

**Implementation Rules of the Food Safety Law Of People's Republic of China  
(Draft calling for comments)**

**China Food and Drug Administration  
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**Chapter 1 General Rules**

**Article 1** These rules are formulated in with the PRC Food Safety Law (hereafter as Food Safety Law).

**Article 2** Food producer and trader shall conduct production and trading activities according to laws, regulations and food safety standards, take effective measures to prevent and control food safety risks, prevent and minimize food safety hazards and safeguard food safety.

**Article 3** The Food Safety Commission of the State Council shall be responsible for research, deploy, coordinate and guide works on national food safety. It shall draft national food safety strategies, propose major food safety policies as well as measures, analysis as well as solve major food safety problems and supervise the enforcement of food safety responsibilities.

The General Office of the Food Safety Commission of the State Council shall undertake daily work, organise the drafting of national food safety plan, coordinate to solve the major problems during the drafting and enforcement of food safety laws, regulations and standards, supervise the implementation of major national food safety decisions, appraise and assess the execution of the food safety duties of provincial people's government and relevant ministries of the State Council, and guide the settlement of major food safety accidents.

**Article 4** Local people's government at county level or above shall be responsible for the territorial management of food safety in its respective administrative area, improves the food safety supervision and administration mechanism, strengthens the food safety governance system and the governance capacity building, and ensures the deployment of staff, funds and technological support for food safety supervision. It shall undertake the responsibilities of regional food safety risks and major food safety accidents happened.

The responsibilities of the Food Safety Commission of local people's government at county level or above and its General Office are formulated in the

responsibilities of the Food Safety Commission of the State Council by the local people's government at county level or above.

**Article 5** Local people's government at county level shall set up food and drug supervision and administration agencies in townships or in particular areas to perform relevant duties under the necessity of the areas, population, supervision targets, etc. in the respective administrative regions.

**Article 6** Township people's government and subdistrict office shall be responsible for ruling out food safety hidden dangers, information reporting, assistance to law enforcement, and publicity as well as education. They shall take effective measures and strengthen food safety management.

**Article 7** The state shall include food safety knowledge in the national civilisation education and the primary and middle school education curriculum, strengthen the dissemination of scientific and legal knowledge on food safety, and raise food safety awareness across the country.

**Article 8** Local people's government at county level or above shall set up special food safety award projects and funds to honour and reward organisations and people that contribute significantly in the food safety risk monitoring and assessment, standard formulation, supervision, major activities support, emergency issues responding, case investigation, scientific research, publicity and education as well as co-governance.

## **Chapter 2 Monitoring and Assessment of Food Safety Risks**

**Article 9** The Health Administration Department of the State Council shall work with the and Management Supervision Department, the Quality Supervision Department and the Agriculture Administration Department of the State Council to conduct and publish national food safety risk monitoring plan.

The Health Administration Department of the people's government at the level of province, autonomous region and direct-controlled municipality shall file a record of food safety risk monitoring plan in the respective region to the Health Administration Department of the State Council. The Health Administration Department of the State Council shall report the records to the Food and Drug Supervision and Administration Department, the Quality Supervision Department and the Agriculture Administration Department of the State Council.

**Article 10** The national food safety risk monitoring plan shall include the following food without food safety standards and relevant harmful factors in the key monitoring targets:

1. the food which is with high risk, widely circulated and largely consumed;
2. The food which is easily harm the health of infant and young children as well as other specific population;
3. The food which received many consumers' negative feedbacks;
4. The food that causes food safety accident abroad.

The food that has food safety standards shall be inspected and sampled by the food and drug supervision and administration department, the quality supervision department and the agriculture administration department. The Health Administration Department of the State Council shall evaluate and amend the food safety national standards according to the results of the food safety risk monitoring and inspection timely.

**Article 11** The Health Administration Department, the Food and Drug Supervision and Administration Department, the Quality Supervision Department and the Agriculture Administration Department of the State Council shall conduct the monitoring of food safety risks based on the national monitoring plan for food safety risks within its respective responsibility range.

The Health Administration Department of the State Council shall be responsible for organizing risk monitoring of foodborne diseases, food contamination and harmful substance in food. The Food and Drug Supervision and Administration Department of the State Council shall be responsible for organizing risk monitoring of harmful factors in production and sales of food as well as in catering services. The Quality Supervision Department of the State Council shall be responsible for organizing risk monitoring of the residual of pesticide and veterinary drugs as well as other contamination substance in the cultivation of edible agricultural products and animal husbandry. The Grain Administration Department of the State Council shall be responsible for organizing risk monitoring on heavy metal and other contamination substance in grains.

The relevant departments shall coordinate and discuss the issues which are under their responsibilities respectively during the food risk monitoring, take effective measures and minimize as well as control food safety risks.

**Article 12** The health administration department, the food and drug supervision and administration department, the quality supervision department and the agriculture administration department shall make full use of technical institutions with corresponding capacities and social third-party technical institutions to monitor the food safety risks.

The technical institutions in charge of food safety risks monitoring shall conduct the work according to the monitoring plan and the scheme of food safety risks and job specifications, guarantee the authenticity, accuracy and completeness of

the monitoring data.

**Article 13** The Health Administration Department at the provincial people's government shall coordinate with the Food and Drug Supervision and Administration Department, the Quality Supervision Department and the Agriculture Administration Department at the same level to establish a food safety risk monitoring data notification and consultation mechanism to collect and analyse the risk monitoring data, determine the food safety risks, and formulate the monthly, quarter, half-year and annual analysis reports on food safety risk monitoring. The reports shall be submitted to the provincial people's government and the Health Administration Department, the and Management Supervision Department, Quality Supervision Department, Agriculture Administration Department of the State Council within 7 working days. Major potential food safety risks when discovered shall be reported within 2 working days.

**Article 14** The health administration department shall conduct food safety risk assessments if potential food safety risks are discovered during the food safety risk monitoring work. Illegal acts during the Food producer and trader when discovered shall be reported to the food and drug supervision and administration departments.

The food and drug supervision and administration department shall report to the health administration department if food safety risk assessment is necessary during food safety investigation. The health administration department shall conduct food safety risk assessment timely and report the assessment results to the food and drug supervision and administration department.

**Article 15** If the result of food safety risk monitoring demonstrates that food safety risk exists, the food and drug supervision and administration department shall notify the Food producer and trader due to the necessity of risk control. The food business operator shall take immediate measures to determine the risks, suspend the production, distribution and usage of the products, recall the products with food safety risks and report to the Food and Drug Supervision and Administration at the local township level or above.

**Article 16** The quality safety risk monitoring and assessment of edible agricultural products shall be conducted by the Agriculture Administration Department at the township level together with the Health Administration Department and the Food and Drug Supervision and Administration Department at the same level.

**Article 17** The Health Administration Department of the State Council shall coordinate with the Food and Drug Supervision and Administration Department of the State Council on the formulation of work plan on food safety risk

assessment, establishing and managing national food safety risk assessment database, organizing the collection of food safety risk assessment data and research on methodologies.

The Health Administration Department, Food and Drug Supervision and Administration Department, Quality Supervision Department and Agriculture Administration Department of the State Council shall establish an exchange mechanism on food safety risk assessment information and share risk assessment data as well as information.

National food safety risk assessment institutions shall be encouraged to authorize technical institutions with corresponding capacities to undertake national food safety risk assessment tasks.

**Article 18** The National Food Safety Risk Assessment Expert Committee shall be established and managed by the Health Administration Department of the State Council together with the Food and Drug Supervision and Administration Department, the Quality Supervision Department and the Agriculture Administration Department of the State Council.

The National Food Safety Risk Assessment Expert Committee shall be responsible for formulating the technical methodologies and requirements for food safety risk assessment, approving food safety risk assessment report and explaining as well communicate the result of food safety risk assessment.

**Article 19** The Food and Drug Supervision and Administration Department, the Quality Supervision Department and the Agriculture Administration Department of the State Council shall propose to the National Risk Assessment Expert Committee on Agricultural Products to conduct risk assessment if it is found necessary during the supervision and administration work that the safety of certain pesticide, fertilizer, veterinary drug, feed and feed additive needs to be assessed. The National Risk Assessment Expert Committee on Agricultural Products shall conduct risk assessment timely and report to the relevant ministries of the State Council on the result.

**Article 20** The Health Administration Department of the State Council shall organize research work on food consumption, environmental factors that harming food safety, studies on total diet, public awareness and other fundamental data according to the necessity of food safety risk assessment work.

**Article 21** The Food and Drug Supervision and administration Department of the provincial people's government together with other relevant departments at the same level shall conduct overall evaluation on information on food safety risk monitoring, risk assessment, daily supervision, inspection and sampling, case

investigation, special rectification as well as popular sentiment and shall announce food safety risk warning on the food which is evaluated as high safety risky in accordance with responsibilities timely.

**Article 22** The state shall establish a food safety risk communication mechanism. Food safety risk communication shall be conducted scientifically, neutrally, open and transparently, timely and effectively, multilaterally and in manner of communication and consultation.

The state shall encourages Food producer and trader, relevant food safety technical institutions, relevant food industry associations, consumer associations and media participate the food safety risk assessment to promote the social co-governance of food safety.

**Article 23** The Food and Drug Supervision and Administration Department and other relevant departments of the State Council shall formulate the specifications on food safety risk communication works, establish a food safety risk communication mechanism and guide the food safety risk communication works at local level.

**Article 24** The Food and Drug Supervision and Administration Department and other relevant departments of the State Council shall establish a food safety risk communication advisory committee composed of experts in areas of food, public health, clinical medicine and public communication to provide advice on food safety risk communication and participate risk communication. The food safety risk communication advisory committee shall consult with social organisations, Food producer and trader, consumers and news media on risk communication issues if necessary and invite representatives from relevant parties to participate risk communication works.

### **Chapter 3 Food Safety Standards**

**Article 25** The Health Administration Department of the State Council shall coordinate with the Food and Drug Supervision and Administration Department, the Quality Supervision Department, and the Agriculture Administration Department of the State Council to formulate the plan of food safety national standards and the annual implementation plan. The formulation of food safety national standards plan and the annual implementation plan shall be published for public consultation.

**Article 26** The Health Administration Department of the State Council shall coordinate with the Food and Drug Supervision and Administration Department of the State Council to organize a food safety national standard review committee,

formulate measures on food safety standards management, organize the approval, drafting, review and promulgation of food safety national standards.

The Health Administration Department of the State Council shall coordinate with the Food and Drug Supervision and Management Department of the State Council to choose institutions with corresponding technical capacities to draft food safety national standards.

Research institutes, technical institutions, academic bodies and industry associations shall be encouraged to draft food safety national standards jointly.

**Article 27** The Health Administration Department of the State Council shall coordinate with the Food and Drug Supervision and Management Department of the State Council to facilitate the formulation of food safety national standards on the types, scope and dosage of food additives used in catering service and food safety national standards urgently needed in the food safety supervision law enforcement.

**Article 28** The Health Administration Departments of the people's government at the level of province, autonomous region and direct-controlled municipality shall coordinate with the Food and Drug Supervision Management Department at the same level to formulate the plan for food safety local standards as well as its implementation plan and organize the approval, drafting, review as well as promulgation of food safety local standards.

Food safety local standards on functional food, food for special medical purpose, infant and young children formula, food additives, food related products and novel food ingredients shall not be formulated.

**Article 29** The Health Administration Departments of the people's government at the level of province, autonomous region and direct-controlled municipality shall file a record to the Health Administration Department of the State Council within 30 working days after the promulgation of food safety local standards.

The Health Administration Department of the State Council shall correct rectify it timely if the filed food safety local standard infringes laws, regulations as well food safety national standards.

Once a food safety national standard is promulgated, the corresponding food safety local standards shall be immediately repealed. The Health Administration Departments of the people's government at the level of province, autonomous region and direct-controlled municipality shall announce the repeals timely.

**Article 30** Enterprise standards shall apply after the approved by the legal

representative or the chief responsible person. The food production enterprise shall be responsible for the filed enterprise standards.

## **Chapter 4 Food Production and Trade**

### **Part I General Provision**

**Article 31** The Food and Drug Supervision and Management Department of the State Council shall formulate Food producer and trader management specifications in accordance with the social-economic development level, production and operation scale, technological conditions, food safety requirement and other factors.

Food producer and trader shall conduct production and operation in accordance with the Food producer and trader management specifications.

**Article 32** Food producer and trader and operators specializing in food transportation shall not purchase, use store or transport non-edible substance prohibited by official orders by relevant ministries in the production and operation process and shall not use recycled food additives to produce food or food additives.

Medicines, chemical substance except food additive ingredients and other substance potentially harming human health are prohibited to add in the food additives illegally.

**Article 33** Enterprises specialized in semi-manufactured food and extractives shall obtain food production license in accordance with laws and regulations. Selling food by telesales, conferences and workshops shall obtain food operation license in accordance with laws and regulations.

A food producer with food production licenses can sell food manufactured at its manufacture sites without food operation license. A catering service provider with food operation license can sell food prepared by it at the catering service venue without food production license.

**Article 34** The consignee shall obtain food production license if it is consigned to produce food or food additives by a food business operator. The consignor shall be responsible for the legal liability of the food safety of the food production under consignment while the consignee shall be responsible for the production practices.

Both parties shall make a written agreement to produce food under consignment



and clarify the right and responsibilities of both parties in food safety respectively.

**Article 35** The Health Administration Department of the State Council shall coordinate with relevant ministries to consolidate and announce the novel food ingredients, new varieties of food additives, catalogues of new varieties of food related products and relevant food safety national standards, and shall conduct follow-up evaluation on their safety.

**Article 36** The safety assessment materials by an applicant on novel food ingredients, new varieties of food additives and new varieties of food related products to the Health Administration Department of the State Council shall include evidence by relevant industry organisations on technical necessity, safety assessment opinions by professional technical institutions, information on relevant standards formulation as well as the standard text.

**Article 37** The substances which is listed in the Catalogue of Substances Which Are Both Food and Traditional Chinese Medicines by Tradition shall comply with simultaneously following requirements:

1. It shall has been consumed as food in China historically and cause no acute, sub-acute, chronic or any other potential dangers to human health;
2. Its consumption as food shall be recorded in ancient books and no toxicity record is found;
3. It shall be listed in the National Medicine Standards;
4. It shall not cause any harm to wild medicine resource and ecological environment and shall keep the sustainable development of the relevant specie. It shall not be any wild animal or wild plant that belong to the List of Wildlife under Special State Protection and the List of Wild Plants under Special State Protection;
5. It shall comply with the requirements with relevant laws and regulations.

**Article 38** Food producer and trader shall track and save information on purchase, production, processing, packaging, storage, sales, inspection, recall and suspension. All information shall be authentic, accurate and complete to achieve food traceability.

## **Part II Process Control in Production and Operation**

**Article 39** The legal representative or the chief responsible person of a food business operator shall be responsible for the overall food safety of the operation and shall establish as well as enforce the food safety responsibility of the operation.

**Article 40** Food safety management staff shall assist the legal representative or the chief responsible person of a food business operator to undertake the food safety management responsibilities.

The legal representative or the chief responsible person of a food business operator can authorize the food safety management staff to undertake the following food safety management responsibilities:

1. In managing the selection of suppliers;
2. In managing purchase check and delivery inspection and the authenticity of the record;
3. In organizing self inspection on food safety of the enterprise and the authenticity of the self inspection report;
4. In supervision of the enforcement of the control system in the Food producer and trader process;
5. In organizing and implementing the recall of food;
6. In fulfilling the duty of reporting food safety accidents;
7. In other legal duties

**Article 41** Food safety management staff shall be equipped with the professional knowledge on food safety laws and regulations, food safety standards, food safety and food safety management capabilities in accordance with its position.

The Food and Drug Supervision and Management Department of the State Council shall formulate management measures on the assessment of food safety staff in Food producer and trader enterprises.

**Article 42** A food business operator shall conduct inspection and assessment or authorize third-party professional institutions or professionals to conduct inspection and assessment on its food safety condition.

**Article 43** Food producer and trader shall authorize institutions with irradiation qualification to conduct such practice if irradiation is necessary for the food produced and shall conduct inspection according to relevant standards on irradiated food.

Food producer and trader shall inform the food and drug supervision management department of the local people's government at county level of the food processing treatment by the irradiation device unit, the raw materials used for irradiation in a timely manner.

**Article 44** Food producer and trader shall establish food safety information announcement systems and announce Food producer and trader licenses, enterprise standards of food, risk classification, results of check and inspections, and information on food recall, suspension as well as treatment of

non-conforming products to the public in a timely manner.

**Article 45** The food and drug supervision and administration department at the people's government at provincial level or above shall promote the Good Manufacture Practices (GMP) and enforce the Hazard Analysis Critical Control Point (HACCP) system in relatively large-scale Food producer and trader enterprises, Food producer and trader enterprises of meat products and dairy products in accordance with food safety risk condition and the necessity of food safety supervision and administration.

**Article 46** Manufacturers of food, food additives and food related products shall conduct tests by themselves or by entrusting on food, food additives and food related products produced in accordance with food safety standards.

If the shelf life is shorter than the period which is needed for routine testing methods, rapid testing methods can be adopted.

**Article 47** Food operators that sell functional food, food for special medical purpose and infant and young children formula milk powder requiring registration shall check the product registration certificates, check if the product label information complies with the information in the certificates and keep copies of registration certificates.

**Article 48** Food producer and trader shall register the food, food additives and food related products that are expired, deteriorated or recycled, and shall store the products in clearly identified locations separately. The products shall be destroyed or disposed by harmless treatment timely. The operators shall keep records about it.

**Article 49** Food producer and trader shall inspect the food safety assurance capacity of the entrusted storage and logistic enterprises and shall strengthen the food safety management if they entrust other storage and logistic enterprise to store and transport food.

Operators specialized in food storage and transportation shall strengthen the management of process of food storage and transportation to ensure that the condition of food storage and transportation fulfill the food safety requirements.

Entrusted operators to store and transport food shall check and save evidence materials of the identification paper, Food producer and trader licenses, copy of business license, conformity certificates, quarantine and inspection certificates of the consignor and shall undertake the food safety liabilities during the food storage and transportation.

**Article 50** Non-Food producer and trader specializing in food storage and transportation shall file a record at the food and drug supervision and administration department at the local people's government at county level within 30 working days after obtaining the business license.

When it is suggested by information on complaints or case investigations which indicates that non-Food producer and trader may violate food safety laws and regulations, food safety national standards during the food storage and transportation, the food and drug supervision and administration department shall handle it in accordance with laws and regulations on a timely manner.

**Article 51** If temperature and humidity control is needed during food storage and transportation, insulation equipment, refrigerator equipment or freezer equipment shall be equipped and maintained to be under effective operation state.

The people's government at county level or above shall undertake effective measures to support cold-chain transportation.

During the storage and transportation of edible agriculture products, substance such as non-edible chemical substance or any other substance that can harm human health shall not be added and food additives shall not be used exceeding the allowed range and limits.

**Article 52** Records on food storage and transportation shall be kept to ensure the traceability during storage and transportation.

Storing and transporting food by entrustment, both parties shall make a written agreement and shall clarify the rights and liabilities of both parties in the food safety respectively.

**Article 53** Catering service providers shall notify the name, applicable range and dosage of the food additives which are used in the food prepared by the catering service providers.

**Article 54** The catering service provider shall make entrustment contract with the centralized disinfection service provider of tableware and drinkware if the catering service provider entrust the disinfection service provider to provide service on cleaning and disinfection service. The catering service provider shall check and keep the business license, disinfection conformity certificates of the disinfection service provider of tableware and drinkware.

**Article 55** Centralized disinfection service providers of tableware and drinkware shall set up a full-time or part-time hygiene inspector position, shall establish and

improve hygiene management system and hygiene management records and shall conduct production and operation activities in accordance with hygiene guidelines.

**Article 56** Institutions such as school, kindergarten, nursing homes, healthcare institutions, and construction sites that have canteens shall conduct food safety self-check in the canteens to rule out potential risks and shall submit reports on the self-check to the food and drug supervision and administration departments of the local people's government at county level regularly.

Institutions which contract their canteens to external parties shall follow the requirements of laws and regulate strictly, shall enhance supervision and inspection, and shall urge the contractors to implement all food safety management systems. Both parties shall make a written agreement and shall clarify the rights and liabilities of both parties in food safety respectively.

**Article 57** Local people's government at the county level or above shall strengthen the governance of food safety in rural areas and shall clarify the food safety management system and requirements in the collective dining activities in rural areas to prevent food safety accidents.

The organizers and the contractors of collective dining activities in rural areas shall undertake the main responsibilities of food safety, shall purchase, store and process food in accordance with food safety requirements and shall file reports in accordance with relevant regulations.

**Article 58** Both parties shall make a written agreement clarifying the rights and liabilities of both parties in food safety areas when a catering service provider hire a catering service management enterprise to manage the service. The catering service provider shall undertake the food safety legal liabilities of the catering service.

**Article 59** Food additive operators shall establish sales ledger system of food additives, shall record the name, specification, quantity, production date or batch numbers, shelf date and sales date of the food additives as well the name, address, contact details of the purchasers accurately and shall maintain relevant documentations. The record and maintenance term of the documentations shall follow the requirements of the paragraph 2 of the Article 50 in the Food Safety Law.

Food additive operators shall file records to the food and drug supervision management department of the local people's government at county level within 30 working days after obtaining business licenses.

**Article 60** Third-party internet food business platform providers shall file records on the URL, IP address, IP approval certificates, company name, legal representatives and copies of their personal identification card as well as contact details to the food and drug supervision and administration departments of the local people's government at the county level or above within 30 working days after obtaining business licenses.

Third-party internet food business platform providers shall publish food safety management system on the platform for inquiries from internet Food producer and trader as well as consumers.

Third-party internet food business platforms shall publish the information on unlawful acts of Food producer and trader that accessed to the networks on the prominent position of the websites.

**Article 61** Internet Food producer and trader shall obtain Food producer and trader license in accordance with laws except as otherwise provided by laws and regulations. The scope of business of the internet Food producer and trader shall be identical with the scope of business of the physical transactions.

**Article 62** Internet Food producer and trader shall file records on the information on URL, IP address and other relevant information at the food and drug supervision and administration departments which issued the business licenses within 30 working days and shall publish their business licenses, production and operation licenses as well as other relevant information on the first page of their websites or the main page of their business activities in prominent position.

Internet Food producer and trader shall update the information timely when food business production and operation licenses or other relevant information are changed.

**Article 63** Local people's government at province level or above shall promote food safety electronic traceability system in food categories with high risks and relatively large-scale Food producer and trader enterprises gradually according to the local conditions. Food producer and trader enterprises are encouraged to undertake IT measures to collect and track data as well as information of production and operation.

**Article 64** Food producer and trader enterprises and food wholesale markets shall report food safety relevant data and information to the food and drug supervision and administration departments of local people's government at county level or above in accordance with the regulations of the Food and Drug Supervision Management Department of the State Council accurately.

Third-party internet food business platform providers shall save the information

such as registration information of food accessed to network, edible agricultural products, food additives operators as well as transaction data and shall report the information to the food and drug supervision and administration departments of local people's government at county level or above in accordance with the regulations of the Food and Drug Supervision Management Department of the State Council accurately.

**Article 65** Food producer and trader shall suspend operation, recall and dispose unsafe food in accordance with the requirements of the national food recall mechanism.

Classification management is applied in food recall according to the severity and emergency of food safety risks:

1<sup>st</sup> class recall: when the food has caused or is likely to cause severe health damages or even death after consumption, the food business operator shall start the recall within 24 hours after being informed of the food safety risks;

2<sup>nd</sup> class recall: when the food has caused or is likely to cause general health damages after consumption, the food business operator shall start the recall within 48 hours after being informed of the food safety risks;

3<sup>rd</sup> class recall: when the label or the instruction does not comply with the food safety standards and will generally not cause any health damages, Food producer and trader shall start the recall within 72 hours after being informed of the food safety risks.

In the event of food recall, Food producer and trader shall report to the food and drug supervision and administration department of the local people's government at county level or above in accordance with the timeframe set by the recall classification.

**Article 66** Food producer and trader shall take measures such as harmless disposal treatment, destroy and rectification to handle food which is removed from the market due to suspension, recall as well as other reasons.

Unsafe food which cause severe damages to health and human life due to adding non-edible chemical substance illegally, spoilage, dead livestock due to sickness as well as residual of pesticide as well as veterinary drug exceeding maximal level shall be destroyed by the food business operator on the spot.

The food recalled due to non-compliance of label and marks to food safety standards, Food producer and trader shall only continue the sales of food if the food safety can be assured and remedy measures have been taken. Remedy

measures shall be published to the consumers by putting on notice in prominent positions at the operation site during sales.

Local people's government at county level or above shall establish special funds to organize works on storage, harmless treatment and destroy of the unsafe food.

### **Part III Marketing of Edible Agricultural Products**

**Article 67** The founder of the central trading market for edible agricultural products shall report the information such as the name of the market, type of the market, address, legal representative or person in-charge, supervisor for food safety, supervision system for food safety, type of agricultural products, number of the booths, and etc. to food and drug administrative departments of the people's government at the county level for file-recording.

**Article 68** The funder of the central trading market for edible agricultural products shall set up the notice billboard to publicise the information such as, food safety supervision system, results of the testing on edible agricultural products, investigatory result on incompliant edible agricultural products, complains report hotline of supervision authorities.

**Article 69** The funder of the central trading market for edible agricultural products shall bear the supervision responsibilities for the quality and safety of the edible agricultural products trading in the market as follows:

1. Establish and improve the supervision system for safety of edible agricultural products, be equipped with supervision staff for the safety of edible agricultural products and professional technical personnel, conduct training on the safety of edible agricultural products, and enhance the inspection on edible agricultural products;
2. Establish the recording archive for the admission of sellers entering into the central trading market for edible agricultural products, the information such as the name, contacts, code of social credit or ID number, address of the sellers, and also the type of the edible agricultural products, the origin of the products. Such archives shall be kept no less than 6 months after the sellers stop trading in the market;
3. Establish the admission system for the edible agricultural market, the social credit code or the photocopy of the seller's ID card, the certificate of the original of the product, the certificate of the purchasing, or compliance certificate shall be checked and archived;
4. Establish daily check system, conduct inspection on the operational



environment, conditions and behaviors of the admitted sellers, and create the archives for the operation management;

5. Illegal activities and risk potentials, in case of being discovered, shall be stopped and reported to food and drug administrations of local people's government at county levels, investigation work shall be coordinated.
6. Make response plan for food safety incident, regularly check the implementation of prevention measures for food safety in the market, and eliminate the incident potentials.

**Article 70** Apart from the responsibilities laid down in Article 69, the funder of wholesale market for edible agricultural market shall fulfill the responsibilities as below:

1. Sign agreement on the quality and safety of edible agricultural products with the sellers admitted into the market, specify the rights and responsibilities of both sides. It's not allowed to admit any sellers into the market if there's no agreement signed for the quality and safety of the edible agricultural products;
2. Be equipped with inspection equipment and technicians, or delegate food inspection agency which is accredited, to conduct sampling inspection or speedy inspection frequency according to the type and risk classification of the edible agricultural products, and publish results of inspection in a timely manner.;
3. Print and produce the sales license with unified format, with stating the name, origin, quantity, sales date of the edible agricultural products, and name, address, contacts of the sellers;

**Article 71** Edible agricultural product sellers with intention to be admitted into the central trading market for edible agricultural products, shall provide original certificate, purchasing proof, compliance proof of the edible agricultural products according to relevant laws and regulations. For those who cannot provide the mentioned documents, speedy inspection or sampling inspection shall be conducted in the central trading market. Only compliant sellers can be allowed to enter into the market.

Sales of meat products which requires quarantine measures according to relevant regulation, the seller shall provide the compliant quarantine certificate; for the sales of meat products, the seller shall provide proof documents such as inspection compliance certificate and so on.

Sales of imported edible agricultural products, the seller shall provide the inspection and quarantine certificate of the entry of the consignment.

**Article 72** For the unpacked edible agricultural products entering into the wholesale and retail market, information like the name, origin, producer's

name or the seller's name (first name and family name) shall be publicized in a visible place in the booth (counter).

**Article 73** Sellers of edible agricultural products shall establish the stock checking scheme by honestly recording the name, origin, quantity, stock entry date of the edible agricultural products, and the name, address, contacts of the suppliers, and the relevant certificate shall be archived. For purchasing the imported edible agricultural products, the origin of the edible agricultural products, name, address, contacts of the domestic agent shall be recorded honestly. The record and certificates shall be kept no less than 6 months.

For the enterprise using centralized distribution mode, the integrated in-stock checking and recording system can be established at its headquarters.

#### **Part IV Label, Instruction and Advertisement**

**Article 74** Food producers shall be responsible for the content of the label and instruction of food and food additives.

Food producer and trader shall not change the information such as food production date and shelf life in the label and instructions violating laws.

**Article 75** The labeled food production date and shelf life of bulk food sold by food operators shall be authentic, clear, easy to read and identical with the content labeled by the food producers.

Food producer and trader shall label the earliest production date and the shortest shelf life of mixed bulk food if bulk food of different production dates are mixed together during the sales.

The original production date of food repacked by the Food producer and trader shall not be changed and the shelf life shall not be extended.

**Article 76** Edible agricultural products after preliminary processing such as washing and stripping shall be labeled with shelf life and sold within the shelf life. Edible agricultural products without processing do not need to be labeled with shelf life.

The Food and Drug Supervision and Management Department of the State Council shall coordinate with other relevant departments of the State Council to determine the shelf life of edible agricultural products after preliminary processing and packaging by categories according to the practical conditions.

**Article 77** Prepackaged food directly produced by using Genetically Modified Organism (GMO) ingredients shall label clearly in accordance with relevant regulations.

Label requirements of GMO food shall follow the requirements in the Regulations on Administration of Agricultural Genetically Modified Organisms Safety.

**Article 78** Words such as “special supply for”, “exclusively for”, “tailor made for” or “manufacture under the supervision of” shall not appear on the labels or in the instructions. It is forbidden to use words such as “no added” or “no contained” to emphasize not using substances which cannot be used or contained in food according to food safety standards. GMO food and ingredients which are not approved by the state cannot be labeled as “non-GMO”.

Except functional food, any other food shall not claim or imply any health protection function by no means nor in any carriers.

The relevant content on the labels of functional food, food for special medical purpose and infant and young children food shall be identical with the content of registration or record filed. Except functional food, food for special medical purpose and infant and young children formula, any other food shall not prescribe the quantitative intakes or daily intake portion on the label.

Irradiated food shall be labeled as irradiated food on the labels or in the instructions. Irradiated ingredients shall be labeled in the ingredient lists.

## **Part V Special Food**

**Article 79** Functional food, food for special medical purpose and the recipes of infant and young children formula milk powder under registration management shall obtain registration certificates from the Food and Drug Supervision and Management Department of the State Council.

**Article 80** The Food and Drug Supervision and Management Department of the State Council shall coordinate with the Health Administration Department of the State Council and the National Traditional Chinese Medicine Administration Department to formulate, adjust and announce the catalogue of ingredients for functional food and the health protection function catalogue of functional food claims approved.

The catalogue of ingredients for functional food and the health protection function catalogue shall aim at the purpose of public health protection, shall follow the principles of scientificity, open as well as transparency and fairness principles and shall be under dynamic management. The Food and Drug Supervision and Management Department of the State Council shall coordinate with the Health

Administration Department of the State Council and the National Traditional Chinese Medicine Administration Department to adjust the health protection function catalogue of functional food and ingredient catalogue in a timely manner according to the scientific research development and the registrations of functional food.

**Article 81** When announcing the catalogue of ingredients for functional food, relevant technical requirements such as the name, dosage, production process technologies, active ingredients and testing methods of the ingredients shall be published.

Ingredients in the catalogue of ingredients for functional food change substantially after reproduction processing such as extraction and purification shall be regarded as excluded from the catalogue of ingredients for functional food.

Health protection functional ingredients which do not aim at provide nutritional substance shall be regulated as functional food ingredients and shall not be applied as new food ingredients. Food other than functional food shall not use ingredients of functional food.

**Article 82** Onsite inspection of the production site of the applicant for functional food production license shall be conducted during real time production process. Samples shall be taken from the pilot sample productions and shall be inspected.

Functional food manufacturers shall be equipped with the testing capacities which are adequate for product varieties and scope.

**Article 83** Applicants for registration of functional food shall organize relevant research works, shall produce pilot sample products in manufacturers complying with functional food GMP and shall submit testing report provided by the legally qualified testing institutions.

**Article 84** Food and drug supervision and administration departments shall complete the registration, archive and reference of the filed records of the functional food and infant and young children formula which are required by law to file records in accordance with regulations. Record registration numbers shall be given to applicants in accordance with the matters of record.

Once obtaining the record registration number, the applicant for producing functional food domestically shall apply for corresponding production license within 3 months. The recorded product recipes, production process and other technical requirement shall comply with the requirements of production licensing.

Once obtaining the record registration number, the applicant for producing

functional food abroad shall import relevant products within 3 months. Declaration documentations for importation and inspection reports shall be submitted to the local food and drug supervision and administration departments at provincial level simultaneously.

**Article 85** Under one of the following circumstances, the Food and Drug Supervision and Management Departments of the State Council shall organize re-evaluation of functional food and can take supervision and administration measures such as withdraw functional food registration certificates or adjust the catalogue of the ingredients for functional food according to the re-evaluation results and announce to the public:

1. According to the scientific research development, acknowledgement of the safety or the health protection function of certain or certain type of functional food has changed;
2. Results of risk monitor and assessment indicate that certain or certain type of functional food can bear potential health risks;
3. Other conditions which require re-evaluation of functional food.

**Article 86** The Food and Drug Supervision and Management Department of the State Council shall entrust qualified food testing institutions to undertake the testing and validation works of registration of functional food, food for special medical purpose and infant and young children formula milk powder products. And the list of the testing institutions shall be published.

Applicants for the registration of food for special medical purpose and recipes of infant and young children formula milk powder products shall be the enterprises equipped with research and development capacities, production conditions and testing capacities for all testing items required in standards, which are required by the food for special medical purpose or infant and young children formula milk powder to be registered. The enterprises shall comply with the GMP and implement HACCP system.

**Article 87** Manufacturers of functional food, food for special medical purpose and infant and young children formula shall organize their production according to the registered or recorded technical requirements of product recipes and production process.

Infant and young children formula products shall only be launched to the market when items such as ingredients, food additives, product recipes and labels of infant and young children formula are recorded and published to the public.

If pre-treatment process such as ingredient extraction and purification is involved in the functional food production process, the manufacturers shall be equipped with the ingredient pre-treatment process capacities in accordance with the

product varieties and production scope.

**Article 88** The name of functional food shall not contain words which claim or indicate product functions.

The label of health protection function claimed by functional food shall strictly follow the formulations in the catalogue of health protection function. The wording shall not be changed at discretion.

**Article 89** Functional food, food for special medical purpose and infant and young children formula shall be sold in special counters or areas and the special counters or areas shall be labeled with “Special Counter/Area for Functional Food”, “Special Counter/Area for Food for Special Medical Purpose”, and “Special Counter/Area for Infant and Young Children Formula” in prominent positions. Functional food, food for special medical purpose and infant and young children formula shall not be stocked together with drugs or other regular food.

In the special counter or area for functional food, a notice that “this product shall not replace medicine” shall be labeled in prominent positions.

The nutritionally complete foods with a nutrient-adapted formulation specific for a disease of food for special medical purpose shall be distributed at healthcare institutions or by pharmacy retailers while other food for special medical purpose products can be distributed at food operation sites.

**Article 90** Imported food for special medical purpose and imported infant and young children formula milk powder shall be registered in accordance with laws.

**Article 91** The advertisement of the nutritionally complete foods with a nutrient-adapted formulation specific for a disease of food for special medical purpose shall be approved according to the management of advertisement of prescribed drugs while the advertisement of other food for special medical purpose products shall be approved according to the management of advertisement of OTC drugs.

**Article 92** Manufacturers of infant and young children formula milk powder shall not produce and sell products with trademarks, company names and address only registered abroad in China. Milk or milk composition products from animals other than cow and goat shall not be used to produce infant and young children formula milk powder.

Product recipes applying for registration shall be formulated following relevant laws, regulations and food safety national standards and with scientific evidences. The product recipes for the same age group from 1 enterprise shall vary significantly and shall have scientific supporting evidence. In principle, every

enterprise shall not have more than 9 product recipes within 3 product lines.

The name of the Infant and young children formula shall not indicate the optional substance prescribed in the food safety national standards.

The sales of infant and young children formula milk powder shall not be limited regionally and shall not be tailor made for distributors.

**Article 93** The same enterprise shall not use the same recipe for different food for special medical purpose products and functional products under different brands.

Functional food with same registration certificate or record number shall use the same trademark.

## **Part V Food Inspection**

**Article 94** Food and Drug Supervision and Management Department and Quality Supervision Department shall conduct random sample inspections on food, food additives and food related products according to the division of responsibilities.

The food safety supervision and sampling inspection shall be performed according to the inspection items and testing methods stipulated in food safety standards. The works such as case inspection, accident investigation and emergency response can adopt the inspection items and the testing methods not stipulated in the food safety standards to analyse and determine the causes of food safety problems. In case of adopting the testing methods not stipulated in the food safety standards, it shall follow the principles of advanced technologies and get the permission from the food and drug supervision and administration department of the People's Government at or above provincial level.

**Article 95** When conducting sample inspection for food safety supervision, the food and drug supervision and administration department and the quality supervisory department can conduct the sampling by themselves, or entrust the food inspection institutions with statutory qualification for sampling. The number of persons conducting the sampling shall not be less than two.

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

**Article 96** The food and drug supervision and administrative department shall follow the requirements of the internet food sampling inspection program, shall determine the purchaser of sample, payment account, registration account, recipient's address and contact information, shall save the purchasing bills, and shall record the name, type and quantity and so on of the samples drawn for sampling inspection.

Upon reception of the sample, the purchaser of sample, sampling person of the unit conducting the inspection, and the law enforcement officers of the food and drug supervision and administration department shall jointly unpack and check the sample, have the sample and reserved sample sealed respectively, and notify the internet food business operator. In case of purchasing through a third-party internet food platform provider, the third-party platform provider can be required to assist in notifying the internet Food producer and trader simultaneously.

**Article 97** The food and drug supervision and administration department organizing and conducting internet food supervision and sampling inspection shall notify the received inspection results to the sampled internet Food producer and trader in a timely manner. In case of purchasing through a third-party internet food business platform, the third-party business platform provider shall be notified simultaneously.

Shall the internet Food producer and trader not be reached, the inspection results can be notified with the assistance of the third-party platform provider. Shall inspection fail, and the internet Food producer and trader are not reachable, the third-party platform provider can be required to remove the online food sales information of the internet Food producer and trader and the business service provided by the third-party platform shall be suspended.

In case the inspection results cannot reach internet Food producer and trader due to the incomplete contact details of internet Food producer and trader, the food and drug supervision and administration department can publish relevant results and information on its government website.

**Article 98** In case the food safety supervision and sampling inspection result is qualified, the institution undertaking the inspection shall submit the inspection report to the food and drug supervision and administration department organizing and conducting the supervision and sampling inspection within 10 working days. In case the inspection result is disqualified, the institution undertaking the inspection shall report to the food and drug supervision and administration department organizing and conducting the supervision and sampling inspection in a timely manner.

In case the food and drug supervision and administration department receive negative inspection results indicating that it may cause severe harm to public health and life, it shall notify the inspection result to the food and drug supervision and administration department where f the sampled food business operator locates, and the food and drug supervision and administration department where producers and importers labeled on the package or label locate.

Upon reception of notification, the food and drug supervision and administration department shall notify the relevant food business operator immediately to undertake such measures as suspending operation and recalling unsafe food to eliminate and control the food safety risk and shall conduct investigation and handling it in a timely manner. In case the food business operator fails to fulfil relevant obligations in accordance with relevant provisions, the food and drug supervision and administration department shall demand them to fulfil its obligations.



**Article 99** In case the relevant seal and the signature of an inspection institution is certified by a qualified third-party service provider, the electronic version of an inspection report issued by the institution has the equal legal effect as that of a paper version.

**Article 100** Under any of the following circumstances, inspection cannot be re-conducted:

1. Where the inspection conclusions indicate that the microbiological indicator exceeds the limit;
2. Where the reserved sample for re-inspection exceeds the shelf life;
3. Where the application for re-inspection is put forward exceeding the specified timeframe;
4. Where the re-inspection on the reserved sample is impossible due to other reasons.

**Article 101** In case a food business operator disagrees with the inspection conclusions and applies for a re-inspection according to provisions of Food Safety Law, the applicant of re-inspection cannot entrust an institution conducting re-inspection if conflict of interests exist between the applicant and the institution.

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

The food business operator shall not cease to fulfil relevant obligations such as suspending operation and recall during applying for re-inspection.

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

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

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

**Article 104** The national entry-exit inspection and quarantine authorities shall implement supervision and administration on import & export of food, food additives and food related products as well as and food at frontier ports food in

accordance with the provisions of the Food Safety Law and the Rules.

The national entry-exit inspection and quarantine authorities shall publish the inspection and quarantine certification document of foods and food additives to the public and for free query by the public.

**Article 105** The national entry-exit inspection and quarantine authorities shall implement graded and classified administration on import food in accordance with their responsibilities based on the conditions such as the food safety risk, food safety control capacities of enterprises, food safety condition of exporting countries or regions.

**Article 106** When importing foods, food additives and food related products, an 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 and relevant approval documentations. As for declaration, the conformity 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, 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 the entry-exit inspection and quarantine authorities, and shall publish on the official website.

**Article 107** In case of importing special food requiring registration or record-filing management, an importer or its agent shall submit the registration certificates or the record-filing certificates in accordance with the provisions of the Food Safety Law and the Rules to the entry-exit inspection and quarantine authorities. The entry-exit inspection and quarantine authorities shall implement supervision and sampling inspection in accordance with the requirements prescribed in the registration certificates or the record-filing certificates.

**Article 108** The supervision and sampling inspection of exported food shall be conducted by the entry-exit inspection and quarantine authorities. Shall there be requirements in international treaties and protocols, the entry-exit inspection and quarantine authorities shall conduct the supervision and sampling inspection in accordance with the requirements in the international treaties and protocols.

**Article 109** The entry-exit inspection and quarantine authorities shall implement supervision and sampling inspection during the importation process of imported foods, imported food additives and imported food related products. For those products entering the domestic market for sales, the supervision and sampling inspection on them shall be conducted by the food and drug supervision and administration departments.

The entry-exit inspection and quarantine authorities shall conduct detention and

inspection on foods, food additives and food related products with high safety risks. On those with regular risks, sampling inspection shall be conducted. On those with low risks, the on-site inspection shall be conducted.

**Article 110** The overseas exporters and overseas food producers exporting food to China shall guarantee that the food exported to China comply with the Food Safety Law, provisions of other relevant laws and regulations, and requirements of the food safety national standards. Importers shall establish audit systems on overseas food exporters and overseas food producers.

**Article 111** In case an importer recalls imported food, the exit-entry inspection and quarantine authorities shall notify the food and drug supervision and administration 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 process of planting and breeding, raw and auxiliary materials control, production, packaging, storage, and transportation.

**Article 113** For the overseas producer of imported food which has been certified by the Chinese GMP and the HACCP system, the certification authority shall conduct follow-up investigation according to law. For enterprises no longer complying with certification requirements, the certification authority shall revoke the certification according to law, shall notify the relevant departments of the State Council, and shall announce to the public.

**Article 114** The imported pre-packaged 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 functional food, imported food for special medical purpose and imported infants and young children formula milk powder, the Food and Drug Supervision and Administration Departments of the State Council can organize the on-site verification on the quality management system of the producers thereof, as well as the implementation of the GMP of functional food and record-filing.

Food producer and trader shall not import the food containing raw materials only used for health food in the name of regular food.

**Article 116** In case of any food safety accidents or other public health events occurred abroad that may affect China, or any severe food safety problems found in imported foods, food additives, and food related products, the national entry-exit inspection and quarantine authorities shall release imported food safety risk alerts in a timely manner, and shall decide to take the following control measures:

1. To implement and to enhance supervision and detaining inspection;
2. To return or destroy the products;
3. To apply restricted import with conditions

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 E-commerce, it shall comply with the relevant provisions on food import and export in the Food Safety Law and the Rules.

Measures for supervision and administration of importing food, food additives and food related products in the form of cross-border E-commerce shall be formulated by the Quality Supervision, Inspection and Quarantine Department of the State Council together with relevant departments of the State Council separately.

## **Chapter 7 The Treatment on Food Safety Incidents**

**Article 118** The treatment on food safety is based on hierarchical management.

The food safety incidents with extreme significance are investigated and treated by the State Council food and drug supervision and administration departments, after consulting with relevant State Council departments, and under the unified leadership of the State Council.

The significant, relatively big and normal food safety incidents are investigated and treated by the food and drug supervision and administration departments of the people's government at province, municipality and county levels, after consulting with other relevant departments, and under the leader of the people's government at the same level.

**Article 119** The people's governments at the province, autonomous region, and municipality levels shall draw up the emergency planning of the food safety incidents, and get it revised and improved according to the change of the actual situation.

The local people's government at county level or above shall do well the management on the emergency plan for food safety incidents, and enhance the supervision, inspection and guidance on the emergency management work done by the food producing or trading enterprises, and shall conduct emergent drill at least once every 3 years.

The local people's governments at county level or above shall include the training on the emergency plan for food safety incidents into the daily programme of the leadership training, civil servants training, and emergency management staff training.

**Article 120** The people's government at province, autonomous region and municipality levels shall draw up the plan for the establishment of the food safety emergency system.

The local people's government at county level or above shall improve the management institutions for the emergency management of food safety, improve the emergency and management scheme, ensure the budget for guarantying the emergency plan, improve emergency facilities, establish well the storage of the resources for emergency and the construction of the emergency crews, enhance training on emergency training, drill and evaluation.

Local people's government at county level or above shall conduct surveillance, early-warning work for food safety incidents, enhance the work of gathering, analysis and judgment on the food safety related information, and release early warning according to the extend of emergency of the food safety incidents, development situation and the extend of possible harm.

**Article 121** Food and drug supervision and administration departments of people's government at county level or above shall consult with health administrative departments at the same level to establish the reporting scheme for the surveillance of food safety incident information, establish the direct reporting internet system for the food safety incident information covering the food producer and trader with certain scale, the third-party on-line food trading platforms, medical institutions, disease prevention and control agencies, and implement unified supervision and management on the report of the food safety incident information.

**Article 122** Food producer and trader shall establish food safety emergency management scheme, treatment plan for incidents and reporting system for emergent incidents.

Food producer and trader with certain scale and relevant parties shall often organise and conduct emergency drill with certain target.

**Article 123** Food safety incident information fall into one of the scenarios, investigatory treatment shall be conducted in a timely manner:

1. The food provided by food producer or trader has caused food poisoning.
2. Food contamination has caused when food producer or trader produce, process, store, transport and sell food by human factors or other factors, and has caused harm for the public human beings or will possibly caused harm to human being.

**Article 124** The place where the food safety incident occurs, control measures like to seal the food, raw materials, tools and equipment, which can possibly cause food safety incidents, shall be adopted, and shall report to food and drug supervision and administration departments of the people's government at county level within 2 hours after the incident happened.

If the hospitalised patient or the public health emergent incidents dealt by medical care and disease prevention and control institutions are related to food safety, food and drug supervision and administration department and health administration departments of people's governments where the incident happened, shall be notified.

Health administration departments shall timely organise disease prevention and control agencies to deal with the health situation on the spot, and conduct epidemiological investigation on factors relating to food safety, relevant authorities shall provide assistance. The disease prevention and control agencies at county level shall submit the preliminary report on epidemiology after consulting with health administration department and food safety supervision and administration department at the same level within 24 hours, and submit the final report within 7 working days after the investigation is concluded.

In case of discovery of food safety incident information by the disease prevention and control agencies and technical agencies, like the agency for food testing, they need to report to food and drug supervision and administration department of people's government at county level or above in a timely manner.

**Article 125** Health administration department of people's government at county level or above shall consult with food and drug supervision and administration department at the same level to establish the scheme of surveillance and report of food-borne diseases and food safety incidents information, and mobilise disease prevention and control agencies to verify the reported disease information. For the information related to food safety, health administration department shall report to upper level health administration department and the people's government at the same level within 2 hours, and notify the food and drug supervision and administration department at the same level at the same time.

Article 126 Health administration, quality supervision, agricultural administration, public security and other relevant authorities of local people's government at county level or above shall report to food and drug supervision and administration department at the same level at a timely manner in case of discovery of food safety incident. If food and drug supervision and

administration department finds that the food safety incident information is related to a certain authority, then the food and drug supervision and administration department shall notify the relevant authority in a timely manner.

**Article 127** After local people's government at county level or above has received food safety incident information, it shall timely organise food and drug supervision and administration department, health administration, agriculture administration, quality supervision, public security departments to investigate and to verify. If the incident is identified as food safety related, food and drug supervision and administration department shall consult with health administration, agricultural administration, quality supervision, public security departments to conduct investigation and treatment.

When the investigation on food safety incident is finished, food and drug supervision and administration department shall present the final report on the food safety incident to people's government of the same level and to food and drug supervision and administration department of the upper level according to relevant regulations.

If emergency plan shall be launched after the food safety incident occurred, people's government at county level shall establish the conduction agency to deal with the incident and launch the emergency plan.

**Article 128** The emergency plan and the related investigation on the other food safety issue beyond the food safety incident can be implemented according other relevant regulations in This Chapter.

## **Chapter 8 Supervision Work**

**Article 129** State Council food and drug supervision and administration departments are mainly in charge of registration and file-recording of relevant special food, mobilize to conduct national food safety supervision sampling inspection, inspection on the control system and unannounced inspection, create the unified food safety information platform, conduct investigation on significant food safety illegal activities, tackle with food safety incidents with great significance according to relevant laws and regulations, and to prevent the systematic food safety risks.

The food and drug supervision and administrative departments of provinces, autonomous regions, municipalities directly under the central government are mainly in charge of the production license management for special food, organization of food safety supervision and sampling inspection, control

system inspection, unannounced inspection at provincial level, publication of regional food safety information according to laws and regulations, conduction of investigation for cases of violating food safety, tacking with significant food safety incidents, and the prevention of regional food safety risks.

The food and drug supervision and administrative departments of municipal people's governments at county level are mainly in charge of production license management for food, conduction of regular supervision and sampling inspection on food safety, publication of regional food safety information, supervision of the products recalling, tackling with illegal activities violating food safety norms. And particularly conduct regular supervision, inspection and sampling inspection on the pesticides, residue of veterinary drugs in the food raw materials sold and purchased by regional food and edible agricultural wholesale markets, supermarkets and catering services, and on the small food production and processing workshops and food vendors.

**Article 130** The State Council food and drug supervision and administrative authority can assign agencies to conduct patrolling supervision on the food safety work done by the local people's governments.

**Article 131** The food and drug supervision and administration, quality inspection, agricultural administration of county and above level people's governments, pursuant to food safety surveillance, risk assessment, supervision and inspection, inspection and sampling inspection, accident management, accident investigation, shall manage the regional food safety by grading the risks.

**Article 132** Food safety inspector scheme shall be created at national level. Food and drug supervision department of people's governments above province level shall establish full-time food safety inspector team, to conduct on-spot inspection on good manufacture practice and the implementation of HACCP norms conducted by food safety producer and operator with certain scale. The State Council food and drug supervision and management authorities make the specific management rules.

**Article 133** When food spoilage, mildew and insect, doping of foreign bodies and other abnormal sensory properties are discovered during the supervision and inspection done by the food safety supervision and inspection, quality supervision departments, the proof can be taken by photos and videos.

If the concerned party refuses to sign or cannot sign due to special reason, the reason shall be stated and confirmed by the signatures of more than 2 law enforcement personnel on the spot.



**Article 134** If the proof could be possibly destroyed or lost, or difficult to be obtained afterwards, the law enforcement personnel of food and drug supervision and administration, quality supervision, agricultural administration can firstly register and keep the relevant contracts, bills, account book, storage equipment for digital data and other relevant documents.

**Article 135** If a food producer or operator is being registered for investigation because of being suspected for conducting unlawful acts against food safety, the food safety supervision and management department can suspend the acceptance of the relevant administrative application; for those being accepted, the proceeding work shall be ceased, the ceasing during will not be counted into the limited during of administrative licensing.

**Article 136** The superior food and drug supervision and administrative departments can directly tackle with the food safety violation cases which are managed by the lower level food and drug supervision and administrative department if it's considered necessary, or can designate food and drug supervision and administrative departments of other regions to tackle with. The food and drug supervision and administration department which is located in the place where the food safety incident occurred, shall provide cooperation.

**Article 137** The State Council health administrative authority shall coordinate with other State Council authorities to timely publish the list (and the testing method) of the added or possibly added inedible chemical substances and other substances which can possibly harm human health, according to food born disease information, risk surveillance, risk assessment and other supervision and administrative information.

**Article 138** For the pathogenic microorganism, pesticide residue, veterinary drug residue, bio toxin, pollutants, and other substances of harming human health, whose residue limits and testing methods are not yet made, the State Council health administrative authority shall coordinate with State Council agricultural administrative, food and drug supervision and administrative authorities to make temporary limit and temporary testing method and get them published to the society to serve as the reference for production, business operation and supervision administration.

**Article 139** State Council food and drug supervision and administrative, quality supervision, agricultural administrative departments can conduct evaluation on speedy food testing methods according to the need of food safety supervision. For those passed evaluation, can be defined as the speedy testing method at the national level.

The food and drug supervision and administration, quality supervision, agricultural administrative department of county or above level people's government can use national food safety standards, or adopt speedy testing method which is defined by state council food and drug supervision and administration, quality supervision, agricultural administrative departments, to conduct sampling inspection.

For the food which is shown not compliant with food safety standards according to the result of sampling inspection, can be inspected according to the regulation laid down in Article 87 of the Food Safety Law; Food producer and operator shall adopt measures of ceasing sales to control the risks. For the food which is determined as non-compliant with food safety standards according to the result of sampling inspection, its sampling inspection results can be served as the basis for administrative penalty.

**Article 140** The State Council food and drug supervision and administration departments make the specifications of speedy testing techniques, can also delegate the food and drug supervision and administration departments of provinces, autonomous regions and municipalities directly under the State Council, relevant industrial associations or professional technical institutes to conduct evaluation on the speedy testing methods suggested by relevant enterprises and scientific institutions. For those passed evaluation, shall be published in the society.

The State Council food and drug supervision and administration departments can delegate the food and drug supervision and administration departments of people's governments at province, autonomous regions and municipality directly under the State Council to conduct on-spot inspection on the production situation and the application dossier of the enterprise who submitted application for speedy inspection method, and to make samples.

Food and drug supervision and administration departments of the people's government at province, autonomous region, and municipality directly under the State Council shall make management rules on speedy test, regulate the verification and utilisation of the speedy method, and conduct supervision and inspection on the utilization of speedy method in the food safety supervision management within the jurisdiction.

**Article 141** For the food speedy testing method which is not yet been evaluated by State Council food and drug supervision and administration authority, food and drug supervision and administration departments of the people's government of province, autonomous region and municipality directly under the State Council can make relevant management rules and

specification of technical evaluation on food speedy testing method, mobilise relevant technical authorities to conduct evaluation on food speedy testing methods according to the supervision needs within the jurisdiction. For those passed evaluation, can be used for preliminary food safety screening test within the jurisdiction.

**Article 142** State Council food and drug supervision and administration authority shall establish credit system for food producers and operators, create and improve the disclosure scheme for credit-lost information and encouragement scheme for credit-kept information, make research on how to connect food safety credit evaluation result to the credit systems of industry access, credit financing, securities insurance, to fully restrict the food safety credit-lost behaviors.

**Article 143** Food and drug supervision and administrative department shall timely publish the information of license insurance, results of daily supervision and inspection, and investigative management on unlawful acts.

The information of license insurance include the name of producer and operator, social credit code (ID card number for individual operator), legal representative (person in charge), residency address, venue of production and operation, type or item of the food being produced and operated, number of the license, validation date, name of the daily supervision and administration, complaint hotline, licensing insurance authority, insurance person, date of licensing and so on.

The information of daily supervision and inspection include the name of the producer and operator, social credit code (ID card for individual operator), legal representative (person in charge), residency venue, license number, inspection date, inspection items, inspection result, and so on.

The information of investigative management on unlawful acts include the name of the case, the name of the person or the name of the enterprise being punished, main facts of unlawful acts, type of the punishment, basis of the punishment, result of the punishment. For those whose license is suspended, its legal representative, person in charge and the name and ID number of other related personal bearing direct responsibility shall be published to the society.

**Article 144** Health administration department of the people's government at county level shall conduct supervision and inspection on the centralized cutlery disinfection place, conduct timely investigative management for those incompliant with food safety laws and regulations and relevant health rules and requirements, the relating supervision results shall be published to the

society.

**Article 145** For the food producer or operator which regards one of the following situations, food and drug supervision and administration departments shall arrange communication session with its legal representatives or major person in charge:

1. Occurrence  
of food safety incident which aroused great social concern;
2. Not timely  
deal with the food safety incident being complained and reported and has aroused significant social concern;
3. Not timely  
adopt effective measures of troubleshooting and eliminating a hazard and not implement food safety liabilities;
4. Other  
situation that considered by food and drug supervision and administration department of people's government at county or above level that liability communication session is necessary.

In case unlawful acts exist in food producer and operator, liability communication session will not affect the administrative measures according to laws and regulations, the following-up situation of the liability communication session shall be published to the society.

For the party requested for liability communication session failed to implement correction according to relevant requirements, food and drug supervision and administration departments shall record it into food safety credit archive system and increase the supervision and inspection frequency.

**Article 146** People's government at county level or above shall bear the responsibility of safeguarding food safety within its jurisdiction, make food safety safeguarding plan, specify food safety liabilities, and clarify the expense and conditions for the safeguarding measures.

The organizer of big event shall make clear the food safety administrative department and choose the food producer and operator with capability of safeguarding food safety and supervise the food producer and operator to fulfill their food safety liabilities.

The food producer and operator of providing food for the big event shall bear the major food safety liability, make food safety safeguarding plan and emergency plan, to implement the whole-process control requirements for food safety, and to ensure food safety.

Food and drug supervision and administration, health administration, agricultural administration, quality supervision departments of people's government at county level or above shall ensure food safety for the big event according to food safety safeguarding plan, enhance evaluation on suppliers and inspection on food. If necessary, can employ professional personnel to evaluate.

Professional agencies in the society are encouraged to be invited by the organiser of the big event to provide food safety safeguarding service for big event.

**Article 147** Superior food and drug supervision and administration departments can conduct unannounced inspection on the work done by the lower level food and drug supervision and administration departments if one the following situations occurs:

1. The food producer or operator is suspected of violating food safety laws and regulations and possibly create serious damage or significant social impact;
2. Food safety hidden danger exists in food producer or operator, and possibly trigger regional food safety risk, or severe damage or significant social impact;
3. Insider source complains or reports that certain food producer or operator has severe unlawful acts or significant danger of food safety;
4. Out of other necessary reason to conduct unannounced inspection

Unannounced inspection shall be conducted by casual inspection principle and procedures and requirements of on-spot supervision and inspection.

**Article 148** Food and drug supervision and administration departments of people's government at county level or above shall establish food safety complaint and report agencies, publish the food safety complain and report hotline, and establish internet information management system for complaints and reporting.

Food safety complaints and reporting acceptance agencies shall regularly wrap up and analysis food safety complaints, and come up with the suggestions to improve food safety supervision and administration measures.

**Article 149** State Council food and drug supervision and administration authority shall coordinate with other relevant State Council authorities to

compile capacity building standards for food safety supervision and administration, clarify the requirements of capacity building for food safety supervision and administration agencies, personal, equipment and facilities at all levels.

People's government at county level or above shall include the expense on food safety supervision and inspection, sampling inspection, risk surveillance, administrative licensing, awareness campaign, capacity building into the financial budget, and set up designated budget for emergency measures, investigations, reporting awards, safeguarding for big events.

**Article 150** State Council food safety supervision and inspection departments shall make overall training programme, food safety supervision and administration departments of people's government of province, autonomous region, municipality directly under the central government shall be in charge of organization of evaluation on trainings.

Law enforcement personnel of food safety supervision and administration departments shall be trained no less than 40 hours on food safety, and be examined, for those failed to pass the exam are not allowed to commit to food safety law enforcement work.

**Article 151** Food safety and drug supervision and administration departments of people's government at county level or above shall make regional annual inspection plan and define the inspection frequency according to risk grading.

In case of discovery of unlawful acts during the inspection on food producer and operator, investigatory administration measures shall be made according to laws and regulations. The inspection facts and result of investigatory administration shall be recorded. The inspection record shall be co-signed by inspection personnel and relevant person in charge of the food producer and operator and then be archived.

Inspection results shall be pasted on the operational venue and published on internet.

**Article 152** Food and drug supervision and administration departments, as delegated by people's government at its same level, can make liability communication session with person in charge of the lower people's government if it doesn't fulfill the legal responsibilities, or doesn't diminish the regional significant food safety hidden danger.

**Article 153** State Council food and drug supervision and administration departments shall coordinate with State Council health administration,

agricultural administration, quality inspection departments to enhance food safety information system, establish the unified food safety information platform to consolidate food safety information resources to realise the food safety information co-sharing.

**Article 154** State Council food and drug supervision and administration departments shall regularly draw up and publish the national food safety annual report.

**Article 155** Food safety statistical survey scheme shall be established at the national level. The State Council food and drug supervision and administration department shall coordinate with other State Council departments like statistical department to establish food safety statistical index system, and organise to conduct food safety related statistical survey work.

Food and drug supervision and administration departments of the people's government at county level or above shall coordinate with statistical departments at the same level to refer to the national food safety statistical survey scheme and statistical index system to establish and improve the regional food safety statistical survey scheme and statistical index system, and organise the conduct food safety related statistical survey work.

Food safety producer and operators, industrial associations shall cooperate with food safety supervision and administration departments to conduct food safety statistical survey work according to laws and regulations.

**Article 156** The case investigatory agencies affiliated with food safety supervision and administration departments of people's government at county level or above can act on their own to conduct law enforcement measures like the supervision and administration measures on on-spot inspection, sampling inspection, sealing-up and detaining, investigation on cases.

**Article 157** Per the one of the listed activities discovered by food safety supervision and administration, quality supervision department of people's government at county level or above, the relevant investigatory clues and proofs shall be transmitted to public security departments within 3 working days:

1. Producing food with non-food raw materials, adding chemical substances other than food additives, or substances that may cause harm to human health, or use recovered food as raw materials, or trading the above-mentioned foods;
2. Producing and trading staple and supplementary food dedicated to infants or other specific populations, while the nutritional ingredients of which fail to

- |    |   |           |
|----|---|-----------|
| 3. | comply with food safety standards;<br>meat of any poultry, livestock, animals, or waterborne animals which have been killed by disease, poison or any unidentified cause; or producing and trading products produced by such meat;                  | Trading   |
| 4. | meat that have not been quarantined following requirements or fail to pass such quarantine, or producing or trading meat products which have not been inspected or fail to pass such inspection;  | Trading   |
| 5. | or trading food expressly prohibited by the State from production and trading for disease prevention and control purposes;  | Producing |
| 6. | or trading foods added with medicine;   | Producing |
| 7. | or trading pollutants like pathogenic microorganisms, pesticide residues, veterinary drug residues, bio toxins, or heavy metals or other substances in the food and food additives which are above the safety limit may cause harm to human health; | Producing |
| 8. | relevant suspected food safety criminal acts.   | Other     |

Public security departments shall take timely measures to inquire, verify, check, identify and obtain the proof materials to conduct preliminary investigation.

On alleged to constitute a crime, public security departments shall timely open the case for investigation according to laws and regulations in a timely manner, on the case not alleged to constitute a crime, it is for administrative departments to conduct administrative penalty according to laws and regulations.

**Article 158** People’s government at county level or above shall establish and improve the coordination between food safety administrative law enforcement and criminal justice, clarify the clue notification, transmission of the case, consultation on the case, information sharing, publication of the information, investigation and supervision of the handling of the case; coordinate and supervise the criminal food safety case investigation.

**Article 159** State Council food safety supervision and administration authority shall coordinate with State Council justice authority to draw up management rules on food safety judicial testimony, specify qualification conditions, determine the catalogue for food safety justice testimony agencies and personnel.



The delegated party to conduct food safety justice testimony shall come from the catalogue of food safety justice testimony agencies and personnel.

**Article 160** When encountering with one of the following situations during the law enforcement process by food and drug supervision administration, and quality supervision departments, public security departments shall provide assistance if needed:

1. violent  
confrontation against laws or occurrence of mass incident;
2. reject, resist,  
or hamper the law enforcement on food safety supervision;
3. destroy or  
hide evidence or person in charge escaped;
4. obtaining  
evidence is needed for significant difficult case;
5. other  
scenarios regulated by laws;

**Article 161** If public security authority need technical support and information verification from food safety supervision and administration, quality supervision departments during their investigation on food safety criminal case, food and drug supervision and administration, quality supervision department shall provide assistance.

**Article 162** For the case transferred by food safety supervision and administration, quality supervision, health administration departments, public security departments shall conduct investigation within 3 working days.

If the unlawful act involves illegally adding non-edible substances, drugs, or meat from animal or poultry died of disease which may severely harm the human health, shall conduct investigation without any delay.

**Article 163** Food and drug supervision and administration, quality supervision, agricultural administration departments shall enhance communication and coordination with public security departments, and establish and improve the evidence transferring scheme.

The evidence transferred by food and drug supervision and administration, quality supervision, agricultural administration department to public security departments, can be digitally achieved, photocopied and stamped and then served as the basis for administrative penalty.

For the evidence transferred by food and drug supervision and administration, quality supervision, agricultural administration departments, public security departments can use it as the evidence of criminal case if it is verified as compliant with criminal evidence standards.

**Article 164** For the food safety unlawful acts discovered by public security departments, if there is no criminal fact concluded after the investigation, or the criminal act is obviously minor or there is no need to be prosecuted for criminal liability after the case is opened for investigation, administrative liability shall be prosecuted and the case shall be transferred to food and drug supervision and administration, quality supervision, agricultural administration departments.

Public security departments shall also transfer the stamped photocopies of the evidence materials to food and drug supervision and drug administration, quality supervision, and agricultural administration departments. Relevant departments shall verify the transferred evidence materials and get them used if they are compliant with the evidence standards for administrative law enforcement.

Article 165 For the case judged by people's courts that administrative penalty, like license suspension, shall be conducted but not yet being conducted by food and drug supervision and administration, quality supervision and agricultural administration departments, after verification, food and drug supervision and administration departments shall give administrative penalty to the facts and evidences confirmed by the written judgment of people's court.

**Article 166** The designated agencies of food and drug supervision and administration can conduct supervision, inspection, administrative guidance to the regional food producer and trader on their own.

The designated agencies of food and drug supervision and administration can send warnings, give administrative penalty of less than 5000RMB on their own.

The designated agencies of food and drug supervision and administration as approved by person in charge in the food and drug supervision and administration departments of people's government at county level or above can conduct administrative compulsory measures like sealing up and detaining to prevent food safety risks.

## **Chapter 9 Legal liabilities**

**Article 167** If the food producer or trader continues to produce or trade when their license is suspended, cancelled or expired, and the administrative

licensing is cancelled or withdrawn, the food and drug supervision and administration departments of people's government at county level or above can give penalty according to Clause I, Article 138 of the Food Safety Law.

**Article 168** Per the activities is of "severe circumstance" as laid down in Clause I, Article 123 of the Food Safety Law, but not serious enough to be considered as a crime, shall be given penalty by food and drug supervision and administration department of people's government:

1. Producing food with non-food raw materials, adding chemical substances other than food additives, or substances that may cause harm to human health, or use recovered food as raw materials, or trading the above-mentioned foods with the trade value more than 1000RMB or being punished administratively according to food safety laws and regulations within one year;
2. Producing and trading staple and supplementary food dedicated to infants or other specific populations, while the nutritional ingredients of which fail to comply with food safety standards, with the trade value more than 1000RMB or being punished administratively according to food safety laws and regulations within one year;
3. Trading meat of any poultry, livestock, animals, or waterborne animals which have been killed by disease, poison or any unidentified cause; or producing and trading products produced by such meat, with the trade value more than 1000RMB or being punished administratively according to food safety laws and regulations within one year;
4. Trading meat that have not been quarantined following requirements or fail to pass such quarantine, or producing or trading meat products which have not been inspected or fail to pass such inspection, with the trade value more than 1000RMB or being punished administratively according to food safety laws and regulations within one year;
5. Producing or trading food expressly prohibited by the State from production and trading for disease prevention and control purposes, with the trade value more than 1000RMB or being punished administratively according to food safety laws and regulations within one year;
6. Producing or trading foods added with medicine, with the trade value more than 1000RMB or being punished administratively according to food safety laws and regulations within one year;
7. Other

scenarios as laid down in laws and regulations .

**Article 169** Per the activities fall into one of the following which is not serious enough to be considered as a crime, food and drug supervision and administration department of people's government shall give penalty according to Clause 1, Article 123 of the Food Safety Law:

1. Using non edible substances during the production, trading, storage, transportation of the food;
2. Using dumped or recovered food additives to produce or process food and food additives;
3. Using substance which may harm human health to soak or fumigate food, or with similar way;
4. Purchasing or store non edible chemical substances which expressly prohibited by relevant authorities during food production and trading;
5. Using non edible chemical substances to forge food additives;
6. Adding medicines, chemical substances other than food additives raw materials or other substances may harm human health in the food additives;
7. Clean and disinfect utensils and tools by detergent or disinfectant which is not suitable for food production and trading;
8. Other scenarios as laid down in laws and regulations

In case of using prohibited substances like prohibited pesticides, veterinary drugs in the plantation or farming of edible agricultural products, penalty shall be given by agricultural administration departments of people's government at county level or above according to the First Clause.

**Article 170** Producer of special food commits one of the following activities, State Council food and drug supervision and administration authority shall cancel its special food registration certificate:

1. Producing special food by using non food raw materials or adding chemical substances other than food additives or substances may harm human health;
2. Adding medicines in the production of special food;
3. Mobilising

- production of special food by non registered food formulation or other processing procedures, and with the value above 10000RMB and below 20000RMB;
4. Producing infant formula in subpackaging way, or different brand of health food, food for special medical purpose, infant formula is produced by the same manufacture by using the same formula, with the value of more than 10000RMB or below 20000RMB;
  5. Other scenarios as regulated by laws and regulations.

**Article 171** Per activities fall under one of the following scenarios, but not serious enough to be considered as a crime, food and drug supervision and administration departments of people’s government at county level or above can give penalty to the “severe scenario” according to Clause 1, Article 124 of the Food Safety Law;

1. Producing or trading food or food additives with substances of pollutants like pathogenic microorganisms, pesticide residues, veterinary drug residues, bio toxins, heavy metals with above 2 times of the safety limit, or other substances may harm human health, or with the value of more than 30000RMB;
2. Producing food or food additives by food raw materials or food additives exceeding shelf life, or trading the above-mentioned food or food additives, and with the value of more than 30000RMB;
3. Producing or trading food with food additives beyond the usage scope or safety limit, and with the value of more than 30000RMB;
4. Producing or trading food or food additives of spoilage, rancidity, mildew insect, filthy dirty, doping foreign bodies, or sensory abnormality, and with the value of more than 30000RMB;
5. Producing or trading food and food additives with labeling fake production date, shelf life, or exceeding shelf life, and with the value of more than 30000RMB;
6. Producing or trading unregistered health food, food for special medical purpose, infant formula, or mobilising production according to unregistered product formulation and processing procedures, and with the value of more than 20000RMB;
7. Producing infant formula in the sub-packaging way, or producing different brands of

- infant formula by the same manufacture by using the same formula, and with the value of more than 20000RMB
8. Producing food by using new food raw materials, or producing new food additives which has not yet passed safety evaluation, and with the value of more than 30000RMB;
  9. Food producer or trader still rejects to recall or stop trading after food and drug supervision and administration department has instructed it to recall or stop trading;
  10. Caused severe food poison or food-born disease with harmful consequence;
  11. Continue to produce or trade after food and drug supervision and administration departments have instructed to take corrective measures or stop producing and trading;
  12. Caused damage mainly to special group of people, such as disable people, senior people, pregnant women, children, or critical patients as confirmed by medical insurance;

**Article 172** Per activities fall under the following scenarios, but not serious enough to constitute a crime, food and drug supervision and administration departments of people's government at county level or above can give penalty according to Clause 1, Article 124 of the Food Safety Law:

1. Food producer or trader does not adopt necessary control measures, like stop producing or trading, or recall problematic food during the verifying inspection, or evaluation on the objection authenticity, or safety hidden danger is found in the result of food safety surveillance.
2. Violating liabilities ldy on food safety laws and regulations and has caused food safety incidents;
3. Producer of infant formula violating the regulations of Article 92 of This Implementation Rule;
4. Food producer or trader does not recall unsafe food according to the limited period of time;
5. Traders of imported food can not provide hygiene certificate, exit-entry inspection and quarantine certificate, Chinese label or inspection mark;
6. Producer of

- producing special food does not change the registration or change the production license when the production conditions, processing procedures have changed;
7. Producing normal food by using the raw materials of producing health food;
  8. Other scenarios as regulated in laws and regulation;

**Article 173** Per activities fall under one of the following “severe scenarios” as laid down in Clause 1, Article 125 of the Food Safety Law, food and drug supervision and administration department of people’s government at county level or above, can give penalty:

1. Producing and trading polluted food and food additives by packaging materials, containers, transportation means, and with the value of more than 20000RMB;
2. Producing and trading pre-packaging food or food additives without label, or the label or instruction of food or food additives is not compliant with food safety laws and regulations, and with the value of more than 30000RMB;
3. Producing or trading GMO food but without labeling according to relevant regulation, and with the value of more than 30000RMB;
4. Food producer or trader purchases or uses food raw materials or food additives, or food related products which are not compliant with food safety standards, and with the value of more than 20000RMB;
5. Other scenarios as regulated in laws and regulations;

**Article 174** Per activities fall under the following scenarios, food and drug supervision and administration departments of people’s government at county level or above shall give penalty according to Clause 1, Article 125 of Food Safety Law:

1. Fake, exaggerated character or image is used in food label or instruction, or these character or image can cause misunderstanding among consumers;
2. Food but labeled with the name of the drug or health food, or is claimed to possess the drug or health food functions;
3. The enforcement standards, ingredients list, or relevant compulsory labeling contents is falsely labeled;

4. For the food additives used in food and shall be labeled but not labeled according to relevant regulations, or the way of labeling is not compliant with food safety laws and regulations or other food safety standards;

**Article 175** Per activities fall under the “severe scenarios” according to Clause 1, Article 126 of the Food Safety Law, food and drug supervision and administration department of people’s government at county level or above shall give penalty:

1. Food and food additive producer does not inspect the purchased food raw materials, produced food or food additives, and the value of the food which is not compliant with food safety standards is above 30000RMB;
2. Food producer or trader does not establish food safety management rules according to relevant regulations, or does not train, evaluate food safety management personnel according to relevant regulations, and has caused food safety incidents involving more than 10 persons and less than 30 persons;
3. Producer and trader for food and food additives, who does not check the license or relevant certificate of the incoming goods, or does not establish relevant incoming goods checking record, outgoing goods checking record, and sales record according to relevant regulations, and the value of the food produced or traded which is incompliant with food safety standards is above 30000RMB;
4. Food producer or trader does not draw up food safety incident emergency plan and the food safety incident has effected 10-30 persons;
5. The drinkware, tableware and the container for food for direct eating is not cleaned, disinfected or the disinfection is not compliant; or the catering service facilities, equipment are not regularly maintained, cleaned or examined, and the related food safety incident has affected 10-30 persons;
6. The food producer and trader who does not obtain the health certificate, or commits to the job of producing or trading food for direct eating while having the disease defined by the State Council health authority as harmful for food safety, the related food safety incident has affected 10-30 persons;
7. Food trader does not sell the food according to relevant regulations, and has occurred food safety incident affecting more than 10 persons;
8. Producer of health food does not do file-recording with food and drug supervision and



- administration departments, or does not mobilise production with the value of more than 3000RMB according to the file-recorded product formulation, manufacturing procedures;
9. Producer of  
infant formula does not do file-recording job with food and drug supervision and administration departments for the food raw materials, food additives, product formula, labels and so on; and the value of the related food has exceeded 20000RMB;
  10. Producer of  
special food does not establish production quality control system according to relevant regulations with the value of related food exceeding 20000RMB, or failed to submit the self-inspection report more than 2 times;
  11. Food  
producer or trader does not regularly inspect and check its food safety situation, or no updated measures have been taken when the conditions for production and trade have changed, with the value of related food exceeding 30000RMB;
  12. Venues  
which require the centralized catering services, like schools, kindergarten institutions, nursing institutions for the aged people, construction site, failed to fulfill the food safety liability and has caused food safety incident;
  13. Food  
producer or catering service provider does not draw up or implement the control requirement during production and trading process, and has caused food safety incident affecting 10-30 persons;
  14. Other  
scenarios regulated by relevant laws and regulations;

**Article 176** Per activities fall under the following scenarios, food and drug supervision and administration department of people's government at county level or above shall give penalty according to Clause 1, Article 126 of Food Safety Law:

1. When food  
producer or trader produce food or trade food, they do not wear clean working outfit and hat according to relevant regulations, or when they sell the food for directly eating without package, they do not use non-poisonous and clean sale utensils;
2. Food  
producer or trader does not establish the usage system and recording system for food additives;
3. Food  
catering service provider uses the non-cleaned or non-disinfected kitchenware, tableware, or the food catering service provider does not ask for and archive the certificate of disinfection when purchased and uses the

kitchenware and tableware from the centralised disinfection services or delegated disinfection services;

**Article 177** Per following scenarios committed by kitchenware and tableware centralized disinfection services, health administrative departments of people's government of county level or above shall give penalty according to Clause 1, Article 126 of the Food Safety Law:

1. Does not arrange hygiene manager, or does not establish hygiene management system or hygiene management archiving system;
2. Commits to production activities in compliant with health regulations;
3. Incompliant kitchenware and tableware is found in the result of supervision and sampling inspection.

**Article 178** Per activities fall into the following scenarios, food and drug supervision and administration departments of people's government at county level or above shall instruct to correct, or give warnings; for those rejects to correct, penalty ranging from 5000RMB to 50000RMB shall be given:

1. Food trader does not set up effective protection facilities against dust, flies and so on, or uses package or label which is not compliant with food safety requirements;
2. Food trader or seller of edible agricultural product does not separately store the fresh food or cooked food and the hidden danger of cross contamination exist;
3. Food storage service provider does not archive the ID of the storage in charge person, license or photocopy of the business license;
4. Food producer or trader does not establish food traceability system and has caused the food untraceable;
5. The third party platform provider for on-line food trade, funder of the centralised food trading market, renter of the food counter, or organiser of the food exposition, does not establish food safety incident emergency plan;
6. The container or packaging materials for for food raw materials, semi-finished food product, finished food product, directly contact the floor or uncleanly objects.
7. The self-supplied water is not complaint with the national hygiene standards for

- drinking water in daily life;
8. Catering service provider is not equipped with effective facilities for the disinfection of kitchenware and tableware;
  9. The detergent or disinfectant used in the process of food production or trading is not compliant;

**Article 179** For the food produced or traded by food producer or trader is compliant with food safety standards but not compliant with the enterprise standards indicated, food and drug supervision and administration department can instruct the food producer or trader to correct. Consumers can require to withdraw the food or ask for compensation, food producer or trade shall bear civil liability according to laws and regulations.

**Article 180** Per activities committed by the third party platform provider for on-line trade, food and drug supervision and administration of people's government at county level or above shall give penalty according to Clause 1, Article 131 of the Food Safety Law:

1. Failed to provide the information of file-recording information of the on-line traded food and food additives, and trading data;
2. Transfer, falsify, manipulate, delete the trading date of on-line traded food and food additives.

**Article 181** If food producer or trader illegally hide, transfer, use with authorization, sell, destroy the objects being sealed or detained by food and drug supervision and administration department, food and drug supervision and administration of people's government at county level or above shall confiscate the illegal gains, and give the penalty of 10-20 times of the value of the goods being hidden, transferred, used without authorization, sold and destroyed and revoke the license; for the case constitutes a crime, criminal responsibility shall be affixed according to law.

**Article 182** "Refuse, resist, or interfere" behaviors as regulated by Clause 1, Article 131 of the Food Safety Law include:

1. delay or escape the supervision, inspection or investigation by the on-site law enforcement personnel;
2. Prohibit the law enforcement personnel to enter in to the sites of production, trade and storage for more than 1 hour;

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| 3. | Provided<br>relevant contract, bill, accountant book and digital data not compliant with requirements |
| 4. | Other<br>scenarios regulated by laws and regulation.  |

**Article 183** Per activities fall into the following scenarios, relevant authority shall give penalty under its responsibility according to the “severe scenario” described in Clause 1, Article 133 of the Food Safety Law:

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|----|---|
| 1. | Refuse,<br>resist, hamper the food safety supervision law enforcement by ways of assaulting, insulting, cursing, threatening; |
| 2. | Destroy or<br>hide evidence or the person in-charge escaped;  |
| 3. | Revenge the<br>informer or witness.   |

**Article 184** If penalty is given according to Clause 1&2 of Article 135, Article 137, Clause 2 of Article 138, Clause 1 of Article 139, the State Council food and drug supervision and administration authority, quality supervision authority and so on shall publish the name, ID number and other relevant information of the person in charge and other person in charge on their websites.

If the applicant for administrative approval hide relevant information or provides falsified documents to apply for administrative license, the administrative authority cannot accept or not to give administrative approval and give warning, the applicant cannot apply again for administrative approval within one year.

If the administrative approval is obtained by cheating or bribing by the approved person, the administrative authority can give administrative penalty according to law, and the applicant cannot apply for the administrative approval within 3 years; for the case constitutes a crime, the criminal liability shall be reaffixed.

**Article 185** If food producer or trader falsifies, alters food production and trading license, product registration certificate, label, instruction, testing report, quarantine certificate, accreditation certificate or provides falsified documents during the supervision and inspection, food and drug supervision and administration of the people’s government at county level or above can give penalty between 50000-100000RMB; for those who has food production or trade license, the license shall be suspended; for the case constitutes a crime, criminal liability shall be reaffixed according to law.

**Article 186** Per activities fall under one of the following scenarios, severe penalty shall be given:

1. The unlawful activity has caused severe damage or significant social impact;
2. The unlawful activity has caused systematic or regional food safety risk;
3. Illegally produces or trades special food
4. Causes more than 2 times food safety incident at normal level or relatively big level;
5. Intentionally commits the unlawful activity or gross negligence;
6. Other scenarios need to be severely punished according to law.

If a single unlawful activity has violated various clauses, the highest penalty shall be given.

**Article 187** Food producers or traders commit one of the following activities, shall be given a lesser punishment or the punishment shall be mitigated.

1. It is proven by evidence that it was not intentional or there is no gross negligence, and the violating behavior is minor, the value of the involved goods is relatively small and caused no harm;
2. Actively report to food and drug supervision and administration department and caused no harm;
3. Actively recall the unsafe food and caused no harm, and adopted effective measures to mitigate or eliminate food safety risks;
4. Report or coordinate with supervision and administration department to investigate the undiscovered unlawful acts, and has significant contribution;
5. Other scenarios shall be given lesser punishment and mitigated punishment.

If the unlawful act is minor, corrected timely, and caused no harm, the administrative penalty shall not be given.

**Article 188** The medical care institutions and their staff fails to report food safety incident information, or the disease control agency does not conduct epidemiology investigation report or does not present the report in the limited period of time, the health administrative department of people's government at county level or above shall instruct to correct; for those refuse to correct,

penalty ranging from 5000-50000RMB shall be given.

Article 189 Per activities fall under the one of the following scenarios, the advertisement supervision departments of people's government at county level or above shall instruct the advertiser in charge, advertisement agents, advertisement releaser to stop releasing advertisement, the advertisement shall be corrected in public, the advertisement income shall be confiscated, 50000RMB penalty shall be given for the advertisement expense less than 10000RMB, 5 times of the value of the advertisement expense shall be given for the advertisement expense more than 10000RMB and the food and drug supervision and administration departments of people's governments at provincial level or above shall decide to suspend the sales of the related food or food additives, and get it published in public. For those still being sold, food and drug supervision and administration of people's government at county level or above shall confiscate the unlawful obtains and sold food and food additives, and the penalty ranging from 20000 to 50000RMB shall be given:

1. Advertisem  
ent is not evaluated and approved;
2. The  
approval number of the advertisement is withdrawn or cancelled;
3. The  
advertised product is prohibited being sold by the relevant national  
authorities;
4. The  
advertisement was re-evaluated by food and drug supervision and  
administration departments of people's governments of provinces,  
autonomous regions and municipalities directly under the central  
government, as incompliant;
5. Change or  
alter without authorization the advertisement being approved after  
evaluation;
6. Including  
the prohibited contents by laws and regulations.

**Article 190** Falsely, exaggeratedly or cheatingly promote the health food or food for special medical purposes or food additives by means of telephone call, lectures, conferences and organised travelling, the food and drug supervision and administration departments of the people's government of county level or above shall confiscate the illegal obtains, and the penalty ranging from 50000 to 200000RMB shall be given to the organsier in charge; for the case constitutes a crime, criminal liabilities shall be reaffixed according to law.

With knowing that the above mentioned acts are unlawful but still provides venue or other conditions to the agencies or personnel, the food and drug

supervision and administration departments of people's government of county level or above shall instruct to stop unlawful acts, and confiscate the illegal obtains, and the penalty ranging from 50000 to 100000RMB shall be given; if consumer's legal rights are infringed, the food and food additives producer and trader shall bear the associated liability.

**Article 191** Producing, importing or trading certain special food with special dosage, the label and instruction book which claims health function but not get registered as health food, the food and drug supervision and administration departments of people's government at county level or above shall investigate according to Clause 1, Article 124 of the Food Safety Law. For the case constitutes a crime, it has been transferred to the public security departments for investigation according to law.

**Article 192** If the staff from food and drug supervision and administration, quality supervision, agricultural administration, health administration departments of people's governments at county level or above, commits intentionally unlawful acts or gross negligence, the supervisory organ or the authority in charge of the official's appointment at the same level shall affix the administrative liability to the involved personnel. For the case constitutes a crime, it shall be transferred to justice authority.

If the significant food safety unlawful acts or food safety incident is caused by the food producer or trader, and the evidence can prove that the staff of the food and drug supervision and administration, quality supervision, agricultural administration, health administration departments has already fulfilled the food safety supervision and administration liabilities, the administrative liabilities of the relating personnel shall be exempted.

**Article 193** For the food purchased by consumers during the recalling period after the food producer or trader has released recalling notice, no punishment compensation or minimum compensation shall be implemented.

If food trader continues to sell related products after having received recalling notice, penalty shall be given according to Clause 1, Article 124 of the Food Safety Law.

**Article 194** If the unlawful acts committed by food producer or trader is suspected to constitute a food safety crime, during the period of the establishment of the investigation, the examination before prosecution, and the examination, in order to prevent and to control the food safety risk, food and drug supervision and administration departments can give administrative penalty like instruct to stop production and trading, or suspend the licenses, and so on.

## **Chapter 10 Supplementary provisions**

**Article 195** For the purpose of this Implementation Rule, the following terms shall have the meaning defined hereunder:

Edible agricultural product means the plants, animals, microorganisms and their related products which are obtained during the agricultural activities of plantation, farming, picking-up, fishing, protected agriculture, biological engineering and so on, and formed after the preliminary processing procedures, like sorting, shelling, peeling, smashing, cleaning, cutting, freezing, waxing, classification, packaging and so on, but their basic natural properties and chemistry nature is not changed.

Catering service means the service activities to provide food directly to consumers after on-spot processing.

Food safety risk assessment means the scientific assessment on the possible negative effects to human health caused by the biological, chemical or physical harm brought to food, food additive, or food related products, including the identification of the harm, description of the harm characteristics, exposition assessment, the description on the risk features and so on.

Food safety risk communication means the process of the food safety stakeholders mutually communicate information and suggestions on food safety risk, risk factors and risk awareness in their respective work.

Health food means the food with health function claim, or with the objective of supplementing nutrients like vitamins and mineral substances, with the functions of adjusting human bodies, not with the purpose of curing diseases, with the ingredients of specific functions, is suitable to specific group of people, and with regulated dosage.

Unpacked food means the food without package of defined portion and needs to be weighted before selling. It includes the food without package and the packed food without defined portion.

Food with special edible dosage means the food being carried by capsule, oral liquid, solid granules, pills and so on, and is required to take with defined portion or required daily dosage quantity.

Food packing means the food production activity that food producer or trader divide the food into smaller portions and then pack them into pre-packaged food with smaller package, after certain processing control, but without affecting the food safety. The activity dividing the food with big package for sale



during the trading process, but without processing it as pre-packaged food, is not considered as food packing.

Health product imported for the first time means the health product of not coming from the same country, same plant and not manufactured by the same formula.

Food speedy testing method means the testing methods utilised in food safety related areas and with the feature of fast, simple and sensitive.

Food safety professional technician means the staff with the education and practice background in food safety related natural science majors, like food, biology, chemistry, medicine and so on, and possess the professional knowledge and techniques in food biology, chemical and physical features, food processing procedures, the features of food safety production facilities and equipment, food contamination source, food safety risk control requirements, food safety inspection techniques.

Toxin and harmful food raw materials means the substances prohibited by laws and regulations to be used in food production and trading activities; substances included in the lists published by State Council authorities like "*List of Non-Edible Substances Likely to be Illegally Added in Food*", "*List of Substances Likely to Be Illegally Added in Health Food*"; pesticides and veterinary drug and other toxin and harmful substances prohibited by the Notices issued by State Council relevant authorities; and other substances which are harmful to human health.

Existence of flaws will be determined in the label and instruction book of the food and food additives when the essential contents of the non food safety labeling and instruction book, like the distance between characters, size of the characters, punctuation mark, traditional and simplified Chinese characters, rounding intervals, are not in accordance with regulations, but will not affect food safety and will not create misunderstanding for the consumer's food safety consumption.

Value of the goods means the total market value of the food, food additives and food products produced and traded by producer and trader, or of the edible agricultural products illegally traded. The value of the food raw materials and food additives is calculated by the purchasing price, the value of semi-final product is calculated by the sum of raw material price and other costs, the value of the final product is calculated by published selling price. The selling price of the single piece of the product for sale is calculated by the unit price indicated in the price tag of the seller. If there is no price indicated, the market retail price shall be calculated by the average price per unit piece in the region

where the product is being investigated.

The illegal obtains means the total business income obtained after the unlawful acts committed. If the food producer or trader does not commit intentionally unlawful act and has fulfilled the responsibility of checking on incoming goods and asking for certificate and bills, and has evidence to proof that it is not aware that the raw materials purchased or food traded are not compliant with food safety standards, and there is no harmful consequences caused, the value of the illegal obtains can be deducted with the purchasing expense of the purchased food and raw materials which have been sold.

**Article 196** File-recording means that the process that the administrative counterpart register, archive, publish and for future reference the relevant materials according to relevant regulations.

**Article 197** For the food additives which is not specified in this Implementation Rules, can refer to the relevant applicable food regulations to this Implementation Rules.

**Article 198** The national port mentioned in this Implementation Rules means the international port for the entry and exit of personnel, luggage, consignment, containers, transportation means, objects, and postal items, and the agencies and regions providing services for the entry and exit of personnel, luggage, consignment, containers, transportation means, objects, and postal items.

The supervision and administration on the food safety beyond the regions of ports, airports, stations, land borders and national river frontiers is in charged by food and drug supervision and administration departments.

**Article 199** In order to ensure the application of the registration of special food, if it is needed to apply for the registration of health food, food for special medical purposes, and infant formula products, technical examination fee and inspection and verification fee shall be paid. The charging standards are made by the State Council financial authorities, State Council pricing authorities by consulting with State Council food and drug supervision and administration departments.

**Article 200** This Implementation Rule will be implemented from XX Year XX Month XX Day.