Implementation Rules of Food Safety Law of the People’s Republic of China
(Revised draft for comment)
China Food and Drug Administration
(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 provincial 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.

**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 provincial 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 provincial 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,
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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 notify 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 provincial 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 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 provincial 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.
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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 to 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 supervision, 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 supervision, 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 supervision, inspection and quarantine department under the State Council, in conjunction with relevant departments under the State Council.