection and unannounced inspection at the province level, announcing the food safety information within the region under the law, carrying out inspection of food safety irregularities, handling major food safety accidents under the law and preventing and controlling the regional food safety risks.

The food and drug administrative departments under the People's Governments at the city and county level are mainly responsible for food production and trading license management, conducting daily food safety supervision, inspection and sampling inspection, announcing the food safety information within the region under the law, supervising over the enterprise's product recall, and investigating and handling food safety violations under the law. Focus shall be placed on daily supervision, inspection and sampling inspection of the food and edible agricultural products wholesale and retail markets, malls and supermarkets, and catering service units, the pesticide residue or veterinary drug residue in the raw materials of food sold or purchased, and the food produced and traded by food production and processing small workshops and food vendors within the administrative region.

Article 130 The food and drug administrative department under the State Council may establish resident agencies according to the work requirements, supervising and inspecting the food safety tasks of local People's Government.

Article 131 The food and drug administrative department, quality supervisory, agriculture administrative and other departments under the People's Government at or above the county level will conduct risk tiered management of the food safety within the administrative region according to the food safety risk monitoring, risk evaluation, supervision and inspection, supervision and sampling inspection, accident handling, case investigation and handling and etc.

Article 132 The State sets up the food safety inspector system. The food and drug administrative departments under the People's Governments at or above the province level will set up full-time food safety inspectors teams, conducting on-site inspection of good operational norms, hazard analysis and critical control points system implementation of food production and trading enterprises above the designated size. Specific measures for administration will be formulated by the food and drug administrative department under the State Council.

Article 133 In case that the food and drug administrative, quality supervisory and other departments have discovered food spoilage, mildew and rot, mixture of

foreign substance and other abnormalities in sensory properties of the food during the on-site supervision and inspection, they may collect evidence by taking photos and videos.

In case that the person concerned refuses to sign or is unable to sign for other special reasons, the reasons shall be indicated, which may be confirmed by signatures of more than 2 law enforcement officers on site.

- Article 134 In case of possible loss of evidence or difficulty to obtain evidence later, the law enforcement officers of the food and drug administrative, quality supervisory, agriculture administrative and other departments may register and keep first relevant contracts, bills, account books, sale and purchase records, storage equipment of electronic data and other materials under the law.
- Article 135 In case of case filing and investigation of the food producer and trader due to suspected food safety violations, the food and drug administrative department may suspend accepting its relevant administrative license application during the period of investigation and handling; for the already accepted application, suspend handling, and the period of suspension will not be counted into the administrative license period.
- Article 136 Where the food and drug administrative department at the higher level deems it necessary, it may directly investigate and handle the food safety violation cases within the jurisdiction of the food and drug administrative department at the lower level, or designate the food and drug administrative department in other regions to investigate and handle, and the food and drug administrative department where the case has occurred shall provide cooperation.
- Article 137 The health administrative department under the State Council shall announce in time the list and the testing method of the discovered non-food chemical substance and other substances which may endanger human health, which is added or may be added into food, according to the foodborne disease information, risk monitoring, risk evaluation and other supervision and management information, in conjunction with relevant departments under the State Council.
- Article 138 In case that no residue limit and testing method is specified for pathogenic microorganisms, pesticide residue, veterinary drug residue, heavy metal, biological toxin, pollutants and other substances which endanger human health, the health administrative department under the State Council shall specify the temporary residue limit and testing method in conjunction with the agriculture administrative, food and drug administrative and other departments under the State Council and announce them to the public, as the basis for production and trading and supervision and management.
- Article 139 The food and drug administrative, quality supervisory, agriculture administrative and other departments under the State Council may assess the fast food testing methods according to the food safety supervision

requirements. After passing the assessment, it may serve as the fast testing method as provided by the State.

The food and drug administrative, quality supervisory, agriculture administrative and other departments under the People's Government at or above the county level may adopt the national food safety standards or the fast testing methods determined by the food and drug administrative, quality supervisory, agriculture administrative and other departments under the State Council to conduct sampling inspection and testing of food.

For food whose testing results have shown that it may not conform to food safety standards, it shall be inspected in accordance with Article 87 of the Food Safety Law, and the food producers and traders shall take such measures as suspending sale to control risks. If the testing results have determined that relevant food fails to conform to the food safety standards, the results may be used as the basis for administrative punishment.

Article 140 In case that the food and drug administrative department under the State Council formulates the codes for assessment of fast testing technology, it may entrust the food and drug administrative department of provinces, autonomous regions and municipalities, relevant industry association or professional technical institution to assess the fast testing methods proposed by relevant enterprise and scientific research institution. It will be announced after passing the assessment.

The food and drug administrative department under the State Council may entrust the food and drug administrative department under the People's Government of provinces, autonomous regions and municipalities, and relevant professional technical institution to conduct on-site verification and sampling of the production and application materials of the enterprise that applies for fast testing method assessment.

The food and drug administrative department under the People's Government of provinces, autonomous regions and municipalities shall formulate regulations on management of fast testing work, standardize the acceptance and use of the fast testing method, and supervise and inspect the use of the fast testing method in food safety supervisory management within its jurisdiction.

Article 141 For the fast testing method not assessed by the food and drug administrative department under the State Council, the food and drug administrative department under the People's Government of provinces, autonomous regions and municipalities may formulate relevant management measures and technical assessment codes for food fast testing method, and organize professional technical institutions to carry out assessment of the food fast testing method according to the supervisory management requirements within the jurisdiction. After passing the assessment, it may be used for preliminary screening of food safety within the jurisdiction.

Article 142 The food and drug administrative department and other departments under the State Council shall set up the food producers and traders credit information system, establish and improve the credit record negative information disclosure system and trustworthiness incentive system; study and promote the linking up between food safety credit evaluation results and industry access, financing credit, security issuance and other credit system, and give full play to the role of restraining the food safety discreditable behaviors.

Article 143 The food and drug administrative department shall announce in time the license issuance, daily supervision and inspection results, violation investigation and handling and other information.

License issuance information includes the name of the producer and trader, social credit code (ID Card No. for individual operator), legal representative (person in charge), domicile, production and trading premises, category or item of food produced or traded, license No., validity term, daily supervision and management body, daily supervision and management personnel, complaint and report hotline, issuance authority, issuer, date of issuance and other information.

Daily supervision and inspection results information includes the name of the producer and trader, social credit code (ID Card No. for individual operator), legal representative (person in charge), domicile, license No., time of inspection, contents of inspection, and results of inspection and other information.

Violation investigation and handling information includes the case name, name of the punished, main violation facts, category of punishment, basis for punishment, and punishment results and etc. In case of revocation of the license, names and ID Card numbers of the legal representative, executive in charge being directly responsible, and other persons being directly responsible of the food producer and trader shall be announced at the same time.

Article 144 The health administrative department under the People's Government at the county level shall carry out supervision and inspection of units carrying out centralized disinfection of tableware and drink-ware, and shall investigate and handle in time in case of discovery of non-compliance with the food safety laws, regulations and relevant hygienic code, and announce the supervision and inspection results to the public.

Article 145 Under any of the following circumstances, the food and drug administrative department and other departments may have an accountability conversation with the legal representative or main principal of the food producer and trader:

- (1) Occurrence of food safety problem, which has attracted high social concern;

- (2) Failure to handle food safety problem complained and reported in time, which has caused larger social influence;
- (3) Failure to take effective measures in time to identify and remove food safety hidden danger, and fulfill the food safety responsibility;
- (4) Other circumstances deemed necessary for the accountability conversation by the food and drug administrative department under the People's Government at or above the county level.

In case of violation by the food producer and trader, the accountability conversation will not affect the administrative resolution made under the law, and the accountability conversation and follow-up handling shall be announced to the public.

In case that the interviewed fails to implement rectification for no justified reasons, the food and drug administrative department shall record it into the food safety credit file and increase the frequency of supervision and inspection.

Article 146 The People's Government at or above the county level shall be liable for localized management of food safety guarantee for important activities, make the food safety guarantee plan, specify food safety responsibilities, and put the guarantee funds and conditions in place.

The important activity organizer shall specify the food safety management authority, choose the food producer and trader with food safety guarantee ability, and urge it to fulfill the food safety obligations.

The food producer and trader providing food for important activity shall assume main responsibility for food safety under the law, make the food safety guarantee plan and emergency response plan, and implement the whole-process control requirements over the food safety to ensure food safety.

The food and drug administrative, health administrative, agriculture administrative, quality supervisory and other departments under the People's Government at or above the county level shall strengthen food safety guarantee of important activity according to the food safety guarantee plan, and strengthen review of suppliers and food inspection. When necessary, they may engage professionals for assessment.

Important activity organizer is encouraged to engage social professional institutions to provide food safety guarantee service for important activity.

Article 147 Under any of the following circumstances, the food and drug administrative department at the higher level may conduct unannounced inspection, and supervise over the work of the food and drug administrative department at the lower level:

- (1) In case of suspected violation of food safety laws and regulations by the food producer and trader, which may cause serious hazard or great social impact;

- (2) In case of hidden danger existing in the food producer and trader, which may trigger regional food safety risks or cause serious hazard or great social impact;
- (3) In case of the internal informant's complaints and reports of serious violation behavior or serious food safety hidden danger existing in relevant food producer and trader;
- (4) Other circumstances necessary for organization of unannounced inspection.

The unannounced inspection shall be conducted according to the principle of random inspection and the procedure and requirements of on-site supervision and inspection.

Article 148 The food and drug administrative department and other departments under the People's Government at or above the county level shall set up the food safety complaint and reporting organ, announce the food safety complaint and reporting hotline, and establish the complaint and reporting network information management system.

The food safety complaint and reporting acceptance organ shall regularly summarize and analyze food safety complaint and reporting information, and put forward suggestions to improve food safety supervision and administration.

Article 149 The food and drug administrative department under the State Council shall make standards for the food safety supervision and administration ability construction, and specify requirements on ability construction of food and drug administrative organs, personnel, facilities and equipment at various levels, in conjunction with relevant departments under the State Council.

The People's Government at or above the county level shall incorporate funds for food safety supervision and inspection, sampling inspection, risk monitoring, administrative license, publicity and education, ability construction etc. into the financial budget, and set up special funds for emergency handling, case investigation and handling, reporting reward, important activity guarantee and etc.

Article 150 The food and drug administrative department and other departments under the State Council are responsible for making the training syllabus, and the food and drug administrative department and other departments under the People's Governments of provinces, autonomous regions and municipalities are responsible for organizing examination.

The law enforcement officers of the food and drug administrative department and other departments shall take no less than 40 class hours' food safety professional training every year every person, and take examination, and those failing in the examination shall not be engaged in law enforcement of food safety.

Article 151 The food and drug administrative department under the People's Government at or above the county level shall make the annual inspection plan for this administrative region, and determine the inspection frequency according to the risk level.

Law and rule violations detected in inspecting the food producer and trader shall be handled under the law, and the inspection and handling result shall be recorded. The inspection record will be filed on record after signed by the inspector and relevant principal of the food producer and trader.

The inspection result shall be posted at the business premises and announced on the network.

Article 152 Entrusted by the People's Government of the same level, the food and drug administrative department may conduct accountability conversation with the main principal of the People's Government at the lower level which fails to fulfill the legal responsibilities and to remove the regional major food safety hidden danger in time.

Article 153 The food and drug administrative department under the State Council shall strengthen food safety informatization construction, set up an unified food safety information platform, integrate food safety information resources and realize food safety information sharing, in conjunction with the health administrative, agriculture administrative, quality supervisory and other departments under the State Council.

Article 154 The food and drug administrative department under the State Council shall prepare and release the national food safety status report regularly every year.

Article 155 The State shall set up the food safety statistical investigation system. The food and drug administrative department under the State Council shall set up the food safety statistical indicators system and organize to carry out statistical investigation related to food safety, in conjunction with the statistics department under the State Council.

The food and drug administrative department under the People's Government at or above the county level shall establish and improve the statistical investigation system and statistical indicators system of food safety within the administrative region, and organize to carry out statistical investigation related to food safety by reference to the national statistical investigation system and statistical indicators system of food safety, in conjunction with the competent statistics department at the same level.

The food producer and trader, industry association and other organization shall coordinate with the food and drug administrative department in carrying out statistical investigation of food safety under the law.

Article 156 The case inspection organ directly affiliated to the food and drug administrative department under the People's Government at or above the county level may take such supervisory management and law enforcement

measures as on-site inspection, sampling inspection, sealing up and detainment, and case investigation in its own name.

Article 157 In case of discovery of any of the following circumstances, the food and drug administrative department, quality supervisory and other departments under the People's Government at or above the county level shall transfer clues and evidence related to the case to the public security organ within 3 working days:

- (1) Produces food by utilizing non-food raw materials, adds into food any chemical substances (other than food additives) or any substances that may endanger people's health, produces foods by utilizing recycled food as raw materials, or sells the food listed above;
- (2) Produces or sells the staple food or dietary supplement that specially are targeted for sales to infants and young children and other group of people with special needs, whose nutrition facts do not conform to the food safety standards;
- (3) Sells the meats of the poultry, livestock, animal, or aquatic that dies due to disease, poison or any unknown reason, or produces or sells the products made of meat listed above;
- (4) Sells the meat without quarantine or that fails in quarantine, or produces or sells the meat product without quarantine or that fails in quarantine;
- (5) Produces or sells the food that the State explicitly prohibits to produce or to sell due to special need, such as disease prevention etc.;
- (6) Produces or sells the food in which the drug has been added;
- (7) Produces or sells food and food additive in which the content of pathogenic microorganism, pesticide residue, veterinary drug, biological toxin, heavy metal and other pollutants and other substances, which endanger the human health, exceeds the food safety standard limit;
- (8) Other behaviors which are suspected to constitute crimes related to the food safety.

The public security organ shall timely take such measures as inquiry, search, investigation, authentication, and taking of evidence materials, and conduct preliminary investigation.

In case of suspicion of constituting a crime, the public security organ shall file a case for investigation in time under the law; in case of not constituting a crime, the administrative department shall impose an administrative penalty under the law.

Article 158 The People's Government at or above the county level will establish and improve the convergence mechanism between the food safety administrative law enforcement and the criminal justice, clarify such matters as clue

notification, case transfer, conference on details of a case, information sharing, information release, and supervision over inspection and handling, and coordinate and urge the investigation and handling of food safety violation criminal cases.

Article 159 The food and drug administrative department under the State Council will formulate the measures for management of food safety judicial authentication, clarify the qualification conditions and determine the list of food safety judicial authentication institutions and authentication personnel, in conjunction with the judicial administrative department under the State Council.

Those who are entrusted to carry out food safety judicial authentication shall be chosen from the list of food safety judicial authentication institutions and authentication personnel.

Article 160 Where during the supervision and management and the law enforcement, the food and drug administrative, quality supervisory and other departments need the assistance from the public security organ under any of the following circumstances, the public security organ shall provide assistance:

- (1) Occurrence of violence against law or triggering the mass event;
- (2) Refuses, obstructs, impedes food safety supervision and law enforcement;
- (3) Destroys, conceals evidence or the party concerned runs away;
- (4) Requires assistance in taking evidence for serious difficult cases;
- (5) Other circumstances as provided by laws and regulations.

Article 161 Where the public security organ needs technical support and information verification from the food and drug administrative, quality supervisory and other departments in investigating the food safety criminal case, the food and drug administrative, quality supervisory and other departments shall provide assistance.

Article 162 For cases transferred by the food and drug administrative, quality supervisory, agriculture administrative and other departments, the public security organ shall examine within 3 working days.

If relevant violation involves such case as illegal addition of non-edible substance, illegal addition of drug, production and operation of the poultry and livestock died of disease, which seriously endangers the human health, it shall be examined immediately.

Article 163 The food and drug administrative, quality supervisory agriculture administrative and other departments shall strengthen communication and coordination with the public security organ, and establish and improve the evidence convergence mechanism.

Evidence transferred by the food and drug administrative, quality supervisory, agriculture administrative and other departments to the public

security organ may be used as the basis for administrative punishment by keeping the electronic data, photocopy of the written evidence attached with seal.

For the evidence transferred by the food and drug administrative, quality supervisory, agriculture administrative and other departments, the public security organ may use it as the evidence for the criminal case after verifying that it meets the criminal evidence standards.

Article 164 In case that, in respect of the food safety violations discovered, the public security organ finds that there is no facts of crime, or deems that the facts of crime are obviously minor and no criminal responsibility needs to be affixed but the administrative responsibility shall be affixed under the law, it shall transfer the case to the food and drug administrative, quality supervisory, agriculture administrative and other departments in time.

The public security organ shall at the same time transfer the photocopies of relevant evidence materials attached with seals to the food and drug administrative, quality supervisory, agriculture administrative and other departments. After verified by relevant department and deemed to meet the requirements for evidence of administrative law enforcement cases, it may be used as relevant evidence.

Article 165 For a case where the people's court has given the judgment and where the food and drug administrative, quality supervisory, agriculture administrative and other departments shall impose such administrative punishment as revocation of the license but no punishment has been imposed, after verification, the food and drug administrative and other departments may impose the administrative punishment under the law based on the facts and evidence determined in the judgment of the people's court.

Article 166 The resident agency of the food and drug administrative department may carry out supervision and inspection, administrative guidance and etc. over food producers and traders within the administrative region in its own name.

The resident agency of the food and drug administrative department may impose such administrative punishment as a warning and a penalty of less than RMB 5,000 in its own name.

With the approval of principal of the food and drug administrative department under the People's Government at or above the county level, the resident agency of the food and drug administrative department may take such administrative compulsory measures as sealing up and detainment to control food safety risks in its own name.

## **Chapter 9      Legal Liabilities**

Article 167 In case that the license of a food producer or a trader is revoked, terminated or expired, or its administrative permit is revoked, or withdrew, but the food producer or trader continues its production or sales, the food and drug

administrative above county level shall impose the penalty in reference to Subsection 1 of Article 122 of Food Safety Law.

Article 168 Under following circumstances, in case of not reaching the level of the criminal prosecution, the food and drug administrative above county level shall impose penalty under the criteria of “severe violation” in reference to Subsection 1 of Article 123 of Food Safety Law:

- (1) Anyone produces food in non-edible raw materials, adds any chemical substances other than food additives or any substances that may endanger people’s health into food, produces foods by utilizing recycling food as raw materials, or sells the food listed above, with the total value of the products more than RMB 1,000, or that had been in administrative penalty for any food safety law violation in past one year;
- (2) Anyone produces or sells the staple food or dietary supplement that specially are targeted for sales to baby other group of people with special needs, whose nutrition formula does not conform the food safety standard, with the total value of the products more than RMB 1,000, or that had been in administrative penalty for any food safety law violation in past one year;
- (3) Anyone produces or sells the meats of the poultry, livestock, animal, or aquatic, that is killed by disease, poison, or any unknown reason, or produces or sells the products made of meat listed above, with the total value of the products more than RMB 1,000, or that had been in administrative penalty for any food safety law violation in past one year;
- (4) Anyone sells the meat without quarantine or that fails in quarantine, or produces or sells the meat product without quarantine or that fails in quarantine, with the total value of the products more than RMB 1,000, or that had been in administrative penalty for any food safety law violation in past one year;
- (5) Anyone produces or sells the food that the state explicitly prohibits to produce or to sell due to special need, such as disease prevention, etc., with the total value of the product.
- (6) TS more than RMB 1,000, or that had been in administrative penalty for any food safety law violation in past one year;
- (7) Anyone produces or sells the food in which the drug has been added, with the total value of the products more than RMB 1,000, or that had been in administrative penalty for any food safety law violation in past one year;
- (8) Other circumstance as prescribed by the laws or regulations;

Article 169 Under following circumstances, in case of not reaching the level of the criminal prosecution, the food and drug administrative above county level shall impose penalty in reference to Subsection 1 of Article 123 of Food Safety Law:

- (1) Anyone utilizes the non-edible substance during its production, sales, storage, or transportation;
- (2) Anyone produces and/or processes the food or the food additives by utilizing the wasted or recycling food additives;
- (3) Anyone process the food by utilizing the substances that may endanger people's health in the way of soakage or fumigation, etc.;
- (4) Anyone purchase or store the non-edible chemical substances that the state has explicitly prohibited during the food production or sales;
- (5) Anyone passes non-edible chemical substances off as food additives;
- (6) Anyone adds illegally the chemical substances, or any other substances that may endanger people's health, other than the drug, or food additives as raw materials;
- (7) Anyone cleans or sterilizes the vessels or appliances for food production or sales by utilizing non-edible detergent or sanitizer;
- (8) Any other circumstances as stipulated by the laws or the regulations;

Article 170 Under the following circumstance, the special food producer's registration certificate of special food shall be revoked:

- (1) Produces the special food in the non-edible raw material, or add the chemical substances other than food additives or any other substances that may endanger people's health;
- (2) Adds the drugs during the production process of the special food;
- (3) Produces or manages the production of the special food not in the product formula or technical specification that has been registered, and the values of the product is between RMB 10,000 to RMB 20,000;
- (4) Product the baby formula milk powder in co-packing arrangement, or produce the health foods, food with special medical purpose or baby formula milk powder in the different brands by one enterprises, however, in same formula; and the value of the products is between RMB 10,000 to RMB 20,000
- (5) Any other circumstances as stipulated by the laws or the regulations.

Article 171 Under any of the following circumstances, in case of not constituting a crime, the food and drug administrative department under the People's government at or above the county level shall impose the punishment under the criteria of "severe violation" in reference to Paragraph 1 of Article 124 of Food Safety Law:

- (1) Produces or sells food or food additive that contains substances that may endanger human health, such as the pathogenic microorganism, pesticide residue, veterinary drug residue, biological toxin, heavy metal, to the extent that the content of such substance exceeds two times of the limit of the food safety standard or that the products value is over RMB 30,000;
- (2) Produces food or food additive with the food raw material or food additive beyond the shelf life, or sells the food or food additives with products value over RMB 30,000;

- (3) Produces or sells the food with food additives utilized beyond the permitted scope or exceeding the limit, with products value over RMB 30,000;
- (4) Produces or sells food and food additives with spoilage, fact rancidity, mildew and rot, filthiness, mixture of foreign substance, adulteration or abnormalities in sensory properties, with products value over RMB 30,000;
- (5) Produces or sells food and food additives indicated with false production date or false shelf life or beyond the shelf life, with products value over RMB 30,000;
- (6) Produces or sells the health food, formula food for special medical purpose, formula milk powder for infants and young children that has not been registered as provided, or organizes the production with the product formula or production technologies and other technical specification that has not been registered, with the products value over RMB 20,000;
- (7) Produces the formula milk powder for infants and young children in sub-packing arrangement, or produces the formula milk powder for infants and young children in the different brands by the same enterprises, however, in the same formula, with the products value over RMB 20,000;
- (8) Utilizes new food raw materials to produce food, or produces new varieties of food additives, which has not passed safety assessment, with the products value over RMB 30,000;
- (9) The food producer or trader refuses to recall or stop trading after the food and drug administrative department has ordered it to recall or stop trading;
- (10) Has caused such harmful consequences as serious food poisoning, and foodborne disease;
- (11) Continues with production and trading after the food and drug administrative department and other departments have ordered it to rectify, and stop production and trading;
- (12) Takes the special groups such as the disabled, the elderly, pregnant and children or the critically ill patients as determined by the medical insurance, as the main infringed objects.

Article 172 Under any of the following circumstances, in case of not constituting a crime, the food and drug administrative under the People's government at or above the county level shall impose the punishment in accordance with Paragraph 1 of Article 124 of Food Safety Law:

- (1) The food producer or trader fails to take such necessary measures as stopping production and trading, and recalling food in issue when the food safety risk monitoring results have shown existence of safety hidden danger in food, during the period of re-inspection or review of authenticity objection;
- (2) Violates the obligations as provided in food safety laws, rules and regulations, and food safety accidents have occurred;

- (3) Any enterprise producing formula milk powder for infants and young children violates Article 92 herein;
- (4) The food producer or trader fails to recall unsafe food within the specified time limit;
- (5) The imported food trader cannot provide sanitary certificate or the certificate of inspection and quarantine for entry-exit goods, Chinese labels and inspection marks;
- (6) The special food production enterprise has not registered change or change of production license as provided in case of change in production conditions and technologies;
- (7) Uses raw materials only for the health food to produce common food;
- (8) Other circumstances as provided by laws and regulations.

Article 173 Under any of the following circumstances, the food and drug administrative department under the People’s government at or above the county level shall impose the punishment under the criteria of “severe violation” in reference to Paragraph 1 of Article 125 of Food Safety Law:

- (1) Produces or sells food and food additives contaminated by packaging materials, containers or means of transport, with products value over RMB 20,000;
- (2) Produces or sells pre-packaged food and food additives without labels, or food and food additives whose label and description does not comply with the provisions of food safety laws and regulations, with products value over RMB 30,000;
- (3) Produces or sells genetically modified food without indication as provided, with products value over RMB 30,000;
- (4) The food producer or trader purchases or uses food raw materials, food additives, and food related products not conforming to food safety standards, with products value over RMB 20,000;
- (5) Other circumstances as provided by laws and regulations.

Article 174 Under any of the following circumstances, the food and drug administrative department under the People’s government at or above the county level shall impose the punishment in accordance with Paragraph 1 of Article 125 of Food Safety Law:

- (1) The food label and description uses false and exaggerated words or pictures which may easily lead consumers to misunderstand;
- (2) The food is indicated with the drug name or health food name, or declares having the functions of drug or health food;
- (3) Falsely indicates the product implementing standards, list of ingredients and relevant mandatory labeling contents;
- (4) Fails to indicate the use of food additives in the food which shall be indicated as provided, or the manner of indicating the food additives

does not comply with the food safety laws and regulations and food safety standards.

Article 175 Under any of the following circumstances, the food and drug administrative department under the People's government at or above the county level shall impose the punishment under the criteria of "severe violation" in reference to Paragraph 1 of Article 126 of Food Safety Law:

- (1) The food and food additives producer fails to inspect the food raw materials purchased and the food and food additives produced, with the value of food not conforming to food safety standards over RMB 30,000;
- (2) The food production and trading enterprise fails to set up the food safety management system as provided, or fails to equip or train and appraise food safety management staff as provided, and the food safety accident involving more than 10 persons but less than 30 persons has occurred;
- (3) The food and food additives producer or trader fails to inspect the license and relevant certificates of incoming goods, or fails to set up and comply with the incoming goods inspection record, ex-factory inspection record and sales record system as provided, with the value of food produced or sold not conforming to food safety standards over RMB 30,000;
- (4) The food production and trading enterprise fails to make the food safety accident handling plan, and the food safety accident involving more than 10 persons but less than 30 persons has occurred;
- (5) The tableware, drink-ware and containers for ready-to-eat food are not cleaned or disinfected before use, or cleaning or disinfection is disqualified, or the catering service facilities and equipment are not maintained, cleaned and checked regularly as provided, and the food safety accident involving more than 10 persons but less than 30 persons has occurred;
- (6) The food producer or trader arranges a person, who has not obtained the health certificate or who suffers from the disease impeding the food safety as provided by the health administrative department under the State Council, with work in contact with ready-to-eat food, and the food safety accident involving more than 10 persons but less than 30 persons has occurred;
- (7) The food producer or trader fails to sell food as provided, and the food safety accident involving more than 10 persons but less than 30 persons has occurred;
- (8) The health food production enterprise fails to file a record at the food and drug administrative department as provided, or fails to organize production according to the product formula, production technology

and other technical requirements filed, with the products value over RMB 30,000;

- (9) Any enterprise producing formula food for infants and young children fails to file a record of the food raw materials, food additives, product formula and label etc. at the food and drug administrative department, with the products value over RMB 20,000;
- (10) The special food production enterprise fails to set up the production quality management system and to operate it effectively as provided, with the food value over RMB 20,000, or fails to submit the self-inspection report regularly for more than twice;
- (11) The food producer or trader fails to conduct inspection and assessment of the food safety situation regularly, or fails to handle as provided in case of change in production and operation conditions, with the food value over RMB 30,000;
- (12) Schools, kindergartens, nursing institutions for the aged, and construction sites and other centralized dining units fail to fulfill the food safety management responsibility as provided, which has caused the food safety accident;
- (13) The food production enterprise or catering service provider fails to formulate and implement production and trading process control requirements as provided, and the food safety accident involving more than 10 persons but less than 30 persons has occurred;
- (14) Other circumstances as provided by laws and regulations.

Article 176 Under any of the following circumstances, the food and drug administrative department under the People's government at or above the county level shall impose the punishment in accordance with Paragraph 1 of Article 126 of Food Safety Law:

- (1) The food production and trading staffs fail to wear clean work clothes and hats as provided in producing or selling food, or fail to use non-toxic and clean sales tools to sell ready-to-eat food without packaging;
- (2) The food producer or trader fails to set up the food additives use system and record;
- (3) The catering service provider uses tableware and drink-ware not cleaned and disinfected or fails to ask for and keep the qualified disinfection certificate in purchasing tableware and drink-ware from the tableware and drink-ware centralized disinfection service unit or entrusting with the disinfection.

Article 177 Under any of the following circumstances, the food and drug administrative department under the People's government at or above the county level shall impose the punishment on the centralized disinfection unit of tableware and drink-ware in accordance with Paragraph 1 of Article 126 of Food Safety Law:

- (1) Fails to set up sanitary administrators and fails to establish the sanitation management system or sanitation management file as provided;
- (2) Fails to carry on the production activities according to the requirements of hygienic practice;
- (3) Supervision and sampling inspection results have shown tableware and drink-ware to be disqualified.

Article 178 Under any of the following circumstances, the food and drug administrative department under the People's Government at or above the county level will order to rectify and give a warning; in case of refusal to rectify, it will impose a penalty of more than RMB 5,000 but less than RMB 50,000:

- (1) The food trader fails to take such effective prevention measures as dust-proof and fly-proof for ready-to-eat food in bulk to be sold or uses packaging and label not conforming to the food safety requirements;
- (2) The food trader and the edible agricultural products seller fail to separately place the raw and fresh food from cooked products, with cross-contamination hidden danger existing;
- (3) The food storage service provider fails to keep the storage person's identity certificate, license or business license photocopies as provided;
- (4) The food producer and trader fails to set up the food traceability system, resulting in inability to trace the food;
- (5) The third-party online food trading platform provider, food centralized trading market owner, food counter leasor and food exhibition organizer fail to establish the food safety accident handling plan;
- (6) The containers and packaging materials for food raw materials, semi-finished products and finished products are in direct contact with the floor or unclean articles;
- (7) Water from self-provided water source does not conform to the drinking water sanitary standards as provided by the State;
- (8) The catering service provider fails to be equipped with effective tableware and drink-ware disinfection and sanitation facilities as required;
- (9) Such cleaning and disinfection products as detergent and disinfectant used in the food production and trading process do not conform to requirements.

Article 179 Where the food produced or traded by the food producer and trader conforms to the food safety standards, but does not conform to the enterprise standards indicated, the food and drug administrative department may order the food producer and trader to rectify. Where the consumer demands return

or compensation, the food producer and trader shall be liable for civil responsibility in accordance with laws and regulations.

Article 180 Under any of the following circumstances, the food and drug administrative department under the People’s Government at or above the county level may impose the punishment on the third-party online food trading platform provider in accordance with Paragraph 1 of Article 131 of Food Safety Law:

- (1) Fails to provide as required such materials as registration information and trading data of the food and food additives trader who uses the platform;
- (2) Arbitrarily transfers, tampers with, falsifies, or deletes the trading data of the food and food additives trader who uses the platform.

Article 181 Where the food producer and trader illegally disposes of the articles sealed up or detained by the food and drug administrative department in such a manner as concealment, transfer, utilization, sale or destruction, the food and drug administrative department under the People’s Government at or above the county level and other departments shall confiscate the illegal gains, impose a penalty equivalent to more than 10 times but less than 20 times of the value of the concealed, transferred, utilized, sold or destroyed goods and revoke the license; in case of constituting a crime, the criminal responsibilities shall be affixed under the law.

Article 182 “Refuses, obstructs or intervenes” as provided in Paragraph 1 of Article 133 of Food Safety Law includes the following circumstances:

- (1) Delays or avoids supervision and inspection, investigation and handling by the on-site law enforcement officers;
- (2) Prohibits the on-site law enforcement officers from entering the production, trading and storage premises for more than 1 hour;
- (3) Fails to provide relevant contracts, bills, account books and electronic data as required;
- (4) Other circumstances as provided by laws and regulations.

Article 183 Under any of the following circumstances, the competent authority shall impose the punishment according to their respective responsibilities under the criteria of “severe violation” in reference to Paragraph 1 of Article 133 of Food Safety Law:

- (1) Refuses, obstructs, or impedes food safety supervision, management and law enforcement in such a manner as assaulting, insulting, abusing or threatening;
- (2) Destroys, conceals the evidence or the party concerned runs away;
- (3) Retaliates against the reporter and witness.

Article 184 In case of qualification penalty imposed in accordance with Paragraphs 1 and 2 of Article 135, Article 137, Paragraph 2 of Article 138, and Paragraph

1 of Article 139 of Food Safety Law, the food and drug administrative, quality supervisory and other departments under the State Council shall summarize and announce on their websites the names, ID Card numbers and relevant information of the executive in charge being directly responsible, and other persons being directly responsible.

In case that the administrative license applicant conceals relevant information or provides false materials to apply for the administrative license, the administrative organ will not accept or reject the administrative license and give a warning, and the applicant shall not re-apply for such administrative license within one year.

In case that the licensee has obtained the administrative license in such an unjustified manner as cheating and bribery, the administrative organ shall impose the administrative punishment under the law, and the applicant shall not re-apply for such administrative license within three years; in case of constituting a crime, the criminal responsibilities shall be affixed under the law.

Article 185 In case that the food producer or trader falsifies and alters the food production and trading license, product registration certificate, label, description, inspection report, inspection & quarantine certificate, authentication certificate and provides false materials in supervision and inspection, the food and drug administrative department under the People's Government at or above the county level will confiscate the illegal gains, and impose a penalty of more than RMB 50,000 but less than RMB 100,000, and the license shall be revoked in case of the food production and trading license; in case of constituting a crime, the criminal responsibilities shall be affixed under the law.

Article 186 Under any of the following circumstances, the food producer and trader shall be given a severer punishment:

- (1) Its violation behavior has caused serious damage or large social impacts;
- (2) Its violation behavior has caused systematic and regional food safety risks;
- (3) Illegally produces and trades special food;
- (4) Occurrence of common food safety accident for more than twice within 1 year, or of food safety accident above the relatively serious level;
- (5) Subjectively intentional misconduct or gross negligence;
- (6) Other circumstances where a severer punishment shall be imposed under the law.

In case that the same violation behavior has violated several provisions of laws and regulations, the punishment shall be imposed in accordance with the provision for severer punishment.

Article 187 Under any of the following circumstances, the food producer and trader shall be given a lighter or mitigated punishment:

- (1) Have evidence proving no intentional misconduct or gross negligence subjectively, and the circumstances of violation are relatively minor with a relatively small products value, and no harmful consequences caused;
- (2) Be initiative in reporting to the food and drug administrative department, with no harmful consequences caused;
- (3) Be initiative in recalling unsafe food, with no harmful consequences caused, and has taken effective measures to mitigate or eliminate food safety risks;
- (4) Reports and cooperates with the administrative department in investigating and handling other unknown violations, with major meritorious service;
- (5) Other circumstances where a lighter or mitigated punishment shall be imposed under the law.
- (6) Administrative penalty will not be imposed in case of minor violation and rectification in time, with no harmful consequences caused.

Article 188 In case that a medical institution and its working staffs fail to report the food safety accident information as provided, or the disease prevention and control institution fails to make the epidemiological investigation report as required or fails to report within the prescribed time limit, then the health administrative and other departments under the People's Government at or above the county level shall order them to rectify under the law; in case of refusal to rectify, a penalty of more than RMB 5, 000 but less than RMB 50,000 will be imposed.

Article 189 Under any of the following circumstances, the advertisement supervisory management department under the People's Government at or above the county level shall order the accountable advertiser, advertising agent, and advertising publisher to stop publishing, correct in public, and confiscate the advertising fees under the law; in case that the advertising fees are less than RMB 10,000, a penalty of RMB 50,000 will be fined together; in case that the advertising fees are more than RMB 10,000, a penalty of 5 times of the advertising fees will be fined together, and the food and drug administrative department under the People's Government at or above the province level will decide to suspend sale of the food and food additives, and announce to the public. In case of continuous sale, the food and drug administrative department under the People's Government at or above the county level will confiscate the illegal gains and the food and food additives illegally sold, and impose a penalty of more than RMB 20,000 but less than RMB 50,000 together:

- (1) The advertisement is not approved after examination and approval;

- (2) The advertisement approval No. is canceled or revoked;
- (3) Relevant department of the State has ordered it to stop production and sale;
- (4) The advertisement is determined to be disqualified after re-examination by the food and drug administrative departments under the People's Governments of provinces, autonomous regions and municipalities where the advertisement is published;
- (5) Arbitrarily modifies or tampers with the examined and approved advertisement;
- (6) Includes contents prohibited from publishing by laws and regulations.

Article 190 In case of false, exaggerated or deceptive publicity and sale of the health food, the formula food for special medical purpose and other food and food additives in the form of telephone, lecture, conference and organizing tourism etc., the food and drug administrative department under the People's Government at or above the county level will confiscate the illegal gains, and impose a penalty of more than RMB 50,000 but less than RMB 200,000 together; in case of constituting a crime, the criminal responsibilities shall be affixed under the law.

In case that a unit or individual who has known of the violation behavior provided in the preceding paragraph, but still provides premises or other conditions, the food and drug administrative department under the People's Government at or above the county level will order it to stop violation, confiscate the illegal gains, and impose a penalty of more than RMB 50,000 but less than RMB 100,000 together; in case of impairment of the consumer's legitimate rights and interests, it shall be held jointly and severally liable with the food and food additives producer and trader.

Article 191 Where, in respect of production, import and trading of quantitative intake edible special dosage form food, the label and description claims the health functions but it is not registered as the health food as provided, then the food and drug administrative department under the People's Government at or above the county level will investigate and handle in accordance with Paragraph 1 of Article 124 of Food Safety Law. In case of suspicion of a crime, it will be transferred to the public security organ for handling under the law.

Article 192 In case of intentional violation or gross negligence of working staffs of the food and drug administrative, quality supervisory, agriculture administrative, health administrative and other departments under the People's Government at or above the county level, the supervisory organ or appointment and removal organ at the same level will affix the administrative liabilities against the working staff of the department pursuant to relevant provisions. In case of constituting a crime, it will be transferred to the judicial organ for handling.

In case of the occurrence of major food safety violation case and food safety accident due to reasons attributable to the food producer and trader, if there is evidence proving that the working staffs of the food and drug administrative, quality supervisory, agriculture administrative, health administrative and other departments have fulfilled food safety supervisory management responsibilities under the law, they shall be exempt from administrative liabilities.

Article 193 After the food producer and trader has released the recall announcement, relevant food bought by the consumer during the announced recall period will not be subject to punitive compensation and minimal compensation.

In case that the food producer or trader fails to stop sale of relevant products upon receipt of the recall notice, they will be punished in accordance with Paragraph 1 of Article 124 of Food Safety Law.

Article 194 In case that the violation by the food producer and trader is suspected of constituting a food safety criminal case, during the case filing and investigation, review and prosecution, and trial periods, in order to prevent and control the food safety risks, the food and drug administrative and other department may impose such administrative punishment as ordering it to stop production and trading and revoking the license etc. under the law.

#### **Chapter 10 Supplementary Provisions**

Article 195 Meanings of the following terms in the Rules are as follows:

Edible agricultural products refer to plants, animals, microorganisms and their products, which are obtained in planting, cultivating, picking, fishing, facility agriculture, biological engineering and other agricultural activities, and formed by primary processing such as sorting, peeling, husking, crushing, cleaning, cutting, freezing, waxing, grading and packaging, whose basic natural characteristics and chemical properties have not changed.

Catering service refers to service activity of providing food to consumers directly through instant making and processing.

Food safety risk assessment refers to scientific assessment of the bad impacts which may cause to the human health by the biological properties, chemical properties and physical properties in food, food additives and food related products, including hazard identification, hazard characterization, exposure assessment and risk characterization etc.

Food safety risk exchange refers to the process where the food safety interested parties exchange information and opinions on food safety risks, risk related factors and risk perception involved in relevant work.

Health food refers to food which is claimed to have the health functions or aims at supplementing vitamins, minerals and other nutrients, able to adjust physiological functions, not for the purpose of treating disease, having special function components, and suitable for special group of people to take with specified intake amount.

Food in bulk refers to food without quantitative pre-packaging, which needs to be sold quantitatively, including food without packaging and non-quantitative packaging.

Quantitative intake edible special dosage form food refers to food in the special dosage form such as capsule, oral liquid, tablet, granule, and pill, which needs to be taken quantitatively or with daily prescribed intake amount.

Food sub-packing refers to the food production behavior where the food producer or trader divides large packaged food into small ones, containing smaller amount of pre-packaged food through certain technique control, under the precondition that the food safety is not affected for the pre-packaged food which will be directly released on the market. Large packaged food being sold off piecemeal and not being processed into pre-packaged food at the food trading stage will not fall into food sub-packing.

First time import of the health food refers to the health food not in the same formula from the same enterprise in the same country.

Food fast testing method refers to testing technique used in food safety related projects, characterized by fastness, simplicity and sensitivity.

Food safety professional technical personnel refers to personnel with study and practice background in food, biology, chemistry, medicine and other food safety related natural sciences specialties, having professional knowledge and technology in food biological, chemical, and physical properties, food production technologies, food production facilities and equipment characteristics, food contamination sources and food safety risk control requirements, and food safety inspection technologies, and being able to identify and control relevant food safety risks.

Toxic and harmful non-food raw materials refers to substance prohibited by laws and regulations from being added or used in food production and trading; substances on the List of Non-edible Food Substances Likely to be Illegally Added into Food and List of Substances Likely to be Illegally Added into health Food announced by relevant department under the State Council; pesticides, veterinary drug and other toxic and harmful substances prohibited from using by announcement of relevant department under the State Council; other substances which endanger the human health.

Flaw in label and description of the food and food additives means circumstances of word space, font size, punctuation marks, simplified and traditional forms, and rounding interval etc. in label and description of food and food additive, which is not non-conforming to relevant requirements, and which will not affect food safety, nor mislead food safety consumption of consumers.

Products value means the total amount of the market price of the food, food additives, and food related products illegally produced or traded by the producer and trader, or the edible agricultural products illegally traded.

Among them, the raw materials and food additives are calculated according to the purchase price, semi-finished products are calculated according to the raw materials price plus other costs, and finished products are calculated according to the sale price. The sale price of a single product produced shall be calculated at the unit price indicated in sale, and the sale price of a single product sold shall be calculated at the unit price indicated on the goods label by the seller. In case of no price marked by the producer and trader, it shall be calculated at the average unit price of the market retail price in the region when the product is investigated and handled.

Illegal gains mean all the operating income from conducting the illegal activities. In case of no intentional violation by the food producer or trader, who has fulfilled such legal obligations as incoming inspection, and asking for certificates and bills, and has evidence proving that it is not aware that the raw materials purchased or food traded does not conform to the food safety standards, with no harmful consequences caused. In calculating the amount of illegal gains, the purchase price of the food sold or raw materials may be deducted.

Article 196 The filing mentioned herein means the process of administrative counterpart's registration, record-filing, announcement and keeping on file for future reference of relevant materials at relevant department pursuant to pertinent provisions.

For filing of enterprise standard, and relevant filings of health food and formula food for infants and young children, relevant departments shall not grant administrative license in a disguised form through review, determination, examination and approval etc.

Article 197 In case of no explicit provisions on food additives in the Rules, the provisions of the Rules on relevant food shall apply, *mutatis mutandis*.

Article 198 The frontier ports named in the Rules mean the international gateways for entry or exit of personnel, luggage, goods, containers, means of transport, articles and postal parcels, and the units and areas providing services for entry or exit of personnel, luggage, goods, containers, means of transport, articles and postal parcels.

The food and drug administrative department is responsible food safety administration in areas other than frontier ports as ports, airports, stations, ground boundaries, and boundary rivers.

Article 199 In order to ensure work requirements of special food registration application, technical evaluation fee and inspection and validation fee shall be paid for application for registration of health food, formula food for special medical purpose, and formula milk powder products for infants and young children. The charging standard will be formulated by the financial department and competent pricing department under the State Council in conjunction with the food and drug administrative department under the State Council.

Article 200 The Rules shall become effective as of dd-mm-yy.