Implementation Rules of Food Safety Law of the People’s Republic of China

Chapter 1 General Provisions

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

Article 2 The local People’s Government at or above county level shall perform the responsibility specified in the Food Safety Law, and improve the ability for supervision and administration of food safety, to ensure supervision and administration of food safety; establish and improve the coordination mechanism between food safety regulatory authorities, and integrate and improve the food safety information network, to realize sharing of food safety information and food inspection and other technical resources.

Article 3 Food manufacturers and traders shall conduct the production and trading activities according to laws, regulations and food safety standards, establish and improve the food safety management system, and take effective management measures to ensure the food safety.

Food manufacturers and traders shall be responsible for the safety for the food manufactured or traded, and for the public, and assume the social responsibility.

Article 4 Food safety regulatory authorities shall publish the food safety information according to Food Safety Law and the Rules, and provide convenience to the public regarding the consulting, complaint and impeaching, and any organization or individual is entitled to enquire about the food safety information from relevant departments.

Chapter 2 Food Safety Risk Surveillance and Assessment

Article 5 The health administrative authorities under the State Council in conjunction with the quality supervision, industrial and commercial administration, food and drug administration (FDA),
commerce and industry and information and other authorities under the State Council shall prepare the national food safety risk surveillance plan specified in Article 11 of Food Safety Law, according to preparation and revision of food safety risk evaluation and food safety standard, food safety regulation, etc.

Article 6 The health administrative authorities of provinces, autonomous regions and central municipalities (“the Provincial health administrative authorities”) shall arrange the quality supervision, industrial and commercial administration, FDA, commerce and industry and information and other departments at the same level to prepare the local food safety risk surveillance program, according to Article 11 of Food Safety Law, and report to the health administration authorities under the State Council for filing.

The health administration authorities under the State Council shall inform the filing to the quality supervision, industrial and commercial administration, FDA, commerce and industry and information and other departments under the State Council.

Article 7 The health administration authorities under the State Council in conjunction with other relevant departments shall make adjustments to the national food safety risk surveillance program, according to Article 12 of Food Safety Law, and if necessary, adjust the national food safety risk surveillance program based on the disease information reported by medical institutions.

After adjustment of the national food safety risk surveillance program, the provincial health administrative authorities shall make the appropriate adjustment to the local food safety risk surveillance program according to the actual local condition.

Article 8 The medical institution, upon finding any patient of food borne diseases, food poisoning, or suspected food borne diseases or food poisoning among admitted patients, shall timely report to the health authorities under the People’s Government at or above the county level.

The health administrative authorities receiving the report shall summarize and analyze the disease information, and timely report to the People’s Government at the same level and report to the higher level health administrative authorities; if necessary, directly report to the health administration authorities under the State Council, and report to the People’s Government at the same level and the higher level health administrative authorities.

Article 9 The health administration authorities at or above provincial level shall, in conjunction with the technical institution appointed by the quality supervision, industrial and commercial administration and FDA at the same level, conduct the food safety risk surveillance.

The technical institution responsible for food safety risk surveillance shall perform surveillance according to the food safety risk surveillance plan and the monitor program, to ensure the true and correct data is obtained; and submit the monitor data and analysis results to the health administration authorities at or above provincial level and the authorities assigning the monitor task, according to the food safety risk surveillance plan and the monitor program.

The personnel for food safety risk surveillance shall collect the samples and relevant data, and can enter the site of the edible agricultural product planting/raising, food production, food distribution or catering services. The samples collected shall be paid according to the market price.

Article 10 When any potential problem of the food safety is indicated in the analysis results of the food
safety risk surveillance, the health administrative authorities under the provincial People’s Government shall timely inform the relevant information to the People’s Government of the cities (with districts) and counties and their health administrative authorities.

Article 11 The health administration authorities under the State Council shall gather and summarize the data and analysis results of food safety risk surveillance, and inform the quality supervision, industrial and commercial administration and FDA, commerce and industry and information and other authorities under the State Council.

Article 12 Under any of the following circumstances, the health administration authorities under the State Council shall arrange the food safety risk evaluation:

1) The risk assessment is required for providing scientific basis in preparing or revising the national food safety standard;

2) When the risk assessment is required to determine the key areas and key types for supervision and management;

3) When any new factor likely to affect the food safety is found;

4) When it is necessary to judge whether any factor becomes the potential problem to the food safety;

5) Other cases that the health administration authorities under the State Council deems necessary to conduct the risk assessment.

Article 13 The agricultural administration, quality supervision, industrial and commercial administration and state FDA and other authorities under the State Council shall provide recommendations on food safety risk evaluation to the health administration authorities under the State Council according to Article 15 of Food Safety Law, including:

1) Source and nature of risks;

2) Data and conclusions of relevant test;

3) Scope of risk;

4) Other information.

The local agricultural administration, quality supervision, industrial and commercial administration, FDA and other departments at or above county level shall assist to gather the information on food safety risk evaluation specified in the above paragraphs.

Article 14 The health administration and agricultural administration under the provincial People’s Government or above shall mutually inform the information on food safety risk surveillance, edible agricultural product quality safety risk surveillance, etc.

The health administration and agricultural administration under the State Council shall timely inform the results of food safety risk evaluation, edible agricultural product quality safety risk evaluation, etc. to each other.
Chapter 3 Food Safety Standard

Article 15 The health administration authorities under the State Council shall, in conjunction with the agricultural administration, quality supervision, industrial and commercial administration and FDA, commerce and industry and information and other authorities under the State Council, prepare the planning and implementation plan of the national food safety standard, for which the opinions shall be gathered from the public.

Article 16 The health administration authorities under the State Council shall select the units with the appropriate technical ability to draft the national food safety standard, preferably, jointly consisting of the research institutions, education institutions, academic organizations, industrial associations, etc.

The health administration authorities under the State Council shall publish the draft of the national food safety standard to the public and gather the opinion from the public.

Article 17 The health administration authorities under the State Council is responsible for organizing the National Food Safety Standard Review Committee as specified in Article 23 of Food Safety Law.

The National Food Safety Standard Review Committee is responsible for review the scientific level, applicability and others of the drafts of national food safety standard.

Article 18 The provincial health administrative authorities shall inform the enterprise standards submitted by companies according to Article 25 of Food Safety Law to the agricultural administration, quality supervision, industrial and commercial administration, FDA, commerce and industry and information and other departments at the same level.

Article 19 The health administration authorities under the State Council and the provincial health administrative authorities shall, in conjunction with the agricultural administration, quality supervision, industrial and commercial administration, FDA, commerce and industry and information and other departments at the same level, track and evaluate implementation of the national and local food safety standards, and make appropriate revisions according to the evaluation results.

The agricultural administration, quality supervision, industrial and commercial administration, FDA, commerce and industry and information and other departments under the State Council or the provincial People’s Government shall gather and summarize the problems finding during implementation of the food safety standards, and inform the health administrative authorities at the same level.

Food manufacturers and traders and food industry associations, upon finding any problem in implementing the food safety standard, shall immediately report to the food safety regulatory authorities.

Chapter 4 Food Manufacture and Trade

Article 20 Any party applying for establishment of the food manufacture company shall first apply for pre-approval of the company name, obtain the permit for food production according to the Food Safety Law, and handle the business registration. The quality supervision and
management administration at or above county level shall review the relevant documents, verify the production site and inspect the products according to the relevant laws and regulations; and approve the company when the relevant documents and site meet the requirements, and the products conform to the food safety standards or requirements.

Other food manufacturers and traders shall first obtain the food production permit, food distribution permit and catering service permit according to law, and handle the business registration; and small food workshops and food pedlars, when there are specific requirements of laws and regulations, shall be handled accordingly.

The effective period of the food production permit, food distribution permit and catering service permit shall be 3 years.

Article 21 When there is any change in the production or trading conditions of the food manufacturer or trader, and the conditions no long meet the requirements, the food manufacturer or trader shall take immediate correction measures; when there occurs any food safety incident with potential risk, stop food production or trading activities immediately, and report to the local county level quality supervision, industrial and commercial administration or FDA; and when new formalities for permit are required, handle accordingly.

The quality supervision, industrial and commercial administration and FDA at or above county level shall strengthen the routine supervision and inspection of the food production and trading activities of the food manufacturer and trader; when finding any case not meeting the requirements for food production and trading requirements, order for correction, and punish according to law; and when it still fails to meet the conditions for production and trading permit, cancel the relevant permit according to law.

Article 22 The food manufacturer and trader shall arrange employees to receive training on food safety, study the laws, regulations, rules, standards and other knowledge on food safety, and establish the training files, according to Article 32 of Food Safety Law.

Article 23 The food manufacturer and trader shall establish the employee filing system according to Article 34 of Food Safety Law. The food manufacturer and trader shall transfer any person who works in direct contact with food for consumption and has a digestive tract infection including dysentery, typhus, viral hepatitis A, and active pulmonary tuberculosis, purulent or weeping skin diseases that adversely affect food safety, to the post with no effect to the food safety.

The personnel of food manufacture and trade shall have the physical examination according to Article 34 (2) of Food Safety Law, including the items specified by the province, autonomous region or central municipality concerned.

Article 24 The food manufacturer and trader shall establish the incoming product inspection and record system, and food shipment inspection and record system, according to Article 36 (2), Article 37 (1) and Article 39 (2) of Food Safety Law, to correctly record the items required by law, or keep the incoming product or sales instruments containing the relevant information. The records and instruments shall be kept for at least 2 years.

Article 25 For the food manufacture group adopting centralized material purchase, the Headquarters may centrally examine the license and product compliance certificate of the suppliers, conduct the incoming product inspection and keep the records; for food materials unable to provide the
Article 26 The food manufacturer shall establish and implement the material acceptance, production process safety management, storage management, equipment management, nonconforming product management and other food safety management systems, and continuously improve the food safety assurance system, to ensure the food safety.

Article 27 The food manufacturer shall prepare and implement the control requirements for the following aspects, to ensure the shipped foods meet the food safety standard:

1) Purchase, acceptance, loading and other aspect of materials;

2) Production techniques, equipment, storage, packaging and other key production procedures;

3) Inspection of materials, semi-finished products or shipment of finished products, etc.;

4) Transport and delivery.

Upon any condition not conforming to the control requirements during the food production process, the food manufacturer shall immediately investigate the reasons and take the corrective measures.

Article 28 The food manufacturer shall record the incoming product inspection and food shipment inspection according to Article 36 and Article 37 of Food Safety Law, and also correctly record the safety management of the food production process. The records shall be kept for at least 2 years.

Article 29 The food wholesale trader shall record the details of the foods sold, including the description, specification, quantity, production Lot No., shelf life, purchaser and contact, sales date, etc., or keep the sales instruments containing the relevant information. The records and instruments shall be kept for at least 2 years.

Article 30 The state encourages the food manufacturers and traders to adopt the advanced technical means to record the items required by Food Safety Law and the Rules.

Article 31 The catering service provider shall prepare and implement the material purchase control requirements, to ensure all the materials meet the food safety standard.

The catering service provider shall not process or use any food or material to be processed when finding any corruption, deterioration, or abnormal condition of the sensory aspect or appearance during the process of preparation or processing.

Article 32 The catering service provider shall make regular maintenance to the facilities and equipment for food processing, storage, display, etc.; and regular cleaning and calibration of the heat preservation facilities and cold storage and refrigeration facilities.

The catering service provider shall clean and sterilize the tableware and drinkware according to requirements, and not use the tableware and drinkware not cleaned or sterilized.

Article 33 The food manufacturer shall make harmless treatment or destroy to the foods recovered from callback according to Article 53 of Food Safety Law, to avoid them return to the market. For the foods for callback due to the label, mark or instruction not conforming to the food safety standard, the food manufacturer can continue to sale the foods after taking the remedies and
the food safety can be ensured; and the remedies shall be informed to customers when selling such foods.

The quality supervision, industrial and commercial administration and FDA at or above county level shall record the callback foods of the food manufacturer not conforming to the food safety standard, and the foods stopped for trading of the food traders not conforming to the food safety standard, and place in the food safety credit files of the food manufacturers and traders.

Chapter 5 Food Inspection

Article 34 The applicant shall apply for re-inspection from the food inspection institutions responsible for re-inspection (“re-inspection institution”) according to Article 60 of Food Safety Law, indicating the reasons.

The list of re-inspection institutions shall be jointly published by the certification and approval administration, health administration, agricultural administration and other authorities under the State Council. The re-inspection results issued by the re-inspection institutions shall be final.

The applicant can select the re-inspection institution at its own discretion. The re-inspection institution and the preliminary inspection institution shall not be the same one.

Article 35 When any food manufacturer or trader has objection to the result of the sampling inspection and applied for re-inspection according to Article 60 of Food Safety Law, and the results of the re-inspection show the food is qualified, the cost of the re-inspection shall be on account of the department conducting the sampling inspection; while when the results of the re-inspection show the food is unqualified, the cost of the re-inspection shall be on account of the food manufacturer or the trader.

Chapter 6 Food Import and Export

Article 36 The food importer shall apply for inspection to the exit-entry inspection and quarantine authorities of the local customs with the contract, invoice, packing list, bill of lading and other necessary documents and relevant approval documents. When the foods are qualified in the inspection, the customs shall release the foods against the clearance certificate issued by the exit-entry inspection and quarantine authorities.

Article 37 When importing the food without applicable national food safety standard, or the new type of food additives or food related products for the first time, the importer shall submit the approval documents required in Article 63 of Food Safety Law to the exit-entry inspection and quarantine authorities, and the exit-entry inspection and quarantine authorities shall conduct the inspection according to the requirements of the health administration authorities under the State Council.

Article 38 When finding any substance in the imported foods not specified in the national food safety standard and possibly endangering the human health, the national exit-entry inspection and quarantine authorities shall report to the health administration authorities under the State Council according to Article 12 of the Food Safety Law.

Article 39 The foreign food manufacturer exporting foods to China shall register according to Article 65
of Food Safety Law, and the registration shall be effective for 4 years. When discovering the registered foreign food manufacturer providing falsified documents or any serious food safety accident is caused to the import food due to its reasons, the national exit-entry inspection and quarantine authorities shall cancel its registration and publish to the public.

Article 40 The imported food additives shall be provided with the label and instructions in Chinese, meeting the Food Safety Law and other laws, regulations and national food safety standards in China, indicating the place of origin of the food additive, and the name, address and contact of the agent in China. The food additives without the label and instructions in Chinese, or the label and instructions not meeting the requirements herein shall not be imported.

Article 41 The exit-entry inspection and quarantine authorities shall inspect the imported foods according to Article 62 of Food Safety Law, and conduct the supervision and sampling inspection according to Article 68 of Food Safety Law, and the specific measures shall be prepared by national exit-entry inspection and quarantine authorities.

Article 42 The national exit-entry inspection and quarantine authorities shall establish the information gathering network, and gather, summarize and report the following information according to Article 69 of Food Safety Law:

1) The food safety information obtained by the exit-entry inspection and quarantine authorities during inspection and quarantine of the import/export foods;

2) The import food safety information provided by the industrial associations and customers;

3) The food safety information and risk warning information issued by international organizations and foreign governmental authorities, and the food safety information provided by foreign industrial associations and other organizations and customers;

4) Other food safety information.

The authorities shall take appropriate measures upon receiving such notice.

The food safety regulatory authorities shall timely report the import/export food safety information received to national entry-exit inspection and quarantine authorities.

Chapter 7 Response to Food Safety Accidents

Article 43 Upon occurrence of any food safety accident, then concerned entity shall immediately take the control measures, e.g. sealing up the foods and materials, tools, equipment, etc. causing or likely to cause the food safety accident, and report to the health administrative authorities under the People’s Government at the county level within 2 hours upon occurrence of the accident.

Article 44 The food safety accident shall be investigated in a realistic and scientific manner, to timely and correctly find out the nature and reasons, determine the responsibilities and propose the corrective measures.

The departments participating in investigation of the food safety accident shall perform the respective duty and cooperate with each other under the coordination of the health administrative authorities, to improve the working efficiency for investigation and treatment of the accident.
The measures for investigation and treatment of the food safety accident shall be prepared by the health administration authorities under the State Council with other relevant departments under the State Council.

Article 45 The departments participating in investigation of the food safety accident shall have the right to inquire about the accident from the relevant entities and individuals, and require to provide the documents and samples.

The relevant entities and individuals shall cooperate in investigation and treatment of the food safety accident, and shall not refuse to provide the documents and samples as required.

Article 46 Any entity or individual shall not impede or interfere with the investigation and treatment of the food safety accident.

Chapter 8 Supervision and Administration

Article 47 The local People’s Government at or above county level shall prepare the annual food safety supervision and management plan according to Article 76 of Food Safety Law, including sampling inspection of foods, and the sampling inspection shall be intensified for the staple and supplementary foods dedicatedly for infants, old people, patients and other specific populations.

The agricultural administration, quality supervision, industrial and commercial administration and FDA at or above county level shall conduct the sampling inspection according to the annual food safety supervision and management plan, and the costs for buying the samples, the inspection fees, etc. for the sampling inspection shall be paid by the financial authorities of the same level.

Article 48 The county level People’s Government shall centrally organize and coordinate the health administration, agricultural administration, quality supervision, industrial and commercial administration and FDA at the same level to conduct the supervision and management of the food manufacturers and traders in the region according to law; and for the food manufacturers and traders with the higher risk of food safety accident, the supervision and management shall be intensified.

After the health administration authorities under the State Council publishes the food safety risk warning information, or the health administrative authorities the provincial People’s Government publish the food safety risk surveillance information according to Article 10 herein, the cities (with districts) and the county level People’s Government shall organize the health administration, agricultural administration, quality supervision, industrial and commercial administration and FDA at the same level to take the appropriate measures, to avoid occurrence of the food safety accident.

Article 49 The health administration authorities under the State Council shall publish the list and test methods of non-food chemical substances and other substances possibly endangering the human health that are added or possibly added in foods, according to the disease information, information on supervision and management, etc.; and the quality supervision, industrial and commercial administration and FDA under the State Council shall take the appropriate regulatory measures.
Article 50 The quality supervision, industrial and commercial administration and FDA authorities can adopt the quick testing methods validated by the quality supervision, industrial and commercial administration and FDA under the State Council for preliminary screening during the food safety supervision and management; for the food possibly not conforming to the food safety standard indicated in the results of the preliminary screening, the test shall be conducted according to Article 60 of Food Safety Law. The results of the preliminary screening shall not be taken as the basis for enforcement.

Article 51 The routine food safety regulation information specified in Article 82 (2) of Food Safety Law includes:

1) Information on implementation of administrative permit according to Food Safety Law;
2) List of foods, food additives and food related products ordered for stop of production or trading;
3) Information on investigation and punishment of illegal food production and trade;
4) Information on special inspection and rectification;
5) Other routine food safety regulation information specified by laws and regulations.

Any information in the above paragraph involving the responsibility of two or more food safety regulatory authorities shall be published jointly by the authorities concerned.

Article 52 The food safety regulatory authorities shall publish the information according to Article 82 of Food Safety Law, and explain and clarify the possible hazard from the relevant food.

Article 53 The health administration, agricultural administration, quality supervision, industrial and commercial administration and FDA, etc. shall disclose the email or telephone NO. to the public, to receive the consulting, complaint and impeaching; and upon receiving the consulting, complaint and impeaching, reply, verify and handle according to Article 80 of Food Safety Law, record the reply, verification and handling, and keep the records.

Article 54 The industry and information, commerce and other authorities under the State Council shall prepare the development planning and industrial policies of the food industry according to its responsibility, take the appropriate measures to promote the industrial structure optimization, and strengthen guidance on credibility system construction of the food industry, to promote the sound development of the food industry.

Chapter 9 Legal Liability

Article 55 When the food manufacturer or trader fails to handle according to Article 21 herein upon any change of the production or trading conditions, the relevant authorities shall order it to make correction, or give warning; and when any serious consequence is caused, give punishment according to Article 85 of Food Safety Law.

Article 56 The catering service provider failing to prepare and implement the material purchase control requirements according to Article 31 herein shall be punished according to Article 86 of Food Safety Law.

The catering service provider failing to inspect the foods or materials to be processed
according to Article 31 (2) herein, or discovering corruption, deterioration or other abnormal condition in sensory aspect or appearance but still processing or using them shall be punished according to Article 85 of Food Safety Law.

Article 57 Under any of the following circumstances, punishment shall be given according to Article 87 of Food Safety Law:

1) The food manufacturer fails to establish and implement the food safety management system according to Article 26 herein;

2) The food manufacturer fails to establish and implement the production process control system according to Article 27 herein or, fails to take corrective measures when discovering any condition not conforming to control requirements during the food production process;

3) The food manufacturer fails to record the safety management during the food production process and keep the relevant records according to Article 28 herein;

4) The trader for food wholesale business fails to record the sales information, keep the record or sales instruments according to Article 29 herein;

5) The catering service provider fails to conduct regular maintenance, cleaning and calibration of the equipment and facilities according to Article 32 (1) herein;

6) The catering service provider fails to clean and sterilize the tableware and drinkware according to Article 32 (2), or uses the tableware and drinkware not cleaned or sterilized.

Article 58 The imported food additives not meeting the requirements of Article 40 herein shall be forfeited by the entry-exit inspection and quarantine authorities; when the value of the imported illegal food additives is less than RMB10,000, the fine of RMB2000 – 50,000 shall be imposed; and when the amount is more than RMB10,000, the fine of 2 – 5 folds of the value of the goods shall be imposed.

Article 59 Any medical institution failing to report the disease information according to Article 8 herein shall be ordered for correction and given the warning by the health administrative authorities.

Article 60 Any entity failing to take measures and report upon occurrence of any food safety accident according to Article 43 herein shall be punished according to Article 88 of Food Safety Law.

Article 61 When the local People’s Government at or above county level failing to perform its statutory duty for food safety supervision and management, giving rise to severe food safety accident and causing serious social impact in the region, the directly responsible officer and other directly responsible personnel shall be given the punishment of a special demerit, demotion, removal from office or dismiss.

When the health administration, agricultural administration, quality supervision, industrial and commercial administration and FDA at or above county level or other administrative departments failing to perform its statutory duty for food safety supervision and management, fails to make proper routine supervision and inspection, or abuse its authority, derelicts the duty or practices favoritism, the directly responsible officer and other directly responsible personnel shall be given the punishment of a special demerit, or demotion; when any serious consequence is caused, removal from office or dismiss; and the chief principal shall
Chapter 10 Miscellaneous

Article 62 The following terms shall have the meanings as follows:

**Food safety risk evaluation**: the scientific evaluation of the possible adverse effect on human health from the biological, chemical or physical hazards of food and/or food additives, including identification of the hazard, description of hazard features, exposure evaluation, description of risk features, etc.

**Catering service**: the service activities of providing foods and consumption sites and/or facilities to customers, through the prompt preparation, processing, marketing, service labor, etc.

Article 63 The agricultural administration under the People’s Government at or above county level is responsible for the quality safety risk surveillance and risk assessment of edible agricultural products according to Law of the People’s Republic of China on Agricultural Product Quality.

The exit-entry inspection and quarantine authorities shall be responsible for supervision and administration of foods at the border port, according to Food Safety Law, the Rules and relevant laws and regulations.

FDA shall execute the strict control of the food with the claim for specific healthcare functions, and measures shall be prepared separately by the State Council.

Article 64 The Rules become effective from issuance.