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## **Implementation Rules of Food Safety Law of the People’s Republic of China** (Revised Draft)

### **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, establish and improve food safety administration system, take effective measures to prevent and control food safety risks to ensure food safety.

**Article 3** The Food Safety Commission of the State Council shall be responsible for analysing the situation of food safety, planning and directing the food safety work; formulating and putting forward major food safety policies and measures; urging the implementation of the responsibilities on food safety supervision and administration. Food safety commission and its executive office of People’s Government at or above the county level shall carry out its work in accordance with the duties stipulated by People’s Government at the corresponding level.

The executive office of the food safety commission shall undertake the daily

work of the commission.

**Article 4** The People's Government at or above the county level shall implement the chief executives responsibility system for food safety supervision and administration work, strengthen capacity building of food safety supervision and administration, establish a unified and authoritative food safety supervision and administration system.

The food and drug administrative department of the People's Government at or above the county level and other relevant departments shall perform their duties according to laws, strengthen coordination, and effectively carry out the food safety supervision and administration work.

**Article 5** The People's Government and sub-district office at township level shall support the food and drug administrative department of the People's Government at the county level and its resident to carry out the food safety supervision and administration work according to the law.

**Article 6** The State has incorporated food safety knowledge into the curriculums of national quality-oriented education and primary and secondary school education, to popularise scientific elementary knowledge and legal knowledge associated with food safety and raise the food safety awareness of the whole society.

**Article 7** Institutions and individuals that have made conspicuous achievements in the food safety work shall be granted commendations and rewards in accordance with the provisions of the Ministry of Human Resources and Social Security and Food and Drug Administration.

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

**Article 8** Provincial, autonomous regional and municipal level public health administrative department shall establish food safety risk monitoring and consultation mechanism together with food and drug administration department, quality supervision departments, to summarize and analysis risk monitoring data, assess food safety risks, deliver the monitoring and analysis report of food safety risks, and report to the provincial, autonomous regional and municipal governments, and the public health administrative department under the State Council.

**Article 9** In case that the results of food safety risk monitoring show there is a food safety hazard, the food and drug administrative department, after confirming the necessity to inform relevant food producers and operators through further investigation, shall inform them promptly.

The food producers and operators receiving notice shall carry on self-inspection, in case finding that their food does not conform to food safety standards or have evidence proving it may be harmful to human health, shall stop the production and operation and recall food products in accordance with Article 63 of the Food Safety Law, and promptly report to food and drug administrative and other relevant departments that issued the notice.

**Article 10** In case that the departments of public health administration and food and drug administration under the State Council, find that the safety of pesticides, fertilizers, veterinary drugs, feeds and feed additives, etc., is required to be assessed, they shall put forward the suggestion for risk assessment to agriculture administrative department under the State Council. Agriculture administrative department under the State Council shall timely conduct risk assessment and notify the relevant departments under the State Council of the assessment results.

**Article 11** The public health administrative department under the State Council shall, according to the food safety risk assessment work, organise and conduct basic research work on food consumption, factors affecting food safety, total dietary, etc.

**Article 12** The food and drug administrative department under the State Council shall, in conjunction with other relevant departments, establish a food safety risk communications mechanism and encourage and support food producers and traders, food safety technical institutions, food-related industrial associations, scientific research institutes, food industry associations, consumers' associations, lawyers' associations and news media, etc., to participate in the food safety risk communications work.

The food and drug administrative department under the State Council shall, in conjunction with other relevant departments, establish the advisory committee of food safety risk communications to provide consultations and suggestions. The advisory committee of food safety risk communications shall be composed of experts in medicine, agriculture, food, nutrition, biology, environment, inspection

and quarantine, journalism and communication and law.

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

**Article 13** The public health administrative department under the State Council shall, in conjunction with food and drug administration, quality supervisory and agricultural administrative departments, etc., under the State Council, develop national food safety standards planning and the annual implementation plan. The national food safety standards planning and the annual implementation plan shall seek public consultations.

**Article 14** Such local food safety standards concerning Health food, formula food for special medical purpose, infant formula food and new food ingredients do not belong to the range of local specialties, and the local standards for food safety shall not be formulated for the above-mentioned foods.

**Article 15** The public 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 public health administrative departments under the State Council for record-filing.

Where the public health administrative departments under the State Council find the violations of food safety standards and national laws and regulations, it shall be rectified in a timely manner.

Once a national food safety standard is published and implemented, the corresponding local food safety standard will be eliminated. The public health administrative departments of the People's Governments of provinces, autonomous regions and municipalities shall publish its abolishment in a timely manner.

**Article 16** When food production enterprises establish enterprise standards, they shall disclose the enterprise standards for free public inspection. Food production enterprises shall develop food safety indicators that are stricter than the national food safety standards or local enterprise standards, and file their record to the public health administrative departments under the People's Governments of provinces, autonomous regions and municipalities. The public health administrative departments under the People's Governments of provinces, autonomous regions and municipalities shall publish enterprise standards for filing on their websites.

## Chapter 4 Food Production and Operation

**Article 17** Enterprises engaging in food production, food sales and catering services shall obtain food production licenses according to law. The food production license is valid for 5 years, and the license for food sales and catering service is valid for 3 years. Sales of edible agricultural products do not require any licenses.

**Article 18** Food and drug administrative department under People's Government at or above the county level shall strengthen the daily supervision and inspection on the production and trading activities of food producers and traders; for those not complying with the requirements of food production and trading, the department shall order to make correction and deal with it according to the law; for those no longer meeting the conditions for food production and operation, the department shall revoke their license according to law.

**Article 19** The public health administrative department under the State Council shall publish the new food ingredients, new varieties of food additives, catalogue of new varieties for food-related products as well as applicable national food safety standards.

The public health administrative department under the State Council shall, in conjunction with food and drug administrative department under the State Council, update the catalogue of substance traditionally considered as both food and Chinese medicine in a timely manner.

**Article 20** The food and drug administrative department under the State Council shall, in conjunction with agricultural administrative department and other relevant departments under the State Council, clarify basic requirements for food safety whole-process of food safety traceability and guide food producers and traders to establish and improve the food safety traceability system.

**Article 21** Food producers and traders shall establish food safety traceability system, and truthfully, accurately and completely record and keep the information of purchase inspection, factory inspection, food sales, etc., in accordance with the provisions of the Food Safety Law, and ensure the traceability of food. The establishment of food safety traceability system shall focus on high risk food, food sold in large quantities and infant formula food and other food for special groups.

**Article 22** The 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 of the enterprise with focuses on supplier management, purchase and factory inspection, production and trading control, food safety self-inspection, etc. The food safety management staff of food production and trading enterprises shall assist the main person in charge of food safety in the enterprises to carry out food safety administration works.

**Article 23** Food production and trading enterprises shall strengthen training and evaluation of food safety management staff. Food safety management staff, with food safety management ability, shall master food safety laws, regulations, standards and professional knowledge that are applicable to their jobs. The food and drug administrative department shall conduct random supervision and examination on the enterprise's food safety management staff. The guidelines for the examination and evaluation will be designed and published by the food and drug administrative department under the State Council.

**Article 24** In the event of entrusting the production of foods and food additives, the entrusted party shall obtain food production license and food additives production license. The entrusting party shall be responsible for the safety of the entrusted food and food additives production, and shall supervise the production behaviour of the entrusted party. The entrusted party shall carry out production in accordance with laws, regulations, food safety standards and the contract.

**Article 25** During the production and trading, food producers and traders shall not purchase, use, store, or transport non-edible chemical substances, explicitly prohibited by the state, that may have added to the food and other substances that may be harmful to human health.

**Article 26** For food requiring irradiation, the food producers and traders shall entrust company with relevant qualifications to conduct irradiation and inspect and mark in accordance with the relevant standards of irradiated food.

**Article 27** Where store and transport the food with temperature, humidity and other special requirements, the heat preservation facilities, cold storage and

freezing facilities shall be equipped and maintain effective operation.

**Article 28** The food producers and traders entrusting food storage and transportation shall conduct investigation on entrusted party's capability of ensuring food safety, and supervise the entrusted party to store and transport food in accordance with the food safety requirements. The entrusted party shall strengthen the management in food storage and transportation, and ensure the food storage and transportation conditions are in compliance with the food safety requirements.

Where party entrusted to store or transport food shall truthfully record the food's name, specification, quantity, production date or batch number, the start and end date of storage or transportation, and the name, address, and contact information of entrusting party and recipient.

**Article 29** The producers and traders of non-food products specializing in food storage operation shall, within 30 working days after obtaining the business license, report to the local food and drug administrative department under the People's Government at the county level for record-filing.

**Article 30** Catering service providers entrusting tableware and drinkwares centralised disinfection service company for disinfection shall check and keep the copy of the company's business license and disinfection qualification certificates.

**Article 31** The school canteens, kindergartens, institutions for the aged, construction sites and other centralised dining units shall regularly carry out self-inspection on canteen food safety, and shall promptly eliminated the food safety hazards when found.

Whoever contracts and operate the canteens of collective dining units shall obtain catering service licenses according to the law, and be responsible for the food safety in the canteen. Centralised dining units shall urge the contractor to implement the food safety management system.

**Article 32** The food producers and traders shall store the deteriorated, over shelf life or recalled food separately in a clearly marked place, take timely measures such as harmless treatment and destroy, and make truthful records.

**Article 33** The People's Governments at or above the county level shall build facilities for the harmless treatment and destroy of food if necessary. Food producers and traders may, in accordance with regulation, use the facilities built by the government to conduct the harmless treatment and destroy of food.

**Article 34** Food and drug administrative department under People's Government at the county level shall clarify the food safety management requirements for group dining activities, and strengthen the guidance on the organisers and contractors of activities and the lessors of tableware, drinkware and other equipment.

**Article 35** In the event of collective trading market and exhibition engaging food operation, the owner and organiser shall report to the food and drug administrative department under People's Government at the county level for record-filing before opening the market or exhibition.

**Article 36** Third-party online food trading platform providers shall properly keep the registration information and the transaction data of food producers and traders joining the platform. In case that the food and drug administrative department need to obtain relevant information during food safety supervision and inspection, case investigation and settlement, the third-party online food trading platform providers shall provide the information as required. The information provided by the third-party online food trading platform providers shall be kept confidential by the food and drug administrative department.

**Article 37** To substances prohibited by the food safety standards, food producers and traders shall not use and claim that the above-mentioned substances are not added in the food label, description and advertisement.

Food other than health food shall not be claimed with health care function.

**Article 38** False publicity on food in any forms including conferences, lectures, and health consultation is prohibited. The food and drug administrative department shall strengthen the supervision and inspection on the sales of food through conferences, lectures, or health consultation, etc. Any false publicity, if found, shall be dealt with promptly.



**Article 39** In case the production technology of health food involves pre-treatment processes of extraction and purification of ingredients, the production enterprise must have corresponding ingredient pre-treatment capability and carry out the pre-treatment on its own

**Article 40** The food and drug administrative department under the State Council shall extensively collect opinions of food production and trading enterprises, industry associations, and consumers when formulating specific measures for the administration of health food in accordance with the provisions of Article 152 of the Food Safety Law.

**Article 41** Producers of food for special medical purpose shall carry out batch by batch inspection of the factory products in accordance with inspect items stipulated by the national food safety standards.

Among formula food for special medical purpose, specific full nutritional formula food shall be sold in medical institutions or pharmaceutical retail enterprises, and shall not be sold on Internet. Medical institutions and pharmaceutical retail enterprises selling specific full nutritional formula food do not need to obtain food sales licences, but shall comply with the provisions of the Food Safety Law and the requirements of the food sales stipulated by this regulation.

**Article 42** The advertisement of specific full nutritional formula food of the food for special medical purpose shall be subject to the administration of prescription medicine advertisement, and the advertisement of the other food for special medical purpose shall be subject to administration for over-the-counter medicine advertisement.

**Article 43** Labels of infant formula food shall truthfully indicate specific sources of ingredients.

Infant formula food with optionally-added substances according to national food safety standards shall not be named after the optionally-added substances.

Infant formula food shall not claim any functions.

**Article 44** Contents of the label and description of health food, food for special

medical purpose and infant formula food shall be consistent with the registered or filed label and description. The food and drug administrative department under the State Council shall publish the registered or the filed label and description of the health food, food for special medical purpose, and infant formula food.

The sale of health food, food for special medical purpose and infant formula food shall be checked whether the contents of the label and description are in consistency with the registered or filed labels and descriptions; those with inconsistent contents shall not be sold.

The health food, food for special medical purpose and infant formula food shall not be sold in a mix of regular food or medicines.

## **Chapter 5 Food Inspection**

**Article 45** When carrying out sampling inspection on food, the food and drug administration department shall entrust food inspection agencies with legally obtained qualifications. The food safety supervision and sampling inspection shall be performed according to the food safety standards, product technology requirements registered or filed in accordance with laws and the inspection items and test methods stipulated in relevant national regulations.

**Article 46** When applying for a re-examination in accordance with the provisions of Article 88 of the Food Safety Law, the re-examination fee shall be paid in advance. In case the re-examination conclusion is consistent with the initial inspection conclusion, the re-examination fee shall be borne by the applicant; in case the re-examination conclusion is inconsistent with the initial inspection conclusion, the re-examination fee shall be borne by the food and drug administrative department that conducted the sampling inspection.

**Article 47** The re-examination agency shall not refuse to undertake any re-examination tasks. If the agency refuses to conduct re-examination twice within a year without any proper reasons, relevant departments under the State Council shall cancel the qualification of the re-examination agency and announce it to the public.

**Article 48** Any units or individuals shall not release food inspection information issued by food inspection agencies without legally obtained qualification, not use

the above inspection information to grade food or food producers and traders, and deceive and mislead consumers.

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

**Article 49** Importers who import food and food additives shall report to the entry-exit inspection and quarantine authorities in accordance with the regulations for inspection, truthfully claim the relevant information of the products, and attach the qualified certification materials; when importing health food, food for special medical purpose and infant formula food with registration administration, importers shall also provide the registration certificates issued by the food and drug administrative department under the State Council.

**Article 50** After arriving at the port, the imported food shall be stored in the place designated or approved by the entry-exit inspection and quarantine authorities. Mass bulk imported food shall be inspected at the port and shall not be moved without inspection; other imported food that needs to be moved shall be subject to the approval of the entry-exit inspection and quarantine authorities, and necessary quarantine or other safety protection measures shall be taken.

**Article 51** According to the principle of risk management, the state exit-entry inspection and quarantine department can confirm, release and implement imported food catalogue for designated ports.

**Article 52** The food not covered by the national food safety standards mentioned in Article 93 of the Food Safety Law refers to the food produced by overseas food producers and food without corresponding national food safety standards in China. It does not include the food that is already covered in general standards of national food safety standards.

After reviewing the relevant standards in accordance with the provisions of Article 93 of the Food Safety Law and deemed to meet the food safety requirements, the public health administrative department under the State Council may grant and release temporarily applicable standards; before the temporarily applicable standards are released, food without food safety national standards shall not be imported.

**Article 53** Importers shall establish examination system for overseas food exporters and overseas food producers, and focus on examining contents as follow:

- (1) Whether the food exported to China by the overseas exporters and overseas food producers conforms to the Food Safety Law, other relevant laws and administrative regulations of China, and the requirements of national food safety standards;
- (2) In order to ensure that the food exported to China conforms to the Food Safety Law, other relevant laws and administrative regulations of China, and the requirements of national food safety standards, the development and implementation of food safety risks control measures by overseas exporters and overseas food production enterprises.

**Article 54** When importers recall imported food in accordance with the provisions of Paragraph 3 of Article 94 of the Food Safety Law, the importers shall report the food recall and treatment situation to the local entry-exit inspection and quarantine authorities.

**Article 55** In case the entry-exit inspection and quarantine authorities find the registered overseas food producers no long meet the registration requirements, they shall order them to rectify within the prescribed time limit, and suspend importing food produced by them during the rectification period; in case the overseas food producers fail to meet the registration requirements after rectification, the national entry-exit inspection and quarantine authorities shall revoke their registration and make an announcement.

**Article 56** For overseas food producers which have passed Good Manufacturing Practice, Hazard Analysis and Critical Control Point systems certification, the certification authority shall implement tracking investigation according to law. If enterprises no longer comply with the certification requirements, the certification authority shall revoke the certification according to law, and announce to the public.

**Article 57** In case food safety incidents occurred abroad may affect China, or serious food safety problems discovered in imported foods, food additives, and food related products, the national entry-exit inspection and quarantine authorities

shall timely carry out early risk warning, and take the following control measures:

- (1) Return or disposal;
- (2) Conditionally restrict the import;
- (3) Suspend or prohibit the import.

**Article 58** Production enterprises of food and food additives for export shall ensure that their food and food additives for export conform to the standards of importing countries (regions) or contractual requirements; in case that China concludes or participates in international treaties or agreements, the requirements of the international treaties or agreements shall be met.

## **Chapter 7 Food Safety Incident Handling**

**Article 59** Food safety incidents shall, in accordance with national plan for emergency to food safety incidents, be administrated by different levels. The food and drug administrative department under the People's Government at or above county level shall, in conjunction with relevant departments at the same level, be responsible for investigating and handling food safety incidents.

The People's Government at or above county level shall timely revise and improve emergency response plans to food safety incidents according to actual situation.

**Article 60** The People's Government at or above the county level shall perfect the emergency response management system, put the emergency response funds in place, improve the emergency response equipment, store emergency response materials storage and build emergency response team, and strengthen emergency response training and drill.

The food production and trading enterprises shall regularly organise and carry out emergency response drills for food safety incidents.

**Article 61** The unit where the food safety incident occurs shall immediately take controlling measures such as sealing up food and ingredients, tools, and equipment which have caused or are likely to cause the incident. The unit where incident

occurs or the unit receiving incident patients for treatment shall report to local food and drug administrative department and public health administrative department under the People's Government at the county level within the time stipulated in the emergency response plans to food safety incidents. The food and drug administrative department of the People's Government at the county level shall report to the food and drug administration department at the higher level in accordance with the provisions of the emergency plan. The food and drug administrative departments of the People's Governments at or above the county level shall, in accordance with the provisions of Article 105 of the Food Safety Law, carry out investigation and handling.

**Article 62** In case that medical institutions find or suspect the patients received are with foodborne disease, they shall timely report the relevant information to the public health administrative department under the People's Government at the county level according to the regulations. In case that the public health administrative department under the People's Government at the county level deemed that the incident is food safety related, they shall notify the food and drug administrative department at the same level within 2 hours.

In case that the public health administrative departments under the People's Government at or above the county level find information related to food safety during investigation of infectious diseases or other public health emergencies, they shall notify the food and drug administrative department at the same level within 2 hours.

The food and drug administrative department shall carry out investigation within 2 hours after receiving the notification from the public health administrative department; in case it is a food safety incident, it shall be investigated and handled in accordance with the provisions of Article 105 of the Food Safety Law.

**Article 63** In case that the food and drug administrative departments under the People's Government at or above the county level need to carry out an epidemiological investigation into related factors during the investigation of the food safety incident, they shall notify disease prevention and control institutions, and assist the disease prevention and control institutions with their investigation. Any units or individuals shall not refuse or obstruct the disease control and prevention institutions to carry out epidemiological investigations. The disease prevention and control institution shall timely submit epidemiological investigation report to the food and drug administrative department and the public health administrative department at the same level after the completion of the investigation.

**Article 64** The food and drug administration, public health administration, quality supervisory, agriculture administration and other departments under the State Council shall regularly analyse national food safety incidents, improve food safety supervision and administration measures, and prevent and reduce incidents.

## **Chapter 8 Supervision and Administration**

**Article 65** The State establishes the food safety inspector system and professional inspecting teams.

**Article 66** In case that the food producer and trader are filed a case and investigated by the food and drug administrative department due to suspected food safety violations, the food and drug administrative department may suspend their administrative license application related to food safety during the period of investigation and processing; for those application already being processed, suspend the review, and the suspension period will not be counted into the administrative license period.

**Article 67** The food and drug administrative department under the State Council, in conjunction with relevant department under the State Council, shall announce the list of non-food chemical substances and other substances which may harm human health that is added or may be added into food, according to the foodborne disease information, risk monitoring information, supervision and administration information, etc. The public health administrative department under the State Council shall be responsible for formulating and announcing the testing method of the above-mentioned substances.

**Article 68** The food and drug administrative departments under the State Council may assess the fast food-testing methods in accordance with the food safety supervision and administration demands. If the testing methods meet the relevant requirements, they can be used for sampling inspection and testing of food.

**Article 69** In case that illegal food business frequently appear on third-party online food trading platforms and cause serious consequences, the food and drug

administrative departments under the People's Government at or above the county level may conduct an accountability conversation with the legal representative or main person of the third-party online food trading platform provider.

**Article 70** The food and drug administrative departments under the municipal People's Government with district, the People's Government at county level, in addition to carry out daily supervision and inspection of food producers and traders according to annual supervision and administration plan for food safety in the administrative area, may also carry out remote supervision and inspection under the organisation of food and drug administrative departments under the People's Government at provincial, autonomous regional, and municipal level.

**Article 71** Under any of the following circumstances, the food and drug administrative departments under the People's Government at or above provincial level may conduct supervision and inspection on the food producers and traders supervised and administrated by the lower level food and drug administrative departments:

- (1) In case of suspected violation of food safety laws and regulations by the food producer and trader, which may cause serious hazard;
- (2) In case of hidden danger in the food producer and trader, which may trigger regional or systematic food safety risks or cause serious hazard;
- (3) Other circumstances that are deemed necessary by the food and drug administrative department under the State Council.

**Article 72** Where the food and drug administrative department under the People's Government at the higher level deems it necessary, it may directly investigate and take over the food safety violation cases within the jurisdiction of the lower level food and drug administrative department under the People's Government, or designate other food and drug administrative departments to investigate. The food and drug administrative department where the case occurs shall cooperate.

**Article 73** The public health administrative department under the People's Government at or above the county level shall carry out supervision and inspection on units that are carrying out centralised disinfection of tableware and drinkware, and shall promptly investigate and process if discovers non-compliance with the laws, regulations, relevant national standards and relevant hygienic code and other



requirements. The results of the supervision and inspection shall be announced to the public.

**Article 74** The food and drug administrative department under the State Council shall, in conjunction with the public health administration, agriculture administration, and other departments, draft and publish the annual national food safety report.

**Article 75** When need food safety risk control while handling criminal cases that are endangering food safety, public security departments shall immediately notify the food and drug administration, quality supervisory and other departments at the same level. Measures shall be taken by these departments according to laws to control food safety risks.

**Article 76** For food producers and trader suspected of endangering food safety crimes, during the investigation, prosecution and trial, in order to control food safety risks, food and drug supervision and administration departments may take necessary control measures.

## **Chapter 9 Legal Liabilities**

**Article 77** In the circumstances as provided in Paragraph 1 of Article 122 of the Food Safety Law, in addition to imposing penalties in accordance with the provisions of Paragraph 1 of Article 122 of the Safety Law, the main person in charge, the managers directly responsible and other persons directly responsible from the unit shall also be imposed a penalty of more than 1 time and less than 5 times of their annual salaries.

**Article 78** Any circumstances below, not constitute a crime, is considered as a serious violation of Paragraph 1 of Article 123 of the Food Safety Law:

- (1) The value of illegally produced and traded food value of more than 30,000 yuan;
- (2) Cause food poisoning to over 5 people or other foodborne diseases.

**Article 79** In the circumstances as provided in Paragraph 1 of Article 123 of the Food Safety Law, in addition to imposing penalties in accordance with the provisions of Paragraph 1 of Article 123 of the Food Safety Law, the main person in charge, the managers directly responsible and other persons directly responsible from the unit shall also be imposed a penalty of more than 1 time and less than 5 times of their annual salaries.

**Article 80** Any circumstances below, not constitute a crime, is considered as a serious violation of Article 124 and Paragraph 1 of Article 129 of the Food Safety Law:

- (1) Illegally produced and traded food, food additives with a total value of over 50,000 yuan, or produced and traded health food, food for special medical purpose, infant formula milk powder with a total value of over 30,000 yuan;
- (2) Illegal import or export food, food additives, food-related products with a total value of over 50,000 yuan;
- (3) Produce and trade food or food additives with pathogenic microorganisms, pesticide residues, veterinary drug residues, biological toxins, heavy metals and other pollutants and other serious material content that is harmful to human health and exceed the limits of food safety standards;
- (4) Cause food poisoning to over 10 people or other foodborne diseases.

For serious offenders that produce health food, food for special medical use, or infant formula milk powder that are not in accordance with the registered product formula or technology requirements, the food and drug administrative departments under the State Council will revoke their registration certificates. Those whose registration certificates are revoked can no longer apply or register any formulas for health food, food for special medical use and infant formula milk powder in 5 years since the date when the penalty decision is made.

**Article 81** In the circumstances as provided in Article 124, Paragraph 1 of Article 129 of the Food Safety Law, in addition to imposing penalties in accordance with the provisions of Article 124, Paragraph 1 of Article 129 of the Food Safety Law, the main person in charge, the managers directly responsible, food safety management staff, and other persons directly responsible from the unit shall also be imposed a penalty of more than 30% and less than 1 time of their annual salaries.

**Article 82** Any circumstances violated Paragraph 1 of Article 125 of the Food Safety Law, or illegally produced and traded food and food additives with a total value of over 100,000 yuan, are considered as a serious violation of Paragraph 1 of Article 125 of the Food Safety Law.

**Article 83** In the circumstances as provided in Paragraph 1 of Article 125 of the Food Safety Law, in addition to imposing penalties in accordance with the provisions of Paragraph 1 of Article 125 of the Food Safety Law, the main person in charge, the managers directly responsible, food safety management staff, and other persons directly responsible from the unit shall also be imposed a penalty of more than 20% and less than 50% of their annual salaries.

**Article 84** Any circumstances violated Article 126 or Paragraph 2 of Article 129 of Food Safety Law which the terms of the above provisions appear again in 6 months after the warning and penalty, or refuse to correct after being penalised, are considered as a serious violation of Paragraph 1 of Article 126 of Food Safety Law.

**Article 85** In the circumstances as provided in Article 126 and Paragraph 2 of Article 129 of the Food Safety Law, in addition to imposing penalties in accordance with the provisions of Article 126 and Paragraph 2 of Article 129 of the Food Safety Law, the main person in charge, the managers directly responsible, food safety management staff, and other persons directly responsible from the unit shall also be imposed a penalty of more than 2,000 yuan and less than 20,000 yuan.

**Article 86** In the circumstances as provided in Article 128 of the Food Safety Law, in case of concealing, falsifying, destroying relevant evidence or causing serious consequences, in addition to imposing penalties in accordance with the provisions of Article 128 of the Food Safety Law, the main person in charge, the managers directly responsible, food safety management staff and other persons being directly responsible of the unit shall also be imposed a penalty of over 20,000 yuan and less than 100,000 yuan.

**Article 87** In the circumstances as provided in Article 130, Paragraph 1 of Article 131 of the Food Safety Law, in case of causing serious consequences, in addition to imposing penalties in accordance with the provisions of Article 130, Paragraph 1 of Article 131 of the Food Safety Law, the main person in charge, the managers directly responsible and other persons being directly responsible of the unit shall also be imposed a penalty of over 20,000 yuan and less than 50,000 yuan.

**Article 88** In the circumstances as provided in Article 132, Paragraph 5 of Article 140 of the Food Safety Law, in case of refusal to rectify or severe violation, in addition to imposing penalties in accordance with the provisions of Article 132, Paragraph 5 of Article 140 of the Food Safety Law, the main person in charge the managers directly responsible, food safety management staff and other persons being directly responsible of the unit shall also be imposed a penalty of over 2,000 yuan and less than 10,000 yuan.

**Article 89** In addition to circumstances provided in Article 126 of the Food Safety Law, food producer and trader will be penalised according to Paragraph 1 of Article 126 and Article 85 of the Rules if their production or trading activities do not comply to Item 5 – 10 of Paragraph 1 of Article 33 of the Food Safety Law, or the national food safety standards for hygiene during food production and trading.

**Article 90** The violation of Paragraph 3 of Article 75 of the Food Safety Law, including using raw material of the health food raw material catalogue to produce food other than health food, will be penalised according to the provisions of Paragraph 1 of Article 124 of the Food Safety Law and Article 81 of the Rules.

**Article 91** The violation of this article, including the following circumstances, will be penalised according to the provisions of Paragraph 1 of Article 125 of the Food Safety Law and Article 83 of the Rules:

- (1) During production and trading, purchase, use, store, transport non-edible chemical substances that may be added to foods and explicitly prohibited by the state and other substances that may be harmful to human health;
- (2) The labels and description of the produced and traded food claimed that do not add substances which may not be used in accordance with the food safety standards;
- (3) The labels and description of the food except health food produced and traded that claim with health function;
- (4) Make use of conferences, lectures, and health consultations and other methods to create false publicity of food;
- (5) Labels of infant formula food produced and traded fail to be indicated with the specific sources of ingredients;

- (6) Infant formula food named after the substances that can be optionally added according to national food safety standard;
- (7) Infant formula food produced and traded is claimed with function;
- (8) The contents of labels, description of health food, food for special medical purpose, and infant formula food produced and traded are inconsistent with the registered or filed labels and description.

**Article 92** In case of any of the following circumstances that violating the provisions of the Rules, penalties shall be imposed in accordance with the provisions of Article 126 of the Food Safety Law and Article 85 of this Rules:

- (1) Fail to record information of food entrusted to store, transport according to the provisions;
- (2) Catering service providers fail to check and keep the documents such as copies of business license and qualified disinfection certificates of tableware and drinkware disinfection service unit;
- (3) The food producers and traders fail to store the food that are deteriorate, over shelf life or recalled in clearly marked place separately, or fail to timely take measures such as harmless treatment, destroy and make truthfully records.
- (4) Specific full nutritional formula food among food for special medical use, are sold by units or individuals except for medical institutions or pharmaceutical retail enterprise, or specific full nutritional formula food are sold on Internet;
- (5) Store and sell health food, food for special medical purpose and infant formula food in a mix with regular food or medicines.

**Article 93** In case of violating the provisions of the Rules, the producers and traders of non-food products specialising in food storage operation, food centralised trading market owner, food exhibition organiser fail to register for filing, the food and drug administration of the People's Governments at or above the county level shall order them to rectify and give them a warning; in case of refusal to rectify, penalties of more than 5,000 yuan and less than 50,000 yuan shall be imposed; in case of severe violation, it shall be ordered to suspend production and business operation.

**Article 94** In case of violating the provisions of the Rules, release food inspection information issued by food inspection institution without legally obtained

qualifications or use the above inspection information to grade food and food producers and traders, mislead consumers, the food and drug administration of the People's Governments at or above the county level shall order them to rectify, in case there are illegal gains, confiscate the illegal gains; in case of refusal to rectify, penalties of more than 50,000 yuan and less than 200,000 yuan shall be imposed; in case constituting a violation of public security management, security administrative penalties shall be granted by the public security departments in accordance with the law.

**Article 95** In case of violating the provisions of the Rules, the food and drug administrative department under local People's Government at the county level fail to clarify the food safety administration requirements for group dining activities, or fail to perform the duty of guidance on group dining activities, resulting in food safety incidents, penalties shall be imposed on managers directly responsible and other directly responsible persons in accordance with Article 144 of the Food Safety Law; in case of severe consequences, the main responsible person shall resign.

**Article 96** In case of violating the provisions of the Rules, the food and drug administrative departments illegally provide others with the information provided by third-party online food trading platform providers, penalties shall be imposed on managers directly responsible and other directly responsible persons in accordance with Article 145 of the Food Safety Law.

## **Chapter 10 Supplementary Provisions**

**Article 97** In case of applying for registration of health food, food for special medical purpose, infant formula milk powder, registration fee shall be paid. The charging standards shall be formulated by the department in charge of price under the State Council in conjunction with the finance department and the food and drug administration department under the State Council.

**Article 98** The Rules shall become effective as of yyyy-month-date.