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## **China - Peoples Republic of**

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## **China Announces Revised Draft Implementing Rules of the 2015 Food Safety Law**

### **Report Categories:**

Policy and Program Announcements

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### **Report Highlights:**

On October 19, 2016, China's State Council Legal Affairs Office (SCLAO) published a revised version of the Draft Implementing Rules of the Food Safety Law for review. The domestic comment deadline ended on November 19, 2016. This report provides an unofficial translation of the revised Draft Implementing Rules.

## Executive Summary

On October 19, 2016, China's State Council Legal Affairs Office (SCLAO) published a revised version of the Draft Implementing Rules of the Food Safety Law for review. The domestic comment deadline ended on November 19<sup>th</sup>, 2016. This report provides an unofficial translation of the revised Draft Implementing Rules.

Compared to the [first draft of the Implementing Rules released by the China Food and Drug Administration \(CFDA\)](#), significant changes in this latest draft include changes in information disclosure, traceability, regulations for special food, and new food standards. Of note, the new draft no longer prohibits the use of Chinese labels (stickers) over foreign language labels on imported prepackaged foods. As of this report, none of the drafts have been notified to the World Trade Organization.

## BEGIN TRANSLATION

### **Implementing Rules of the Food Safety Law of the People's Republic of China (Revised Draft for Review)**

#### **Chapter One General Provisions**

**Article 1** These Rules were formulated in accordance with the Food Safety Law of the People's Republic of China (hereinafter referred to as "Food Safety Law").

**Article 2** The food producers and dealers shall, in accordance with the laws, regulations and food safety standards, carry out production and dealing, establish and improve the food safety management system, adopt efficient management measures to prevent and control risks on food safety, prevent and reduce food safety hazards, and ensure food safety.

**Article 3** The Food Safety Commission under the State Council shall study, deploy and uniformly guide the national food safety efforts, draft the national food safety strategies, propose the major policies and initiatives concerning food safety, analyze and solve major issues of food safety, urge relevant ministries under the State Council and the provincial people's governments to perform the duties in support of food safety, and urge and monitor the deployment and implementation of major decisions concerning national food safety.

The Office of the Food Safety Commission under the State Council shall carry out daily works of the Commission, organize the formulation of the national food safety planning, coordinate with handling major issues arising from formulation and implementation of food safety laws, regulations and standards, assess and review the performance of duties for food safety by the provincial people's governments and the relevant ministries under the State Council, and guide the handling of and publish the information about major food safety incidents.

**Article 4** The local people's government at the county level or above shall administer the local food

safety within its administrative region, establish uniform and authoritative food safety supervision and administration system, strengthen the building of food safety governance system and capability, ensure the effective deployment of food safety regulatory agency, personnel, funds and technical support, and shall be liable for the regional food safety risks and major food safety incidents according to law.

The food safety commission and its office of the local people's government at the county level or above shall reinforce the uniform coordination, supervision and guidance of food safety efforts in its administrative region, and the specific duties shall be specified by the local people's government of all levels by reference to portfolio of the Food Safety Commission and its Office under the State Council.

**Article 5** The people's governments of townships and towns and the sub-district offices shall check the hidden risk of food safety, report relevant information, assist in law enforcement, give promotion and education, and carry out other administrative efforts for food safety in their respective regions.

The people's government of township and towns and the sub-district offices shall support the supervision and administration carried out by the local offices of the food and drug administration according to law.

The people's governments of township and towns and the sub-district offices shall appoint some food safety stewards or informants, and assist the food and drug administration in maintaining food safety. The remuneration for the food safety stewards or informants shall be paid from and counted in the fiscal budget of the people's government at the county level or above.

**Article 6** China will incorporate the food safety knowledge into the national quality education and the courses of education in primary and secondary schools, strengthen the dissemination of scientific knowledge and legal knowledge about food safety, and enhance the consciousness of food safety of the whole society.

The news media shall make publicity of food safety information for public welfare in accordance with the regulations of the relevant authorities and the food and drug administration.

**Article 7** The people's government at the county level or above shall formulate the administrative measures for reward of food safety, grant some rewards and funds for food safety, and give recognition and reward to the entities and individuals who make outstanding contributions to the monitoring and assessment of food safety risk, formulation and implementation of standards, supervision and inspection, protection of major events, handling emergent events, investigation and treatment of cases, review and evaluation, scientific research, promotion and education, and co-governance with the community.

## **Chapter Two Food Safety Risk Surveillance and Assessment**

**Article 8** The National Health and Family Planning Commission under the State Council (NHFPC), together with the China Food and Drug Administration (CFDA), the General Administration of Quality

Supervision, Inspection and Quarantine (AQSIQ), the Ministry of Agriculture (MOA) and other ministries under the State Council, shall jointly formulate and publicize the national food safety risk surveillance plan.

The health administration of the people's governments of provinces, autonomous regions and municipalities directly under the Central Government shall file their local food safety risk surveillance plan with the State Council for record. The NHFPC shall promptly notify such filings to the CFDA, AQSIQ, MOA and other ministries under the State Council.

**Article 9** The NHFPC shall coordinate with and organize surveillance of risks of food borne diseases, food contamination and hazards in foods.

The CFDA shall monitor the risks of contaminants and hazards in the aspects of food production, marketing and catering services.

The AQSIQ shall monitor the risks of hazards of food related products, and of the imported and exported foods.

The MOA shall monitor the risks of the residual of pesticide and veterinary drugs, other contaminants and hazards before the edible agricultural products enter into the production, processing, wholesale and retailing markets.

Relevant ministries under the State Council shall consult with each other for the issues found in food safety risk surveillance within the scope of their duties, take effective measures, and prevent and control food safety risks.

**Article 10** The national food safety risk surveillance plan and program shall prioritize the monitoring on the following foods and relevant hazards that do not have applicable food safety standards:

- (1) The foods with high risk, wide circulation or large consumption;
- (2) The foods that would affect the health of infants and other specific groups of people;
- (3) The foods with a number of complaints about food safety issues from the consumers;
- (4) The foods that trigger food safety incidents outside China.

**Article 11** The NHFPC, CFDA, AQSIQ, MOA and other ministries under the State Council shall make full use of the qualified technical institutions, including third-party private technical institutions, to conduct food safety risk surveillance work.

The technical institute that is authorized to undertake food safety risk surveillance shall carry out works pursuant to the food safety risk surveillance plans, surveillance programs and practices, ensure the truthfulness, accuracy and completeness of the surveillance data. The surveillance data and materials relating to food safety risk surveillance shall not be made public or used for any commercial purpose without permission.

**Article 12** The health administration under the provincial people's government shall, together with the food and drug administration, quality supervision, agriculture administration and other departments of the same level, establish a food safety risk surveillance and reporting system, summarize and analyze the risk surveillance data, study and judge the food safety risks, prepare the monthly, quarterly, semi-annual and annual surveillance reports of food safety risks and submit them to the provincial people's

government and the NHFPC within seven business days after such reports are prepared, with a copy thereof to the food and drug administration, quality supervision, agriculture administration and other departments of the same level. If any food with high safety risk is found, it shall be reported within two business days after the report is prepared.

**Article 13** If the health administration finds any hidden risk of food safety during its food safety risk surveillance, it shall promptly assess the food safety risk and report the assessment results to the food and drug administration and other relevant departments; if it finds any illegal conduct in food production or dealing, it shall promptly report such conduct to the food and drug administration and other relevant departments.

If the food and drug administration finds any hidden risks of food safety during its investigation of food safety, it shall promptly report it to the health administration for food safety risk assessment. The health administration shall promptly report the assessment results to the food and drug administration and other relevant departments.

**Article 14** If the food safety risk surveillance result reveals food safety risk, the food and drug administration and other relevant departments may notify the relevant food producers and dealers as per the needs of risk control.

Upon receiving the notice, the food producers and dealers shall immediately take measures to investigate the risks; if any hidden risk of food safety is found, it shall suspend the production, selling and use of the product, recall the involved foods, and promptly report it to the food and drug administration under the local people's government at the county level or above.

**Article 15** The NHFPC, together with the CFDA, AQSIQ, MOA and other ministries under the State Council, shall jointly set up and manage a National Food Safety Risk Assessment Expert Commission. The National Food Safety Risk Assessment Expert Commission shall determine the technical methods and requirements for food safety risk assessment, review and approve the reports of food safety risk assessment, explain and communicate the results of food safety risk assessment (to relevant government agencies).

**Article 16** The NHFPC, together with the CFDA and other ministries under the State Council, shall develop the working plan of food safety risk assessment, build and manage the national food safety risk assessment basic database, collect basic data and conduct researches on methods of basic data collection. The NHFPC, CFDA, AQSIQ, MOA and other ministries under the State Council shall set up a food safety risk assessment information exchange mechanism to share the risk assessment data and materials.

**Article 17** If the NHFPC, CFDA and AQSIQ deem it necessary to assess the safety of pesticides, fertilizers, veterinary drugs, feeds and feed additives in their supervision and administration, they shall propose the risk assessment to the MOA. The MOA shall promptly conduct risk assessment and report the assessment results to the relevant ministries under the State Council.

The safety assessment of pesticides, fertilizers, veterinary drugs, feeds and feed additives shall be conducted by the relevant assessment commission together with the National Food Safety Risk Assessment Expert Commission.

**Article 18** The NHFPC shall, as per the needs of food safety risk assessment, investigate the basic data

such as food consumption, environmental factors affecting food safety, survey of total diet and public awareness.

**Article 19** The food and drug administration under the people's government at the province level or above shall work with the relevant departments at the same level to conduct comprehensive analysis of food safety status based on the results of food safety risk assessment and information collected from supervision and administration; if the comprehensive analysis reveals any food presents high safety risk, the food and drug administration under the people's government at the province level or above shall timely issue food safety risk alert and make it public.

If a food safety risk is only limited to a specific region, the food and drug administration of the city or county of the said region may issue consumer reminder if necessary.

**Article 20** China establishes the food safety risk communication system.

The CFDA, together with other relevant ministries, shall establish a food safety risk communication mechanism, encourage and support the food producers and dealers, food safety technical institutions, scientific research institutes, food industry associations, consumers' associations, lawyer associations and news media to participate in food safety risk communication.

**Article 21** The CFDA, together with other relevant ministries, shall establish a food safety risk communication advisory commission composed of experts of food, public health, clinical medicine, environment and ecology, quarantine and epidemic prevention, nutrition, journalism and communication, and law, to provide advice and suggestions for food safety risk communication.

### **Chapter Three Food Safety Standards**

**Article 22** The NHFPC, together with the CFDA, AQSIQ, MOA and other ministries under the State Council, shall jointly formulate and publicize planning for the national food safety standards and the annual implementing plan.

**Article 23** The NHFPC, together with the CFDA, shall set up a National Food Safety Standard Review Commission, formulate the administrative measures for national food safety standards; the two ministries shall organize the proposing, drafting, review and publishing of the national food safety standards.

The NHFPC, together with the CFDA, may appoint eligible institutes with the required technical capability to draft the national food safety standards.

Formulating the national food safety standard shall solicit public comments; solutions to highly concerned issues shall be published.

Scientific research institutions, technical institutions, academic societies, industry associations and other entities are encouraged to jointly draft the national food safety standards.

**Article 24** The NHFPC, together with the CFDA, shall formulate the national food safety standards of category/scope/limits for food additives used in the catering service sector, as well as national food

safety standards urgently needed in food safety law enforcement.

**Article 25** The health administration under the people's governments of provinces, autonomous regions and municipalities directly under the Central Government, together with the food and drug administration of the same level, shall formulate the planning of local food safety standards and its implementation plans, and organize to initiate, draft, review and promulgate the local food safety standards.

It is prohibited to develop local food safety standards for health foods, foods for special medical purposes (FSMP), infant formula foods, food additives, food-related products, new food materials, inspection methods/standard procedures related to food safety.

**Article 26** The health administration under the people's governments of provinces, autonomous regions and municipalities directly under the Central Government shall file the local food safety standards with the NHFPC within 30 business days after the standards are promulgated. If the NHFPC finds any filed local food safety standard violates any laws, regulations or national food safety standards, it shall promptly make correction.

Once a national food safety standard is promulgated and entered into force, the corresponding local food safety standard shall be abolished immediately. The health administration under the people's governments of provinces, autonomous regions and municipalities directly under the Central Government shall promptly make a public announcement of the abolished local standard.

**Article 27** A food producer shall be responsible for its enterprise standard, and the enterprise standard shall be implemented upon approval of its legal representative or principal.

Where the enterprise standard of health food, foods for special medical purposes (FSMP) or infant formula powder has incorporated the product formulation, production processes and other technical requirements, the enterprise standard is not required to be filed.

Within 15 business days upon filing an enterprise standard, the health administration under the people's government at the province level or above shall publish the filed enterprise standard on its official website for free viewing and downloading by the public.

The food producer shall publish the effective enterprise standard for the public to view and supervise.

**Article 28** Based on the results of food safety risk surveillance and supervisory random tests, the NHFPC, together with the CFDA, AQSIQ, MOA and other ministries under the State Council, shall promptly conduct follow-up assessment, formulate and revise the national food safety standard.

## **Chapter Four Food Production and Dealing**

### **Section 1 General Provisions**

**Article 29** The CFDA shall formulate the good practices for food production and dealing according to the economic and social development level, scale of production and operation, technical conditions,

requirements of food safety and other factors.

The food producers and dealers shall carry out production and dealing according to the good practices for food production and dealing.

**Article 30** During the course of production and dealing, the food producers and dealers shall not purchase, use, store and transport any non-edible substance expressly banned by the relevant departments, or use any recycled food or food additive to make food or food additive.

It is prohibited to add any chemical other than those listed in the national food safety standard, or any substance that would cause harm to human health in any food additive.

**Article 31** A permit shall be lawfully obtained for food production, sale and catering services. The license is valid for five years.

The producers who produce or make pre-mixed materials or extracts for health foods and sell such materials or extracts on the market shall also obtain the license for production of health foods.

**Article 32** A food producer that has obtained a food production license does not require a food marketing license when selling its produced foods at its production premises or on the Internet. A food dealer which has obtained a food dealing license does not require a food production license when selling its produce or processed foods at its business premises or on the Internet.

**Article 33** A food producer or a dealer shall carry out production or dealing within the scope permitted by the food production or marketing license, and shall not do anything beyond the permitted scope.

**Article 34** Where a food producer or dealer commissions others to produce food or food additive, the commissioned party shall obtain a food production license. The commissioning party shall be legally liable for the safety of foods produced on the commission basis, and the commissioned party shall be responsible for its production.

Where a food producer or dealer commissions others to produce food or food additive, the parties shall enter into a written agreement specifying the rights and obligations of each other with respect to food safety.

**Article 35** Where the production and operation conditions of any food producer or dealer change and it becomes necessary to obtain the license again, the producer or dealer shall apply for the license according to law.

The food and drug administration at the county level or above shall strengthen the daily supervision and inspection on the production and dealing activities of food producers and dealers. If it finds any producer or dealer fails to meet the requirements, it shall order the producer or dealer to immediately make correction and handle it according to law.

**Article 36** The NHFPC shall regularly summarize and publish the catalog of new food ingredients, new types of food additives and new types of food related products, as well as the effective national food safety standards, and conduct follow-up assessment on the safety thereof.

**Article 37** The safety assessment materials regarding new food ingredient, new type of food additive or

new type of food related product submitted by an applicant to the relevant health administration shall include the technically necessary supporting documents given by the relevant industry organization, the safety assessment opinions given by the professional technical institutions, and statement of development of relevant standards and the standard texts, etc.

**Article 38** The substances listed in the catalogs of substances conventionally considered both as food and Chinese medicine shall also meet the following requirements:

- (1) Having been eaten in China, and no acute, sub-acute, chronic or any other potential hazard to human health has been found;
- (2) Having record of being used as food in ancient book, and no toxicity has been found;
- (3) Having been listed in the national drug standards;
- (4) Can maintain sustainable development of the resources of related species, and will not adversely affect the resources of wild medicinal herbs and the ecological environment, and are not the wild animal or plant listed in the catalog of national key protected wild animals or the catalog of national key protected wild plants;
- (5) In conformity with the requirements of relevant laws and regulations.

**Article 39** The food producers and dealers shall establish a food safety traceability system, record and store the information about incoming inspection, and the records shall be true, accurate and complete to ensure that the source and destination of foods are traceable and that there are some persons accountable for the records.

The producers and dealers of health foods, FSMP, infant formulas, meat products, dairy products, edible vegetable oil and distilled spirit shall adopt information means to further the building of traceability system.

**Article 40** The CFDA, together with the agriculture administration, quality supervision and other ministries under the State Council, shall set down the basic requirements for the full traceability of food safety, develop the full data collection indexes, transmission format, interface specifications and coding rules for food safety, to realize the data interlink, interconnection and sharing.

**Article 41** Encourage the food industry associations and other private third parties to invest in the building of traceability information platform, use market-based methods to guide food producers and dealers to build the traceability system, and provide the business enterprises with the professional services for building the traceability system.

## **Section 2 Process Control of Production and Dealing**

**Article 42** The legal representative or principal of a food producer or dealer shall be fully responsible for the food safety of the entity, and shall establish and implement the food safety accountability system for the entity.

**Article 43** The food safety managers shall assist the legal representative or principal of a food producer or dealer in managing the food safety, and shall perform the following duties relating to management of food safety:

- (1) Managing the suppliers;

- (2) Managing the incoming inspection and outgoing inspection, and ensure the trueness of the records;
- (3) Organizing the self-check of food safety, and ensure the trueness of the self-check reports;
- (4) Causing to implement the food production and dealing control system;
- (5) Organizing to recall the foods;
- (6) Reporting food safety incidents;
- (7) Giving publicity and training on the food safety laws, regulations, rules and standards, as well as the professional knowledge of food safety;
- (8) Other duties specified in the laws and regulations.

**Article 44** The food safety managers shall have the professional knowledge about food safety laws, regulations, rules, standards and practices, as well as the food safety management capability compatible with their position.

**Article 45** The food producers and dealers may hire a third party professional institution to regularly inspect and assess its food safety status.

The third party professional institution shall have the required capability to inspect and assess the food safety, and shall ensure the trueness of its inspection and assessment conclusion.

**Article 46** The food and drug administration under the people's government at the province level or above shall, as per the level of food safety risk and the needs of food safety supervision, implement the good manufacturing practices among the food producers with large scale and the food producers of meat products and dairy products, carry out the system of hazard analysis and critical control points, and enhance the level of food safety management.

**Article 47** The producers of foods, food additives and food related products shall inspect or cause to inspect its foods, food additives and food related products in accordance with the food safety laws, regulations, rules and standards, and its enterprise standards.

The food producers shall determine its outgoing inspection items by taking full account of such factors as product characteristics, process characteristics and raw material control. Where it is otherwise provided in the laws, regulations, rules or national food safety standards, such provision shall prevail.

**Article 48** Where a food dealer sells any health food, FSMPs or infant formula powder that must be registered, the food dealer shall check the registration certificate, verify whether the contents of the certificate are consistent with the contents of the product label and instructions, and retain a photocopy or electronic copy of the registration certificate.

Where a food dealer sells any health food or infant formula that must be filed, the food dealer shall check the filing document, and verify whether the information indicated on the label and instructions is consistent with the information posted on the website of the food and drug administration.

**Article 49** The food producers and dealers shall maintain a register of expired, spoiled or recycled foods or food additives, and separately store such foods and food additives at a clearly marked place, promptly destroy them or take other harmless treatment, and maintain relevant records.

**Article 50** Where a food producer or dealer hires a warehouse or logistics service provider to store and transport the foods, it shall examine the food safety ensuring capability of the warehouse or logistics service provider, and shall strengthen the management of food safety.

The business entity that stores and transports foods shall strengthen the management of the processes of food storage and transportation, and ensure the food storage and transportation meet the food safety requirements.

The entity that is hired to store and transport foods shall check and retain a copy of the identity certificate, food production or marketing license, business license, compliance certificate, and inspection and quarantine certificate of the hiring party in accordance with the relevant regulations.

**Article 51** A non-food producer or dealer that stores foods shall file its business license with the food and drug administration under the local people's government at the county level within 30 business days upon issuance of its business license.

If it is found that any entity or individual that stores or transports foods is not qualified for lawful dealing of foods, or it stores or transports any untraceable food, the non-food producer or dealer that stores or transports foods shall promptly report it to the food and drug administration under the local people's government at the county level.

**Article 52** Where the storage or transportation of the foods is subject to the temperature or humidity control requirement, the dealer shall have the insulation, refrigerating or frozen equipment and facilities, and ensure the effective operation of such equipment and facilities.

During the course of food storage and transportation, it is prohibited to illegally add any non-edible chemical or any other substance that would harm human health, or use any food additive beyond the permitted scope or limit.

The relevant departments of the people's governments at the county level or above shall take effective measures to guide and support the food cold chain transportation.

**Article 53** The food storage and transportation shall be recorded to ensure the traceability of the processes of storage and transportation.

Where an entity hires another party to store and transport the foods, the parties shall enter into a written agreement specifying the rights and obligations of each party with respect to food safety.

**Article 54** If the information from complaint, report or investigation reveals a non-food producer or dealer has violated any food safety law, regulation or national food safety standard in food storage or transportation, the food and drug administration shall promptly deal with it according to law.

**Article 55** Where a catering service provider hires a tableware and drinking utensil centralized disinfection service provider to provide cleaning and disinfection service, it shall enter into a contract with the tableware and drinking utensil centralized disinfection service provider, and shall check and retain a copy of the business license, disinfection compliance certificate and other certifying documents of the tableware and drinking utensil centralized disinfection service provider.

**Article 56** A tableware and drinking utensil centralized disinfection service provider shall appoint a full-time or part-time health manager, establish a sound health management system and keep health management files, and carry out its operational activities according to the requirements of good health practices.

**Article 57** The education administration at the county level or above shall examine the food safety of the schools, kindergartens and nurseries within its administrative region, and report relevant information. Whenever it finds any conduct violating the food safety laws, it shall promptly report it to the food and drug administration of the same level.

**Article 58** The schools, kindergartens and nurseries, senior care organizations, healthcare providers and construction sites that have refectory shall perform the duties of a food dealer, shall conduct self-inspection on the food safety in the refectory, eliminate risks and hidden perils, and regularly submit a self-inspection report to the food and drug administration under the local people's government at the county level or above.

The entities that outsource catering services for their refectory shall perform the duties of food safety in strict accordance with the laws and regulations, shall be legally responsible for the food safety, and shall strengthen supervision and inspection, and urge the contractors to implement the various food safety management systems. The owner and the contractor shall enter into a written agreement specifying the rights and obligations of each other with respect to food safety.

**Article 59** The branches of the food and drug administration under the people's government at the county level shall strengthen the supervision and direction on the communal meals in rural areas, clearly specify the food safety management requirements for the communal meals in rural areas, and prevent food safety incidents.

**Article 60** Where a catering service provider hires a catering service management company to manage the services, the parties shall enter into a written agreement specifying the rights and obligations with respect to food safety. The catering service provider shall be legally responsible for the food safety of its catering services.

**Article 61** An online food trading third-party platform provider shall file it with the food and drug administration at the province level within 30 business days after it is approved by the communication authority, and obtain the filing number.

A food producer or dealer that trades foods through its own website shall file the website with the food and drug administration at the city or county level within 30 business days after it is approved by the communication authority, and obtain the filing number.

The food and drug administration at the province, city or county level shall publish the relevant filing information within 7 business days after the filing is completed.

The filing information includes domain name, IP address, telecommunication business license, name of enterprise, name of legal representative or principal, and filing number.

**Article 62** An online food trading third-party platform provider shall properly maintain the registration information, trading data and other data about the producers and dealers of the listed foods, edible agricultural products and food additives, and provide the relevant data and information to the food and drug administration of the local people's government at the county level or above in accordance with the regulations of the CFDA.

**Article 63** An online food trading third-party platform provider shall establish the systems such as examination and registration of the identity of the food dealers, self-inspection of food safety, restraint and reporting of food safety illegal activities, cessation of platform service in case of serious illegal activity, and handling complaints and reports of food safety, and shall publicly announce such systems on the online platform.

The online food trading third-party platform provider shall set up a dedicated online food safety management organ or appoint full-time food safety manager to examine the food trading activities and information on the platform.

**Article 64** The local food and drug administrations at the county level or above may inspect the performance of obligations under the food safety laws, regulations and rules by the online food trading third-party platform providers, through on-site inspection, accessing to and making copy of trading data, and retrieval of technical monitoring data.

**Article 65** Upon occurrence of any of the following circumstances on any online food trading third-party platform provider or any online listed food producer or dealer, the food and drug administration at the county level or above may conduct regulatory interview with their legal representative or principal:

- (1) Any food safety issue which would spread the risk of food safety;
- (2) Failure to timely and properly handle any food safety issue involved in any complaint or report, which would cause any hidden peril of food safety;
- (3) Failure to timely take effective measures to examine and eliminate any hidden peril of food safety or to implement the accountability of food safety;
- (4) Any other circumstance that the food and drug administration at the county level or above considers that it is necessary to conduct regulatory interview.

The regulatory interview shall not affect the administrative sanction to be imposed by the food and drug administration according to law, and the summary of regulatory interview and the subsequent outcome shall be publicly announced.

**Article 66** Upon occurrence of any of the following circumstances, the online food trading third-party platform provider shall immediately cease providing the online trading platform service to the online listed food producer or dealer:

- (1) The online listed food producer or dealer is being investigated or prosecuted due to any suspected offense of food safety;
- (2) The online listed food producer or dealer is imposed any criminal penalty by the people's court due to any convicted offense of food safety;
- (3) The online listed food producer or dealer is detained by the public security authority due to any food safety illegal conduct, or is otherwise imposed public security administrative penalty;

(4) The online listed food producer or dealer is suspended its license, or ordered to stop production or business operation, or otherwise penalized by the food and drug administration according to law.

**Article 67** A food producer or dealer shall order to stop production and dealing of unsafe foods, and recall and dispose of the unsafe foods, in accordance with the national food recall system. Based on the level of severity and urgency of food safety risks, food recall is administered in the following levels:

Level I recall: where the food has caused or would cause serious health harm or death after it is eaten, the food producer or dealer shall initiate the recall within 24 hours after it becomes aware of the food safety risk;

Level II recall: where the food has caused or would cause general health harm after it is eaten, the food producer or dealer shall initiate the recall within 48 hours after it becomes aware of the food safety risk;

Level III recall: where the label or instructions fail to meet the food safety standards, but typically it would not cause health harm, the food producer or dealer shall initiate the recall within 72 hours after it becomes aware of the food safety risk. If there is any defect in the label or mark, but no harm to health would be caused after the food is eaten, the food producer shall make correction and may voluntarily recall the food.

To recall any food, the food producer or dealer shall report it to the food and drug administration under the local people's government at the county level or above within the time limit specified in the corresponding level of recall.

**Article 68** The food producers and dealers shall make remedies, such as harmless treatment, destruction or disposition, to foods that have quit the market due to discontinuation of production and dealing or recall.

For the foods that would endanger the human health under Article 34 of the Food Safety Law, the food producers and dealers shall destroy such foods on the spot.

If any food is recalled due to the reason that the label or mark thereon does not meet the food safety standards, the food producer may continue selling the food provided that it has taken some remedy and it can ensure safety of the food; however, it shall clearly indicate the remedy to consumers at a conspicuous place on the business premises when the food is being sold.

The local people's government at the county level shall set up a dedicated fund, and shall organize to store, make harmless treatment of and destroy unsafe foods.

**Article 69** Where the food produced or marketed by a food producer or dealer requires irradiation, the food producer or dealer shall hire a qualified irradiation service provider to do irradiation, inspect and mark in accordance with the applicable irradiated food standards.

If any irradiated food ingredient is used, it shall be marked in accordance with the applicable rules.

The food producer or dealer shall timely report the commissioned irradiation of the food and the use of irradiated food ingredient to the food and drug administration of the local people's government at the county level.

### **Section 3 Marketing of Edible Agricultural Products**

**Article 70** A founder of centralized trading market for edible agricultural products shall file the information regarding market name and address, name of legal representative or principal with the food and drug administration under the local people's government at the county level within 30 business days upon issuance of its business license.

**Article 71** The centralized trading market of edible agricultural products shall manage the quality and safety of the following edible agricultural products:

- (1) Establish a sound food safety management system and maintain a register of the sellers of edible agricultural products on the market, and procure the sellers to perform their obligations;
- (2) Appoint full-time or part-time food safety managers, and give training on the knowledge of food safety;
- (3) Have testing equipment and inspection personnel, or hire a qualified inspection institution to conduct sampling inspection or speedy test on edible agricultural products, and publish the testing result;
- (4) If it is found that any edible agricultural product fails to meet the food safety standards or there is any other illegal activity, it shall order the seller to immediately cease the sales, make harmless treatment or destruction, and report it to the food and drug administration of the local people's government at the county level.

**Article 72** A founder of centralized trading market of edible agricultural products shall examine the following documents:

- (1) The social credit code or photocopy of the identity card of the seller;
- (2) The certificate of origin or purchase voucher of the edible agricultural products;
- (3) Compliance certificate of the edible agricultural product producer or the farmer specialized cooperative economic organization.

If it fails to provide any certificate or document mentioned above, the market founder shall conduct sampling inspection or speedy testing. Only the edible agricultural products that have passed the sampling inspection or speedy testing may be sold on the market.

**Article 73** Sale of poultry meat requires a quarantine certificate and the stamp of quarantine mark.

Sale of poultry meat products also requires a meat quality inspection conformity certificate. Sale of imported edible agricultural products requires an entry goods inspection and quarantine certificate, customs clearance document and other supporting documents.

**Article 74** Where an edible agricultural product seller sells any unpacked edible agricultural product on a wholesale or retailing market, it shall truthfully announce the name of product, origin, name of producer or seller of its edible agricultural products at a conspicuous place on its booth (counter).

**Article 75** An edible agricultural product seller shall examine the required certifying documents, and

shall not purchase and sell any product if the product fails to meet the requirements.

The seller shall establish a purchase inspection and recording system for edible agricultural products. It shall truthfully record the name, quantity and purchase date of edible agricultural products and the name, address and contact information of the suppliers, and retain the relevant vouchers. The retention period of the records and vouchers shall be not less than 6 months.

An edible agricultural product seller that adopts the means of unified distribution and sale may establish a centralized purchase inspection and recording system at its head office, and all its stores shall maintain a list of the distributions from the head office as well as the relevant product qualification documents. The retention period of the distribution list and product qualification documents shall not be less than 6 months.

A seller that engages in wholesale of edible agricultural products shall establish a sales recording system for edible agricultural products, truthfully record the name, quantity, date of sale of edible agricultural products in wholesale, and the name, address, and contact information of the purchasers, and retain the relevant vouchers. The retention period of the records and vouchers shall be not less than 6 months.

#### **Section 4 Label, Instructions and Advertisement**

**Article 76** Producers of foods and food additives shall be responsible for the contents of the labels and instructions of their food and food additive products.

Food or food additive producers or dealers shall not alter the production date, shelf life or other information indicated on label or instructions, which is in violation of relevant regulations and rules.

**Article 77** The edible agricultural products that must be packed or attached with a label under the applicable regulations may only be sold with the package or attached label. The package or label shall properly indicate, among other things, the product name, origin, producer, production date, and shelf life (if required) of the edible agricultural products; if the storage conditions are related to the shelf life, the storage conditions shall be indicated; if food additives are used, the name of such food additives shall be indicated.

**Article 78** The edible agricultural products that are packed after preliminary processing (such as cleaning and cutting) shall indicate the shelf life, and may only be sold within the shelf life.

**Article 79** Foods that are directly produced from genetically engineered organisms (GMO) materials shall be conspicuously labelled according to relevant regulations.

Labeling of genetically engineered foods shall comply with relevant provisions of the Administrative Rules for Safety of Agricultural Genetically Modified Organism.

**Article 80** For substances that should not be used or contained (in foods) as provided by food safety standards, the claim “not added”, or “not containing” should not be used in product label, product instructions, or advertisements. For GMO foods and materials China has not yet approved, the labels should not contain the phrases such as “non-GMO”.

For health foods, the label may only contain the health functions approved in the registration certificate. Any foods other than health foods should not claim or hint health functions in any form on the package.

The content of the labels and instructions of the health foods, foods for special medical purposes (FSMP) and infant formulas shall be consistent with that of the registration or filing, and the registration number or the filing number shall be indicated.

The labels and instructions of the irradiated foods shall indicate "irradiated foods". The irradiated ingredients shall be indicated in the ingredient list.

**Article 81** If food ingredient contains substance which may cause allergic reaction, the food producer shall indicate so in the ingredient list.

## **Section 5 Special Foods**

**Article 82** The food producer or dealer shall obtain the registration certificate from the CFDA for health foods, foods for special medical purposes (FSMP) and infant formula powders that requires registration before producing, selling and importing the product.

**Article 83** The catalogue of health food materials and the catalogue of allowed function claims of health foods are under dynamic management pursuant to science advancement and health food registration.

**Article 84** The catalog of health food ingredients shall contain such information as the material name, dosage, efficacy, production processes, functional components, testing methods and relevant technical requirements of the ingredients.

Where any ingredient listed in the ingredient catalog of health foods is changed in any aspect of component, dosage and efficacy due to changes in production processes, the ingredient shall be applied for registration as if it is an ingredient not listed in the ingredient catalog of health foods.

The ingredients with health function but not for the purpose of supplementary nutrient shall be managed as materials of health foods, and shall not apply for approval as new food ingredients. The foods other than health foods shall not use ingredients that are only intended for health food production.

For health foods that are nutrients (such as supplement vitamins or minerals, etc.) imported for the first time, such nutrients should be categorized as health food ingredients catalog.

**Article 85** When conducting on-site inspection on the production premises of an applicant for health food production license, the dynamic production processes shall be inspected; the inspectors shall take samples of products rolled off the production line for testing.

**Article 86** The CFDA entrusts food testing institutes with legal qualification to undertake sampling testing of the registration of health foods, foods for special medical purposes (FSMP), and recipe of infant formula powder products; the list of the testing institutes will be published by CFDA.

Companies applying for formula registration for FSMP or infant formula powder products shall have R&D capacity, production capacity and testing capacity as appropriate for such products; they should establish the production quality management system appropriate for the produced foods pursuant to GMP requirements.

**Article 87** A producer of health food, FSMP or infant formula powder shall carry out production pursuant to the registered or filed technical requirements such as formula and production processes.

The enterprise standards of special foods shall meet the registered or filed product technical requirements.

Where the production processes of a health food have the pre-treatment processes such as extraction of ingredient or purification, the producer must have the capability of ingredient pre-treatment compatible with the production varieties and scale.

The producer of infant formula may not sell infant formula products before completing filing of the ingredients, food additives, product recipe and label thereof; such filing information shall be published.

**Article 88** An applicant that applies for registration of health food shall carry out relevant study, produce sample products at a producer that meet GMP for health foods; it shall submit test reports issued by qualified inspection institution.

**Article 89** For health foods and infant formula foods that are subject to record filing, the food and drug administrations should complete the record disclosure and verification work as required, and issue the record filing certificate and record filing register number to the application based on the application.

**Article 90** The health function claims of health foods should comply with requirements of the health function catalogue, and should be labeled pursuant to the content of the registration or record filing; it is not allowed to add/remove words or recombine descriptions.

**Article 91** Food sellers shall set up certain dedicated counter or area to sell health food, FSMP and infant formula powder, and mark the "dedicated area/counter of health food", "dedicated area/ counter of FSMP" and "dedicated area/counter of infant formula" at a conspicuous place on the dedicated counter or dedicated area. The health food, FSMP and infant formula powder shall not be commingled with any drug or regular food being sold.

For health foods, the phrase "This Product Cannot Replace Drug" shall be marked at a conspicuous place on the dedicated counter or dedicated area.

The special whole-nutrient formula foods under the FSMP category should be sold in hospitals or medicine retailers, but not on-line; other FSMP could be sold in food distribution locations or on-line.

**Article 92** Filing registration applications for the whole-nutrient formula foods, the applicant should conduct clinical experiment and submit the experiment reports.

**Article 93** A producer of FSMP shall inspect each batch of factory released products according to the testing items required by the applicable national food safety standards.

**Article 94** The advertisements of specific whole-nutrient formula foods shall be regulated and approved as those for prescribed medicines; advertisements of other FSMP shall be regulated and approved as non-prescribed medicines.

**Article 95** Name and label of infant formula foods should be truthful and standardized, accurate, easy to understand, clear and easy to recognize; (the label) should truthfully mark sources of the materials, and do not contain languages that are false, exaggerated, or absolute; the label should not have content claim and function claims.

Advertisements of infant formula foods should not contain information about the content and function.

In registering recipe of infant formula powder products, the label, product description and the registered recipe will be examined for consistency in content..

**Article 96** Producers shall not sell in China infant formula powder that only have label/company name/address registered abroad; it is prohibited to use milk or milk products of animals other than cow or goat to produce infant formula powder.

The product recipe for registration shall be designed according to the healthy growth rule of infants, and shall meet requirements by relevant laws, regulations and national food safety standards. When an enterprise applies for registration of two or more than two product recipes for the same age group, such product recipes shall have obvious difference and shall have scientific proof. In principle, each enterprise shall have no more than three formula series or nine product recipes.

The wholly-owned subsidiary of a group company that have obtained registration and production license may use the registered infant formula recipe of another wholly-owned subsidiary of the same group company. Prior to the production, the group company shall submit a written report to the CFDA.

For optional additive substance provided in applicable national food safety standards, such substance shall not be embodied in the name of the infant formula.

Infant formula powder producers should not set distribution region restrictions; producers should not tailor products for specific sellers.

**Article 97** An enterprise shall not use the same recipe to register or file special foods under different brands, or use the same name to register or file special food with different recipes

## **Chapter Five Food Testing**

**Article 98** The food test shall be conducted by a qualified food testing institution in accordance with the relevant laws and regulations, as well as the food test practices and the food standards. The food testing institution and its testers shall follow the science, observe professional ethics, and ensure that the testing data and conclusions are objective, impartial, accurate and traceable, and shall not issue any false test

report or any test report containing any inaccurate data and result.

The food and drug regulatory and quality supervisory authorities shall, as per their respective duties, conduct sampling test on the foods, food additives and food related products. The food safety supervisory sampling tests shall be conducted in accordance with the applicable food safety standards, the lawfully registered or filed product specifications, and the test items and test methods specified in the relevant regulations.

Case inspection, accident investigation, emergency response and other works can use the test items and test methods specified in the non-food safety standards to analyze and identify the cause of food safety problems. Use of test methods specified in the non-food safety standards or not provided in any state regulations shall follow the principles of adopting scientific, advanced and reliable technical means, and obtain the consent of the food and drug administration and the quality supervisory department under the people's government at the province level or above.

**Article 99** To conduct sampling test for supervision of food safety, the food and drug administration and the quality supervisory department may take samples by themselves, or hire a statutory qualified food test institution to take samples, provided that the persons taking samples are not less than two.

In terms of inspection and accident investigation, the persons taking samples must be qualified to enforce the law, and the sampling is not limited by quantity, place or qualification of the entity subject to the sampling.

**Article 100** When the food and drug administration conducts sampling test on food being sold on the Internet, it shall identify the persons who purchased the samples and the payment account, registration account number, delivery address and contact information, keep the purchase receipts, and record the name of sampling product, category and quantity.

Upon receiving a sample, the persons taking samples shall check the mail package, seal up the samples and the backup samples, and record the unpacking process by taking pictures or video.

**Article 101** The food and drug administration that conducts the sampling test for supervision of foods being sold on the Internet shall promptly notify the listed online food producer or dealer who was subject to the sampling test of the unqualified test result after it is received. Where the sample product is purchased through an online food trading third-party platform, it shall notify the online food trading third-party platform provider at the same time.

If the contact details of the listed online food producer or dealer are unknown, the notice may be sent with the assistance of the third-party platform provider. If the test fails and the listed online food producer or dealer is unable to contact, the third-party platform provider may be ordered to remove the online food marketing information posted by the listed online food producer or dealer and suspend the trading services provided on the third-party platform.

**Article 102** If the sampling test for supervision of food safety is concluded as meeting the standards, the test institution shall send the test report to the food and drug administration conducting the supervisory sampling test within 10 business days. If it is concluded as failure to meet the standards, the test

institution shall promptly report it to the food and drug administration that conducts the supervisory sampling test.

If the supervisory sampling test is cross-regional, and the food and drug administration conducting the supervisory sampling test receives a testing conclusion of failure to meet the standards, which shows it would cause serious harm to the health and life of the public, it shall immediately report the testing result to the local food and drug administration of the place where the food producer or dealer subject to the sampling test is located, as well as the local food and drug administration of the place where the producer or importer identified in the food package or label is located.

Upon receiving the report, the local food and drug administration shall immediately notify the relevant food producer and dealer to cease the production and dealing or recall the unsafe food, eliminate and control the food safety risk and promptly carry out investigation and handling. If a food producer or dealer fails to perform the relevant duties as required, the food and drug administration shall order it to perform.

**Article 103** Where a test institution uses computer and information technology or automatic equipment system to collect, record, treat, analyze, report and store the test data and relevant information, it shall carry out complete validation on the compliance and appropriateness of such works in accordance with the relevant state regulations, and maintain the record of validation. The validity of the electronic testing reports issued by the test institution shall be determined according to the relevant state laws and regulations regarding signature and seal.

The test institution shall establish a food safety risk information reporting system. If any serious safety problem is found in the inspection, or there is any regional, systematic or industrial food safety risk, it shall promptly report it to the local food and drug administration at the local county level or above, and maintain the photocopy of written reports, the test reports and original records.

**Article 104** The people's governments at the county level or above shall integrate the food testing resources of the food and drug administration, quality supervision, agriculture administration and health administration, and establish a sharing mechanism of testing resources and test results. Encourage the test institutions subordinated to the colleges and universities, scientific research institutes, and private third-party entities to integrate their testing resources into the sharing mechanism.

**Article 105** If a food producer or dealer disagrees with the test conclusion, it may apply for re-test according to the provisions of the Food Safety Law.

In principle, the re-test institution shall submit a re-test report to the food and drug administration that conducts the re-test within 10 business days upon receiving the samples, unless it is otherwise agreed by the food and drug administration, the re-test applicant and the re-test institution.

During the application for re-test, the food producer or dealer shall not stop performing the obligations such as cessation of production or dealing, and recall.

**Article 106** Upon occurrence of any of the following circumstances, the re-test is not allowed:

- (1) The test conclusion shows the microbial indicator fails to meet the standards;

- (2) The application for re-test is submitted after expiry of the prescribed time period;
- (3) The backup sample cannot realize the re-test purpose due to any other reason.

**Article 107** The re-test institution shall conduct the re-test through arbitration in accordance with the relevant standards. If it is impossible to arbitrate, the test method as used in the initial test shall apply. The samples used in the re-test shall be the backup sample for the re-test. After the re-test is finished, the re-test institution shall issue a test conclusion stating whether the re-test result meets the standards.

**Article 108** The re-test costs shall be advanced by the re-test applicant. If the re-test conclusion is the same as that of the initial test, the re-test costs shall be borne by the re-test applicant. If the re-test conclusion is different from the initial test, the re-test costs shall be borne by the initial test institution.

**Article 109** The re-test institutions that are qualified for re-test shall actively take the re-test tasks, impartially carry out re-test according to the regulations, and shall not reject or put off any re-test task. If a re-test institution unreasonably rejects two re-test tasks within a year, its qualification for re-test shall be canceled and a public announcement shall be made.

## **Chapter Six Food Import and Export**

**Article 110** China Inspection and Quarantine Services (CIQ, AQSIQ's local branches), following the Food Safety Law and its Implementing Rules, oversees import and export of foods, food additives and food-related products, as well as foods entering the border/ports. CIQs shall publish the inspection and quarantine certificates of imported foods and food additive, which shall be available to the public.

**Article 111** CIQs shall, according to its jurisdiction, grade and categorize the imported foods based on the food safety risks, food safety control ability of the business entities, and the food safety status of the exporting country or region.

**Article 112** When an importer or its agent imports food, food additive and food related product, it shall make declaration to the CIQs by presenting relevant contract, invoice, packing list, bill of lading and other necessary voucher and approval documents. When making the declaration, the qualification certificate shall be attached as required by the CIQs.

When importing health foods, FSMPs or infant formula powder that requires registration or record filing, the importer or its agent shall provide the CIQs with the proving of the registration or filing obtained in accordance with the Food Safety Law and these Rules. The CIQs shall conduct supervisory sampling test according to the requirements as indicated on the certificate of registration or filing.

The CIQs shall test all items prescribed in the applicable food safety standards on imported infant formulas batch by batch.

For the imported meat animals and animal products, the inspection and quarantine certificates, such as the inbound cargo inspection and quarantine certificate, animal quarantine certificate, and notice of inspection and quarantine treatment, shall be attached as required by the CIQs. The customs shall release the products by virtue of the clearance certificate issued by the CIQs, and

publish the certificates on its official website.

**Article 113** The exported food shall be monitored and randomly checked by the CIQs. If the international treaties or protocols have specific provisions, the CIQs shall follow such treaties and protocols in its inspections

**Article 114** The CIQs shall conduct supervisory sampling test during the import process of the imported foods, food additives and food related products in accordance with the relevant laws, administrative regulations and the relevant national food safety standards regarding imported and exported commodity inspection; after the imported foods, food additives and food related products enter the domestic market, it is the food and drug administration that conducts supervisory sampling test.

The CIQs shall retain the foods, food additives and food related products with high safety risk for inspection; CIQs shall conduct sampling test on the foods, food additives and food related products with regular risks; they shall conduct on-site inspections on products with low risk.

**Article 115** The foreign exporters and foreign food producers who export foods to China shall guarantee that the foods exported to China comply with the Food Safety Law and other applicable laws and regulations and the national food safety standards. The Chinese importers shall establish the system for reviewing foreign food exporter/foreign food producers.

**Article 116** When an importer recalls an imported food, the CIQs shall report it to the food and drug administration of the same level.

**Article 117** The foreign food producers, and the foreign exporters or their agents who export foods to China shall take effective measures to prevent intended chemical/biological/physical harm to the edible agricultural products and foods in the planting, raw material/auxiliary materials control, production, packaging, storage and transportation links.

**Article 118** For the foreign food producers recognized for their good manufacturing practices (GMP), the hazard analysis and critical control point (HACCP) system in China, the certification organization shall conduct the follow-up inspections according to laws. The certification organization shall revoke the certification issued to the producers that fail to meet the certification requirements subsequently. The AQSIQ shall promptly report it to the CFDA, and make a public announcement.

**Article 119** For the imported health foods, FSMP and infant formula powders, the CFDA may conduct on-site inspection to the producers regarding the quality management system and the GMP, and verify the filing. The food producers and dealers are not allowed to import foods as non-health foods that are produced from materials only used in health foods processing.

**Article 120** In the event that a food safety incident or any other public health incident occurs abroad and it may impact China, or any serious food safety problem is detected in imported foods, food additives or food related products, the CIQs shall promptly issue a risk alert for the imported food, and take the following control measures:

- (1) Reinforce the supervision and retain the food for inspection;
- (2) Reject or destroy the food;

- (3) Conditionally restrict import of the food;
- (4) Suspend or prohibit import of the food; and
- (5) Initialize the emergency response plan for imported food.

**Article 121** To import and export foods by cross-border e-commerce, the provisions of the Food Safety Law and these Rules regarding import and export of foods shall be complied with. The specific regulations for supervision and administration of foods, food additives and food related products imported by cross-border e-commerce means shall be otherwise formulated by the AQSIQ and other relevant ministries under the State Council.

## **Chapter Seven Handling of Food Safety Incidents**

**Article 122** The handling of food safety incidents shall be administered in several levels. The extremely serious food safety incidents shall be investigated and handled by the food and drug administration and other relevant ministries under the State Council, as uniformly directed by the State Council.

The serious, less serious and general food safety incidents shall be investigated and handled by the food and drug administration under the people's government of the province, city or county level respectively, together with the relevant department at the same level.

**Article 123** The people's government of the province level shall make development planning of food safety incident emergency response plan, and appropriately amend and improve the planning in view of actual conditions.

The local people's government above the county level shall administer the food safety incident emergency response plans, and strengthen the supervision, inspection and guidance on the food producers and dealers regarding their management of emergency response.

The local people's government above the county level shall include the training of food safety incident emergency response plan in the training of leading cadres, civil servant training, and routine training for emergency response management cadres.

**Article 124** The people's government of the province level shall make planning for building the food safety response system.

The local people's government above the county level shall establish a robust food safety emergency response management agency, improve the emergency response management mechanism, appropriate the emergency response funds, improve the emergency response equipment, build the stock of emergency response resources and emergency response team, and strengthen emergency response training, drill and assessment.

The local people's government above the county level shall monitor and alert food safety incidents, strengthen the collection, analysis and research of food safety information, and promptly post warning in view of the emergency extent, trend and possible harm extent of the food safety incident.

**Article 125** The food and drug administration under the people's government above the county level shall, together with the health administration of the same level, establish a food safety incident information monitoring and reporting system, and establish a food safety incident information reporting network system covering the above-scale food producers and dealers, online food trading third-party platform, medical institutions, and disease prevention and control institutions.

**Article 126** The food producers and dealers shall establish a food safety emergency response management system, develop an accident handling plan and establish an emergency reporting system.

The above-scale food producers and dealers and relevant entities shall regularly organize and carry out emergency drills.

**Article 127** An entity that encounters a food safety incident shall immediately take control measures, such as sealing up the foods and ingredients, tools and equipment that have caused or would cause food safety incidents. The entity that encounters accident and the entity that receives patients for medical treatment shall report the accident to the local food and drug administration and the health administration under the people's government at the county level within 2 hours after the accident is detected.

The health administration shall immediately organize the disease prevention and control institution to take health measures at the accident scene, and carry out the epidemiological investigation regarding the factors relating to the food safety incident. The relevant departments shall give assistance. A disease prevention and control institution above the county level shall submit an initial epidemiological investigation report to the health administration and the food and drug administration of the same level within 24 hours and submit the final investigation report within 7 business days after completion of the investigation.

When disease prevention and control institution, food test institution or any other technical institution become aware of any food safety incident, they shall report it to the food and drug administration under the people's government above the county level within 2 hours.

**Article 128** When a medical institution becomes aware that any patient received by it is infected with any food-borne disease or is a suspected patient of such disease, it shall promptly report it to the local health administration under the people's government at the county level according to the relevant regulations. If the health administration under the people's government at the county level believe that the disease is relevant to food safety, it shall report it to the food and drug administration of the same level within 2 hours.

The health administration and the food and drug administration under the people's government above the county level shall establish a food-borne disease monitoring and reporting system, and organize the disease prevention and control institution to verify the reported disease information.

When the health administration under the people's government above the county level becomes aware of any information relating to food safety incident in investigating and handling contagious disease or any other emergent public health accident, it shall report it to the food and drug administration of the same level within 2 hours.

**Article 129** When the quality supervision, agricultural administration and other relevant departments under the people's government above the county level become aware of food safety incident, they shall promptly report it to the food and drug administration of the same level. When the food and drug administration becomes aware that any food safety incident involves any relevant department, it shall promptly report it to the relevant department.

**Article 130** Upon occurrence of any of the following circumstances, the food and drug administration above the county level shall, together with the health administration, agricultural administration, quality supervision and other relevant departments at the same level to promptly carry out investigation and take measures:

- (1) Any food supplied by a food producer or dealer causes any food-borne disease;
- (2) A food producer or dealer causes food contamination due to any artificial or any other factor during the course of production, processing, storage, transportation, sale or catering service, and thus causes or would cause personal injury to the public;
- (3) Any other food contamination or harmful factor which causes or would cause personal injury to the public.

**Article 131** When a food safety incident is finally identified, the food and drug administration, together with the health administration, agricultural administration, quality supervision and public security authority shall jointly carry out investigation and take measures to ascertain the cause, nature and liability of the accident.

After the investigation of a food safety incident is finished, the food and drug administration shall submit a final food safety investigation report to the people's government at the same level and the food and drug administration at the next higher level according to regulations.

If it is necessary initiate the emergency response plan for a food safety incident, the people's government above the county level shall immediately establish an incident command organ to initiate the emergency response plan.

**Article 132** The relevant provisions of this Chapter Seven shall mutatis mutandis apply to the emergency response plan, investigation and handling of food safety incidents other than food safety incidents.

## **Chapter Eight Supervision and Administration**

**Article 133** The CFDA shall accept registration and filing of special foods, organize to carry out inspection on relevant systems and supervisory sampling inspection on the national food safety, establish a uniform food safety information platform, publish the major food safety supervision and management information according to law, investigate the major cases of illegal activities concerning food safety, take measures in extremely serious food safety incidents, prevent and control systematic food safety risks.

The food and drug administration under the people's governments of provinces, autonomous regions and municipalities directly under the Central Government shall issue the license for production of special foods, organize to carry out the supervisory sampling inspection on food safety at the province level,

publish the regional food safety information according to law, investigate the cases of illegal activities concerning food safety, take measures in serious food safety incidents, prevent and control regional food safety risks.

The food and drug administration under the people's governments at the city or county level shall issue the license for production and marketing of foods, carry out the routine supervisory test and sampling inspection on food safety, publish the regional food safety information according to law, monitor recalls of products by the enterprises, take measures against illegal activities concerning food safety according to law. They shall focus on the routine supervisory inspection and sampling inspection on the wholesale and retail markets of foods and edible agricultural products, stores and supermarkets and catering service providers, the pesticide and veterinary drug residues in the food ingredients being sold or purchased, as well as the foods produced and sold by the small workshops producing and processing foods and by the food vendors.

**Article 134** The CFDA may establish local offices as per the needs of its operations, and inspect and supervise the food safety works carried out by the local people's governments.

**Article 135** The Central Government shall establish the food safety inspector system. The food and drug administration shall establish a team of full-time food safety inspectors to prioritize the on-site inspection on the implementation of good operational practices, hazard analysis and critical control point system by the above-scale food producers and dealers, and the food producers and dealers with high risk, and carry out routine supervision and inspection according to the relevant regulations.

**Article 136** When the food and drug administration or the quality supervision administration detects any food spoilage, mildew or insect, or adulteration or any other abnormal sensory property on the site during the supervisory inspection, it may collect evidence by taking pictures or videos.

**Article 137** Where the food safety supervisory inspection must be signed by the food producer or dealer for confirmation, but the party refuses to sign or is unable to sign due to any special reason, the specific reason shall be indicated and two or more than two law enforcement officers may sign on spot for confirmation.

**Article 138** Where the food and drug administration or the quality supervision administration needs to inquire about the bank account of the food producer or dealer during the course of case investigation, the relevant financial institution shall give assistance.

**Article 139** Where the evidence would be lost or difficult to be collected in future, the relevant contracts, vouchers, books, purchase and sale records, electronic data storage equipment and other relevant materials may be registered and stored in advance according to law.

**Article 140** Where a food producer or dealer is being investigated by the food and drug administration due to any alleged illegal activity concerning food safety, the food and drug administration may suspend the processing of relevant application for administrative license during the course of case investigation and handling; where the application has been accepted, the processing shall be suspended, and the suspension period shall not be counted in the time limit of processing the application for administrative license.

**Article 141** If it is considered as necessary, the food and drug administration at the higher level may directly investigate the case of illegal activity involving food safety subject to the jurisdiction of the food and drug administration of the lower level, or appoint a food and drug administration of another region to investigate the case, and the food and drug administration of the place where the case occurs shall give cooperation.

**Article 142** The NHFPC shall, together with the relevant ministries under the State Council, promptly publish the catalog of the non-edible chemicals and other substances which would harm human health and which have been added or would be added to foods, as well as the test methods of such chemicals and substances, based on the information of food-borne disease, risk surveillance, risk assessment and other information about supervision and administration.

**Article 143** If the food and drug administration detects any non-edible substance in any food by technical means, but the food producer or dealer cannot provide any relevant evidence to prove beyond reasonable doubt; the food producer or dealer shall be subject to the legal liabilities accordingly.

**Article 144** If there is no established residue limit and test method for any pathogenic microorganism, pesticide residue, veterinary drug residue, heavy metal, biotoxin, contaminant, adulteration or counterfeit, or any other substance that would harm human health, the NHFPC, together with the agricultural administration, CFDA, shall establish and publish the provisional limit and provisional test method as the basis of production, trading, supervision and administration.

**Article 145** CFDA, AQSIQ, and MOA may, as per the needs of supervision and administration of food safety, establish relevant administrative measures and technical assessment guidelines, and assess the rapid food test methods; if the assessment result meets the relevant requirements, such methods may be deemed as the national statutory rapid test methods.

The food and drug administration, quality supervision and agricultural administration under the people's government at the county level or above may adopt the national food safety standards or the national statutory rapid test methods to conduct sampling test on the foods.

If the sampling test result shows that the food might not meet the food safety standard, the food shall be tested according to Article 87 of the Food Safety Law, and the involved business entities shall take some measures to control the risk, such as ceasing the sales of the food.

**Article 146** For the rapid test methods which have not been adopted by the Central Government, the food and drug administrations under the people's governments of provinces, autonomous regions and municipalities directly under the Central Government may, as per the needs of supervision and administration of food safety and by reference to Paragraph 1, Article 145 of these Rules, organize the professional technical institutions to assess the rapid food test methods; if the assessment result meets the relevant requirements, such methods may be adopted in the preliminary screening for supervision and administration of food safety by the food and drug administrations of the people's governments at all levels in all provinces, autonomous regions and municipalities directly under the Central Government.

**Article 147** The CFDA and other ministries under the State Council shall establish a food production and dealing credit regulatory system, and strengthen disclosure of bad information and sanction on bad-faith activities. They shall also advance the connection between the result of food safety credit

assessment and the credit systems such as industry access, financing and credit facilities, issuance of securities, and business credit reporting.

When a food and drug administration makes a penalty decision on any illegal activity concerning food safety, the administrative penalty decision shall be published on its website within 20 business days after the administrative penalty decision is issued.

**Article 148** The health administrations under the people's governments at the county level shall conduct supervisory inspection on the tableware and drinking utensil centralized disinfection service providers. If they detects any service provider fails to comply with any law, regulation or food safety standard or fails to meet the relevant health requirement, they shall promptly investigate and impose a sanction, and publish the result of supervisory inspection.

**Article 149** Upon occurrence of any of the following circumstances on any food producer or dealer, the food and drug administration may conduct regulatory interview with their legal representative or principal:

- (1) Any food safety problem which would spread the risk of food safety;
- (2) Failure to timely and properly handle any food safety issue involved in any complaint or report, which would cause any hidden peril of food safety;
- (3) Failure to timely take effective measures to examine and eliminate any hidden peril of food safety or to implement the accountability of food safety;
- (4) Any other circumstance that the food and drug administration under the people's government above the county level considers that it is necessary to conduct regulatory interview.

The regulatory interview shall not affect the administrative sanction to be imposed by the food and drug administration or any other authority according to law, and the summary of regulatory interview and the subsequent outcome shall be publicly announced.

If the interviewed party fails to make correction as required without any justifiable reason, the food and drug administration or any other authority shall increase the frequency of supervisory inspections.

**Article 150** The people's governments above the county level shall administer and ensure the food safety in local major events, develop the food safety assurance plans, clarify the food safety accountability, appropriate the required funds and provide the required conditions.

The organizer of a major event shall appoint a food safety management organ, select the food producers and dealers with the capability of ensuring food safety, strengthen the screening of suppliers and food test, and procure them to perform their duties for food safety. If necessary, the organizer may hire some professionals to make assessment.

The food producers and dealers that supply foods to a major event shall be primarily responsible for food safety according to law, develop the food safety assurance plan and the emergency response plan, implement the thorough food safety control requirements and ensure food safety.

The food and drug administration under the people's government above the county level shall, together with the health administration, agricultural administration, quality supervision and other relevant departments at the same level, strengthen the food safety assurance in major events, and intensify the screening of suppliers and food test according to the food safety assurance plan. If necessary, they may

hire some professionals to make assessment.

Encourage the organizers of major events to hire some private professional institutions to provide food safety assurance services for the major events.

**Article 151** The food and drug administration and other relevant departments under the people's government above the county level shall establish a food safety complaint and report acceptance agency, publish the food safety complaint and report telephone number, and establish a complaint and report network information management system.

The food safety complaint and report acceptance agency shall regularly summarize and analyze the information about food safety complaints and reports, and propose some advices on improving the supervision and administration measures for food safety.

**Article 152** The CFDA shall, together with relevant ministries under the State Council, develop the standards for building the capability of food safety supervision and administration, and clearly specify the requirements for building the capability of the food and drug administrations at various levels in terms of organs, personnel, facilities and equipment.

The people's government above the county level shall include the funds required for food production and marketing administrative license, risk surveillance and assessment, formulation of food safety standards, supervisory inspection, sampling inspection, promotion and education, and capability building in the fiscal budget of the government at the same level, and set up dedicated funds for emergency response, case investigation, reward for reporting, and protection of major events respectively.

The law enforcement vehicles required for food safety supervision and administration shall be administered as special-purpose vehicles.

**Article 153** The CFDA and other relevant ministries under the State Council shall develop the training syllabus for the professional training to food safety law enforcement officers, and the food and drug administrations and other relevant departments under the people's governments of provinces, autonomous regions and municipalities directly under the Central Government shall organize to make assessment.

Each law enforcement officer of the food and drug administration and other relevant departments shall receive professional training on food safety not less than 40 hours every year, and shall be assessed in the training. Any officer fails in the assessment shall not engage in the law enforcement concerning food safety.

**Article 154** The food and drug administrations at the city and county level shall carry out routine supervisory inspections on food production and marketing, and may randomly select some food producers and dealers in their administrative regions and randomly dispatch some inspectors to carry out off-site inspection and cross-inspection.

The food and drug administrations at the city and county level shall organize to carry out routine supervisory inspection according to the annual supervision and administration plan for food safety of

their administrative region, determine the results of supervisory inspections, and publish the result of an inspection within 2 business days after the routine supervisory inspection is finished. They shall also post a routine supervisory inspection record form on a conspicuous place at the production and marketing premises.

The food producers and dealers shall maintain the posted routine supervisory inspection record form to the next routine supervisory inspection.

If the result of routine supervisory inspection on a food producer and dealer basically meets the standards, the inspectors shall advise the requirements for remedy within a prescribed time period on spot with regard to the problems identified in the supervisory inspection. If the result of routine supervisory inspection fails to meet the standards, and there is potential risk of food safety incident, the food producer and dealer shall immediately stop the relevant food production and marketing activities. If the inspection identifies any food safety risk, the food and drug administration may issue a warning to the food producer and dealer and make a public announcement.

If there is evidence proving that the food fails to meet the food safety standards or there is any hidden peril of food safety or any food, tool and equipment are being used for illegal production or marketing, the inspectors may immediately detain and seize such food, tool and equipment, and report it to the food and drug administration of the same level within 24 hours to make up the procedures of detainment and seizure.

**Article 155** Upon occurrence of any of the following circumstances, the food and drug administration and other relevant departments above the county level may carry out unannounced inspection, and supervise the works of the food and drug administration and other relevant departments at the lower level:

- (1) Suspected violation of food safety law or regulation by any food producer or dealer, which would cause serious harm or significant impact on the society;
- (2) Any hidden peril of food safety involving any food producer or dealer, which would cause regional or systematic food safety risk, or would cause serious harm or significant impact on the community;
- (3) Any complaint or report reveals that the concerned food producer or dealer has committed any serious illegal conduct or there is serious hidden peril in food safety;
- (4) Other circumstances if the unannounced inspection is necessary.

**Article 156** If any food causes systematic food safety risk and the test method and test items for such food are expressly provided in the applicable food safety standards, but the local food and drug administration above the county level fail to timely find and eliminate such risk, the people's government at the same level may conduct regulatory interview with its principal.

With the authorization from the people's government at the same level, the food and drug administration may conduct regulatory interview of the principal of the people's government at the lower level who fails to timely eliminate any regional serious hidden peril of food safety.

**Article 157** The CFDA shall organize the NHFPC, MOA, AQSIQ and other relevant ministries under the State Council to strengthen the building of food safety information system, establish a uniform food

safety information platform and integrate the food safety information resources to share food safety information.

**Article 158** The CFDA shall, together with the health administration, quality supervision, agricultural administration and other relevant departments to prepare and publish the annual national food safety status report.

**Article 159** The Central Government shall establish the food safety statistical survey system. The CFDA shall, together with the statistics and other ministries under the State Council, establish the food safety statistical indicators system, and organize to carry out statistical survey relating to food safety.

The food and drug administration under the people's government above the county level shall, together with the statistics department at the same level, establish and improve the food safety statistical work system and statistical indicators system by reference to the national food safety statistical survey system and the statistical indicators system, and organize to carry out statistical survey relating to food safety.

The food producers and dealers, industry associations and other relevant organizations shall cooperate with the food and drug administration in carrying out the food safety statistical surveys according to law.

**Article 160** The inspection agencies with corporate capacity who are established by the food and drug administrations under the people's governments above the county level may carry out on-site inspection, supervisory inspection, case investigation and take other supervisory and administrative measures in their own name.

**Article 161** The local offices of the food and drug administrations may, in their own name, carry out supervisory inspection and give administrative guidance to the food producers and dealers in their respective administrative region.

The local offices of the food and drug administrations may, in their own name, give warning, confiscate illegal gains, confiscate illegal properties, and impose fine and other administrative penalties. The limits of confiscating illegal gains, confiscating illegal properties and imposing fines shall be set by the food and drug administrations at the province level.

**Article 162** Where a food and drug administration, quality supervision administration or other relevant department under the people's government above the county level detects any of the following circumstances mentioned in Article 123 or Article 124 of the Food Safety Law, it shall transfer the relevant case clue and evidence to the public security authority within 3 business days:

- (1) Adulterate any toxic or harmful non-food ingredient during processing, sale, transportation or storage of any food, or use any toxic or harmful non-food ingredient to process any food;
- (2) Use or sell any livestock, poultry, wild animal or aquatic animal which is dead from disease or from unknown cause or fails to pass inspection or quarantine, or any meat or meat product thereof;
- (3) Produce, sell or use any substance expressly prohibited by the Central Government from production and sale for disease prevention and control purpose or any other special purpose;
- (4) Infant formulas that substantially fail to meet the food safety standards;
- (5) Any food that contains any pathogenic microorganism, pesticide residue, veterinary drug

residue, heavy metal, contaminant significantly exceeding the standard limit or any other substance that would harm human health;

(6) Any other conduct of alleged criminal offense involving food safety.

In case of any alleged criminal offense, the public security authority shall promptly place a case on file for investigation according to law; if the alleged conduct does not constitute a criminal offense, but it shall be subject to public security punishment according to law, it shall be punished according to law; if it shall be subject to administrative penalty by the food and drug administration according to law, the case materials shall be transferred to the food and drug administration.

**Article 163** The people's government above the county level shall establish and improve the mechanism to connect the food and safety administrative law enforcement and the criminal justice, clearly prescribe such matters as report of case clues, transfer of cases, connection of evidence, meeting to discuss case details, information sharing, information publication, and suspension on inspection and handling, and coordinate and urge the investigation and prosecution of illegal activities and criminal offenses involving food safety.

**Article 164** During the course of handling criminal cases involving harm to food safety, if the public security authority finds that it is necessary to control the food safety risk, it shall immediately take measures to control the flow of involved products, and to prevent and control food safety risk; if it is necessary to get assistance from the food and drug administration, the food and drug administration shall actively assist in such measures.

If the criminal case details concerning food safety to be released by the public security authority involve food safety risk control, the public security authority shall report it to the food and drug administration and other relevant departments at the same level at least 3 business days in advance. If necessary, they shall jointly release the information and take effective measures to give explanation and direction.

**Article 165** The CFDA, together with the judicial administration under the State Council, shall formulate the administrative measures for forensic authentication of food safety to clearly prescribe the eligibility and qualification, and make a panel of food safety forensic authentication institution and experts.

To delegate the forensic authentication of food safety, the food safety forensic authentication institution and experts shall be selected among those on the panel.

**Article 166** Where the food and drug administration or the quality supervision administration or any other department detects any of the following circumstances during the course of supervision, administration and law enforcement, and it needs the assistance from the public security authority, the public security authority shall give the assistance:

- (1) Violent resistance to law or mass disturbance;
- (2) Refuse, obstruct or impede food safety supervision and law enforcement;
- (3) Destroy or conceal any evidence or any concerned party escapes and hides;
- (4) Any major difficult case which needs assistance in collecting evidence;
- (5) Other circumstances provided in the laws and regulations.

**Article 167** During the investigation of a criminal case involving food safety, if the public security authority needs technical support or information verification from the food and drug administration, quality supervision and other relevant departments, the food and drug administration, quality supervision and other relevant departments shall give the assistance.

During the supervision and administration, if the food and drug administration, quality supervision and other relevant departments need to consult with the public security authority with regard to any issue such as investigation of criminal cases involving food safety and evidence collection, the public security authority shall promptly give a response.

**Article 168** With respect to the cases of alleged criminal offenses transferred by the food and drug administration, agricultural administration, quality supervision and other relevant departments, the public security authority shall review the cases within 3 days upon receiving the transferred case materials, and decide whether to place an case for investigation within 10 days.

With respect to the illegal activities involving illegally adding non-edible substances, illegally adding drug, or production or marketing any livestock or poultry dead from disease or any other cases which cause serious harm to human health, the public security authority shall immediately review such cases.

**Article 169** With respect to the cases which do not constitute criminal offense but shall be transferred to the public security authority for administrative detainment, the local food and drug administration above the county level shall transfer such cases to the public security authority. The local food and drug administration above the county level shall transfer the case transfer cover letter and relevant case files to the public security authority at the same level within 3 days after the decision of case transfer is made.

The public security authority shall accept the cases in accordance with the Procedural Provisions for the Handling of Administrative Cases by Public Security Authority. If the public security authority, through review, believes that the facts about illegal activity are unclear or evidence is insufficient, it may notify the transferring authority in writing within 3 days after the case is accepted, asking the transferring authority to submit supplementary evidentiary materials, or may investigate the facts and collect evidence in accordance with the Procedural Provisions for the Handling of Administrative Cases by Public Security Authority.

If the public security authority believes that the facts of a transferred case are clear and the evidence is conclusive and sufficient, and it decides to impose administrative detainment according to law, it shall send a copy of the decision to the transferring authority within 3 days after the decision is made. If the public security authority believes that the facts of a transfer case are unclear or the evidence is insufficient, and the conditions for administrative detainment are not satisfied, it shall send a written notice to the local food and drug administration above the county level and explain the reason within 5 days after the case is accepted, and it shall also return the case files.

**Article 170** The food and drug administration, quality supervision and agricultural administration may retain an electronic copy or a photocopy affixed with the seal for those electronic or documentary evidence transferred to the public security authority, as the basis of relevant administrative penalty.

If the public security authority, through review and verification, believes that the evidence transferred by

the food and drug administration, quality supervision or agricultural administration meets the criminal case evidence standards, such evidence may be adopted for the criminal case.

**Article 171** If the public security authority, through review, finds that there is no fact of criminal offense with respect to the illegal activities involving food safety, or believes that it is not required to prosecute the criminal liability through investigation, but the person concerned shall be detained according to law, the public security authority shall impose the administrative detention according to law; if it is required to prosecute other administrative liabilities according to law, the public security authority shall promptly transfer the case to the food and drug administration or other relevant department.

The public security authority shall transfer the original evidentiary materials or the photocopy thereof affixed with the seal to the food and drug administration, quality supervision, agricultural administration and other relevant departments. If the relevant department, through review and verification, believes that the evidence requirements for administrative law enforcement are satisfied, the evidence may be adopted for the purpose of relevant case.

**Article 172** With respect to any case where the people's court has rendered an effective judgment, if the food and drug administration, quality supervision and agricultural administration shall also suspend the license or impose any other administrative penalty according to law but the penalty has not been imposed, the food and drug administration, quality supervision and agricultural administration, through review and verification, may impose the administrative penalty based on the facts and evidence recognized in the judgment of the people's court.

**Article 173** If any illegal activity of a food producer or dealer might constitute food safety criminal offense, during the stages of case filing and investigation, review, prosecution and trial, the food and drug administration may order to cease production and business operation, suspend the license or impose any other administrative penalty according to law, in order to prevent and control the food safety risk.

## **Chapter Nine Legal Liabilities**

**Article 174** Where a food producer or dealer continues its food production or marketing activities after its food production or marketing license expires or is withdrawn, suspended or revoked, the food and drug administration under the people's government above the county level shall impose penalty according to Paragraph 1, Article 122 of the Food Safety Law.

**Article 175** Where a food producer produces foods beyond the scope of licensed categories, or a food dealer markets food beyond the scope of licensed business items, it shall be imposed penalty according to Paragraph 1, Article 122 of the Food Safety Law.

**Article 176** Upon occurrence of any of the following circumstances, it does not constitute a criminal offense, but it shall be deemed as "serious circumstance" referred to in Article 123 of the Food Safety Law:

- (1) Produce food with non-food ingredient, produce or process foods added with drug, market meat of any poultry, livestock, wild animal or aquatic animal which is dead from any disease, poison or any unknown cause, or any product made of such meat, or market any meat which has

not been quarantined as required or fails to pass the quarantine, with the value of more than RMB 1,000 or with bad impact;

(2) Add any chemical (except food additive) or any substance that would cause harm to human health in any food, with the value of more than RMB 2,000;

(3) Use any recycled food as ingredient to produce any food, with the value of more than RMB 5,000;

(4) Produce or market any meat product without being inspected or without passing inspection, or produce or market any food expressly prohibited by the Central Government from production or marketing for prevention of disease or for any other special purpose, or produce or market any staple or supplementary food dedicated to infants or other specific groups of people but the nutrient component fails to meet the food safety standards, and the producer or dealer has been imposed administrative penalty within one year due to violation of any food safety law or regulation, or the illegal activity continues more than six month;

(5) Other circumstances provided in the laws and regulations.

Where the producer has any circumstance referred to in Article 123 of the Food Safety Law, but the value of the illegal products cannot be determined due to incomplete production records, the total amount of the products produced and marketed by the producer in the last year shall be deemed as the value.

**Article 177** Upon occurrence of any of the following circumstances, and when it does not constitute a criminal offense, the food and drug administration, quality supervision and agricultural administration under the people's government above the county level shall impose penalty according to Article 123 of the Food Safety Law:

(1) Illegally use any non-edible substance during the production, marketing, storage or transportation of any food;

(2) Use any discarded or expired food additive to produce or process any food or food additive;

(3) Use any substance which would cause harm to human health to process any food or food ingredient by means of soaking, fumigation or otherwise;

(4) Use any non-food chemical as food additive;

(5) Add any chemical (except ingredient of medicine or food additive) or any substance that would cause harm to human health in any food additive;

(6) Use any non-food dedicated detergent or disinfectant to clean or disinfect any production or trading utensil or tool that directly contacts with food;

(7) Other circumstances provided in the laws and regulations.

If any person uses any prohibited pesticide, veterinary drug or any other prohibited substance in planting or breeding of any edible agricultural product, the agricultural administration under the people's government above the county level shall impose penalty according to Paragraph 1 above.

**Article 178** If a producer of special food has any of the following circumstances, the CFDA shall revoke the registration certificate of the special food:

(1) Use any non-food ingredient to produce any special food, or add any chemical not listed in the registered or filed formulation or add any substance that would cause harm to human health in the special food;

(2) Illegally add any drug in the production of the special food;

- (3) Fail to organize production of the special food according to the registered product formulation, production processes or technical requirements, with the value of involved products of more than RMB 10,000 but less than RMB 20,000;
- (4) Produce infant formula powder in sub-packages, or the same company uses the same formula to produce health food, FSMP or infant formula powder of different brands, with the value of involved products of more than RMB 10,000 but less than RMB 20,000;
- (5) Other circumstances provided in the laws and regulations.

**Article 179** Where a food producer or dealer violates Article 49 of these Rules and fails to separately store the expired, spoiled or recycled foods or food additives at a clearly marked place and maintain a register thereof, or fails to promptly destroy them or take other harmless treatment and maintain relevant records, it shall be punished according to Paragraph 1, Article 124 of the Food Safety Law. With respect to the foods sub-packaged by a food producer or dealer, the food producer or dealer changes the original production date or extends the original shelf life, it shall be punished according to Paragraph 1, Article 124 of the Food Safety Law.

Where a producer or dealer produces or markets any new variety of food or food additive made of any new food ingredient which has not passed the safety assessment, it shall be punished according to Paragraph 1, Article 124 of the Food Safety Law.

**Article 180** Upon occurrence of any of the following circumstances, it does not constitute a criminal offense, but the value of involved products is more than RMB 30,000 and it causes a food safety incident, the food and drug administration under the people's government above the county level shall impose penalty according to Article 124 of the Food Safety Law by deeming it as "serious circumstance":

- (1) Produce or market any food or food additive which exceeds the limits under the food safety standards by more than five times in terms of pathogenic microorganism, pesticide residue, veterinary drug residue, biotoxin, heavy metal or any other contaminant or any other substance which would cause harm to human health;
- (2) Use any expired food ingredient or food additive to produce any food or food additive;
- (3) Produce or market any food with any food additive exceeding the prescribed scope or limit;
- (4) Produce or market any food or food additive which is rotten or spoiled, or has rancid fat, or grows with mold or insect, or is dirty or contaminated, or contains foreign matter, or is adulterated with alien substance, or has any other abnormal sensory property;
- (5) Produce or market any food or food additive which is labeled with fake production date or shelf life, or which has passed the shelf life;
- (6) Use any new food ingredient to produce food or produce new variety of food additive, without passing the safety assessment;
- (7) The food producer or dealer refuses to recall the product or stop operation after it is ordered by the food and drug administration to do so;
- (8) The food producer or dealer still continues to carry out production or marketing after it is ordered by the food and drug administration or any other relevant department to make correction and stop production or marketing.

If any person illegally produces or markets any food which is mainly targeted for patients, old people, pregnant women, children or any other special group of people; or produces or markets any health food, FSMP or infant formula powder without being lawfully registered, or produce such product not

according to the registered product formulation, production processes or technical requirements, with the value of involved products of more than RMB 20,000; produce infant formula powder in sub-packages, or the same company uses the same formula to produce health food, FSMP or infant formula powder of different brands, with the value of involved products of more than RMB 20,000, it shall be punished according to Paragraph 1 above.

**Article 181** Where any person produces, imports or markets any food of special formulation with quantitative dosage, and the label or instructions claim any health function but the food is not registered as health food, the food and drug administration under the people's government above the county level shall impose penalty according to Paragraph 1, Article 124 of the Food Safety Law. If it involves suspected criminal offense, the case shall be transferred to the public security authority for handling according to law.

**Article 182** Upon occurrence of any of the following circumstances in violation of these Rules, if it does not constitute a criminal offense, the food and drug administration under the people's government above the county level shall impose penalty according to Paragraph 1, Article 124 of the Food Safety Law:

- (1) Violate the food safety regulatory rules, and cause food safety incident;
- (2) The producer of infant formula powder violates Paragraph 1 or Paragraph 2, Article 91 of these Rules;
- (3) The food producer or dealer fails to recall any unsafe food within the prescribed time period;
- (4) Produce or market any food or food additive with falsified or fraudulent use of place of origin, name or address of producer, certification mark or product name;
- (5) The imported food dealer fails to provide the health certificate, or inbound or outbound goods inspection and quarantine certificate, Chinese label or inspection mark according to law;
- (6) The producer of special food fails to change the registration or production license after the production conditions or production processes have been changed;
- (7) Produce or market any health food that fails to meet the technical requirements;
- (8) Use any ingredient only used in health food to produce regular food;
- (9) Other circumstances provided for in the laws and regulations.

**Article 183** Upon occurrence of any of the following circumstances, with the value of involved products of more than RMB 20,000, the food and drug administration under the people's government above the county level shall impose penalty according to Paragraph 1, Article 125 of the Food Safety Law by deeming it as "serious circumstance":

- (1) Produce or market any food or food additive contaminated by the packaging material, container or transportation vehicle;
- (2) Produce or market any pre-packaged food or food additive without label, or the label or instruction thereof fails to comply with the food safety laws or regulations;
- (3) Produce or market any genetically modified food without proper labeling;
- (4) A food producer or dealer purchases or uses any food material, food additive or food related product not in compliance with the food safety standards;
- (5) Other circumstances provided in the laws and regulations.

If the label or instruction of any food or food additive has any flaw but it will not affect food safety nor mislead the consumers, it shall not be deemed as "serious circumstance" referred to in Paragraph 1 above.

If any person markets any pre-packaged food without the production license, it shall be imposed penalty according to Article 125 of the Food Safety Law.

**Article 184** Where a food producer or dealer has any of the following circumstances, and it causes a food safety incident involving more than ten persons, the food and drug administration under the people's government above the county level shall impose penalty according to Paragraph 1, Article 126 of the Food Safety Law by deeming it as "serious circumstance":

- (1) The food producer or dealer fails to establish the food safety management system or appoint or train and assess the safety management personnel as required;
- (2) The food or food additive producer or dealer fails to check license and relevant documents in purchase, or fails to establish and adhere to the purchase inspection record, the delivery inspection record and the sales record systems as required;
- (3) The food producer or dealer fails to formulate the food safety incident response plan;
- (4) Fail to wash or disinfect the tableware, drinking utensils or containers which hold food for direct consumption before they are used, or the washing or disinfection does not meet the requirements, or fail to maintain, clean or check the catering service facilities or equipment periodically as required;
- (5) The food producer or dealer assigns any person to engage in food contact work, while the person has not obtained the health certificate or has any disease the NHFPC deems harmful for food safety;
- (6) The food dealer fails to sell the foods according to the statutory requirements;
- (7) The health food producer fails to file with the food and drug administration for record as required, or fails to organize the production according to the recorded technical requirements such as product formulation or production processes;
- (8) The producer of infant formula food fails to file the food ingredients, food additives, product formulation or label with the food and drug administration for record, with the value of involved products of more than RMB 20,000;
- (9) The producer of special food fails to establish the quality management system and effectively operate the system;
- (10) The food producer or dealer fails to regularly check and assess its food safety status, or fails to take the required actions when its production and operation conditions have changed;
- (11) The school, child-care institution, nursing institution for the aged or a construction site that provides centralized dining fails to comply with food safety management duties as required;
- (12) The food producer or catering service provider fails to develop or implement the process control requirements for food production and dealing as required;
- (9) Other circumstances provided in the laws and regulations.

If a catering service provider fails to maintain the required samples, it shall be imposed penalty according to Paragraph 1, Article 126 of the Food Safety Law.

**Article 185** If a food producer or dealer violates these Rules and has any of the following circumstances, the food and drug administration under the people's government above the county level shall order it to make correction and give a warning:

- (1) The employees of the food producer or dealer fail to dress in clean clothing and cap in production or sale of foods, or fail to use non-toxic and clean vending tools for directly

consuming food without package;

(2) The food producer or dealer fails to establish the food additive use and record system;

(3) The catering service provider fails to use any tableware or drinking utensil without cleaning or disinfection, or fails to request and maintain the disinfection certificate when it purchases tableware or drinking utensil or receives disinfection service from the tableware and drinking utensil centralized disinfection service provider.

**Article 186** Where the tableware and drinking utensil centralized disinfection service provider has any of the following circumstances, the health administration shall impose penalty according to Paragraph 1, Article 126 of the Food Safety Law:

(1) It fails to appoint health managers or establish the health management system or the health management records as required;

(2) It fails to carry out production activities according to the good health practices;

(3) The supervisory sampling inspection reveals that the tableware or drinking utensil fails to meet the standards.

**Article 187** Any person that violates these Rules and has any of the following circumstances, the food and drug administration shall order him to make correction and give a warning; if the person refuses to make correction, a fine of more than RMB 5,000 but less than RMB 50,000 shall be imposed:

(1) The food dealer fails to use any effective protective facility to prevent dust or fly for the bulk and directly consuming foods, or use any package or label that fails to meet the food safety requirements;

(2) The food dealer or the edible agricultural product seller fails to separately store the fresh foods and cooked foods being sold, and such foods are likely cross-contaminated;

(3) The food warehousing service provider fails to maintain the photocopy of the clients' identity certificate, license or business license as required;

(4) The food producer or dealer fails to establish the food traceability system as required, so that the foods cannot be traceable;

(5) The online food trading third-party platform provider, or founder of centralized food trading market, or food stall leaser or trade fair organizer fails to establish the food safety incident response plan;

(6) The container or packing material of any food ingredient, semi-finished product or finished product directly contacts with the ground or unclean item;

(7) Self-supplied water fails to meet the national drinking water hygienic standard;

(8) The catering service provider fails to have effective tableware or drinking utensil disinfection or cleaning facility as required;

(9) Use any detergent, disinfectant, or cleaning or disinfecting product that fails to meet the requirements during the food production or dealing.

**Article 188** Where the foods produced or marketed by a food producer or dealer meet the national food safety standards or local standards, but fail to meet the indicated enterprise standards, the food and drug administration shall order it to make correction and give a warning; if the food producer or dealer refuses to make correction, a fine of less than RMB 2,000 shall be imposed. Where the consumers request to return the foods or claim damages, the food producer or dealer shall be subject to the civil liabilities according to the laws and regulations.

**Article 189** Where an online food trading third-party platform provider commits any of the following conducts, the food and drug administration under the people's government above the county level shall impose penalty according to Paragraph 1, Article 131 of the Food Safety Law:

- (1) Fail to provide the registration information, trading data or any other required information about the online listed food or food additive producers and dealers;
- (2) Transfer, alter, falsify or remove any trading data about the online listed food or food additive producers and dealers, without permission.

**Article 190** Where an online food trading third-party platform provider fails to make real name registration or examine the license of the online listed food producers and dealers, or fails to perform the obligations of reporting or stopping the online trading platform service, and has any of the following circumstances, the food and drug administration under the people's government above the county level may order the online food trading third-party platform provider to stop trading a part of or all the food varieties:

- (1) It causes death or serious personal injury;
- (2) It causes major or more serious food safety incident;
- (3) It causes serious food-borne disease;
- (4) It damages the legitimate right or interest of the consumers, causing seriously adverse effect on the society;
- (5) It causes any other serious consequence.

**Article 191** Where a food producer or dealer conceals, transfers, uses, sells off, damages or destroys, or otherwise illegally disposes of any item attached or seized by the food and drug administration, the food and drug administration and other relevant departments under the people's government above the county level shall confiscate the illegal gains, impose a fine equal to more than 10 times but less than 20 times of the value of the concealed, transferred, used, sold, damaged or destroyed items, and suspend its license; if such conduct constitutes a criminal offense, the criminal liabilities shall be prosecuted according to law.

**Article 192** The "refuse, obstruct, interfere with" referred to in Paragraph 1, Article 133 of the Food Safety Law shall include:

- (1) Delay or evade the supervisory inspection, investigation or penalty being conducted or imposed by the on-site law enforcement officers;
- (2) Inhibit on-site law enforcement officers from accessing to the production, operation or storage site;
- (3) Fail to provide the relevant contracts, vouchers, books or electronic data as required without justifiable reason;
- (4) Other circumstances provided in the laws and regulations.

**Article 193** Upon occurrence of any of the following circumstances, it shall be imposed penalty according to Paragraph 1, Article 133 of the Food Safety Law by deeming it as "serious circumstance":

- (1) Refuse, obstruct or interfere with the food safety supervision or administration activity by beating, insulting, verbal abuse, intimidation and other means;
- (2) Destroy or conceal any evidence, or the concerned party escapes and hides;
- (3) Retaliate against any law enforcement officer, informant or witness.

**Article 194** Where a qualification penalty is imposed according to Article 135, Article 137, Paragraph 2 of Article 138, or Paragraph 1 of Article 139 of the Food Safety Law, the CFDA, AQSIQ and other relevant ministries under the State Council shall summarize and publicly announce on its website the name, identity card number and other relevant information about the directly responsible officers and other directly responsible persons. The qualification penalty shall be enforced in accordance with the Administrative Penalty Law.

Where an applicant for administrative license conceals the relevant facts or provides false materials to apply for an administrative license, the administrative authority shall reject the application or shall not grant the administrative license, and shall give a warning. The applicant may not apply for the said administrative license again within one year.

Where an administrative license is obtained by the licensee by fraud, bribery or any other improper means, the administrative authority shall revoke the relevant administrative license and impose administrative penalty according to law. The applicant may not apply for the said administrative license again within three years. If the conduct constitutes criminal offense, the criminal liabilities shall be prosecuted according to law.

**Article 195** Where a food producer or dealer falsifies or alters the registration certificate, food production or marketing license, label, instruction, test report, quarantine certificate, certification certificate or provides any false materials in supervisory inspection, the drug and food administration under the people's government above the county level shall confiscate the illegal gains, impose a fine of more than RMB 50,000 but less than RMB 100,000, and revoke the food production or marketing license (if any); if the conduct constitutes criminal offense, the criminal liabilities shall be prosecuted according to law.

**Article 196** For the foods that must be confiscated according to law, the food and drug administration may order the food producer or dealer to take measures such as harmless treatment or destruction, and may supervise the destruction if necessary.

Where the food producer or dealer fails to implement the purchase inspection record system, and thus the foods that do not meet the food safety standards are not traceable or the investigation of illegal activity involving food safety cannot be continued, the penalty shall be aggravated.

**Article 197** Where a food producer or dealer violates the food safety laws and regulations and has any of the following circumstances, the penalty shall be aggravated:

- (1) It causes serious personal injury or significant effect on the society;
- (2) It causes systematic or regional food safety risk;
- (3) It illegally produces or markets any special food;
- (4) It causes any food safety incident;
- (5) It has intention or gross negligence to commit the wrongdoing;
- (6) It refuses or evades the supervisory inspection, or uses violence or threat to obstruct the law enforcement officers from performing their duties;
- (7) It provides any false evidence or destroys any evidence;
- (8) Other circumstances where the penalty shall be aggravated according to law.

If the same illegal conduct violates several provisions of the food safety laws, regulations and rules, the heavier penalty under such provisions shall be imposed.

**Article 198** Where a food producer or dealer has any of the following circumstances, a lighter or mitigated penalty shall be imposed:

- (1) It has no subjective intent or gross negligence, and the offense is less serious, the value of involved items is low, and it did not cause any harm;
- (2) It voluntarily reported the conduct to the food and drug administration, and did not cause any harm;
- (3) It voluntarily recalled the unsafe foods and did not cause any harm, and took effective measures to mitigate or eliminate the food safety risk;
- (4) It reported and cooperated with the regulatory authority in investigating other unknown illegal conduct, and provided major meritorious service;
- (5) It voluntarily took effective measures to maintain the legitimate rights and interests of the consumers, and mitigated or eliminated harm to the consumers;
- (6) Other circumstances where the lighter or mitigated penalty shall be imposed according to law.

Where the illegal conduct was minor and was corrected promptly, and no harm was caused, the administrative penalty shall be exempted.

**Article 199** Where a test institution violates these Rules and has any of the following circumstances, the food and drug administration may expose the test institution to the public, and shall not delegate it to take any task of sampling inspection within five years:

- (1) Illegally replaced the samples, falsified the test data or issued false test report;
- (2) Sought improper interest by utilizing the sampling tests;
- (3) Illegally gave a prior notice to a food producer or dealer who will be subject to the sampling test;
- (4) Made public any information about food safety sampling test without permission;
- (5) Failed to report any test conclusion of non-conformance according to the prescribed time limit and procedures;
- (6) Any other illegal conduct.

Where a re-test institution has any of circumstances described in Item (1), Item (2) or Item (4) of this Paragraph 1, the relevant authority shall remove it from the list of re-test institutions.

Where a food test institution and its test personnel illegally replaced the samples, falsified the test data or issued false test report, the test report shall be void.

**Article 200** Where a medical institution and its personnel violate these Rules and fail to report any information about food safety incident as required, or a disease prevention and control institution fails to report the epidemiological investigation result as required or fails to do so within the prescribed time limit, the health administration and other relevant departments under the people's government above the county level shall order it to make correction according to law; if it fails to make correction, a fine of more than RMB 5,000 but less than RMB 50,000 shall be imposed.

**Article 201** Upon occurrence of any of the following circumstances, the advertisement regulatory authority under the people's government above the county level shall order the responsible advertiser,

advertising operator and advertisement publisher to stop publishing the advertisement, order the advertiser to eliminate the effect within the required scope, confiscate the advertising fee, and impose a fine of more than one time but less than three times of the advertising fee, or where the advertising fee cannot be calculated or is obviously low, impose a fine of more than RMB 100,000 but less than RMB 200,000; where the circumstances are serious, impose a fine of more than three times but less than five times of the advertising fee, or where the advertising fee cannot be calculated or is obviously low, impose a fine of more than RMB 200,000 but less than RMB 1,000,000, and may suspend the business license, and the food and drug administration under the people's government above the province level may decide to suspend the sale of the food or food additive and make a public announcement. If the food or food additive is still being sold, the food and drug administration under the people's government at the county level or above shall confiscate the illegal gains and the food or food additive being sold illegally, and impose a fine of more than RMB 20,000 but less than RMB 50,000:

- (1) The advertisement was posted without review and approval;
- (2) The advertisement approval number was revoked or canceled;
- (3) It was ordered by the relevant national authority to stop production and sale;
- (4) The conclusion of review of the advertisement by the local food and drug administration under the people's government of the province, autonomous region or municipality directly under the Central Government is that the advertisement fails to meet the standards;
- (5) Changed or altered any reviewed and approved advertisement, without permission;
- (6) The advertisement contains any content prohibited by the laws and regulations.

**Article 202** Where any person falsely advertises or sells any health food or FSMP on Internet or by telephone, TV, seminar or conference and the circumstances are serious, the food and drug administration under the people's government above the province may decide to suspend the sale of the food and make a public announcement; if the food is still being sold, the food and drug administration under the people's government above the county level shall confiscate the illegal gains and the food being illegally sold, and impose a fine of more than RMB 20,000 but less than RMB 50,000.

Where any entity or individual provided the place or other conditions while knowing the illegal conduct mentioned in the preceding paragraph, the food and drug administration under the people's government above the county level shall order it to stop the illegal conduct, confiscate the illegal gains, and impose a fine of more than RMB 50,000 but less than RMB 100,000; where the legitimate rights and interests of the consumers are damaged, the entity or individual and the food or food additive producer or dealer shall be jointly and severally liable for the damages.

**Article 203** Where any employee of the food and drug administration, quality supervision, agricultural administration, health administration under the people's government above the county level committed any intentional misconduct or gross negligence, the supervisory authority or appointing authority at the same level shall impose administrative liability on the employee according to the relevant regulations; if the conduct constitutes criminal offense, it shall be transferred to the judicial authority for prosecution.

Where the people's government above the county level, or its fiscal authority or planning authority failed to perform the duties, or failed to provide the required funds, workforce, technical support or any other support, and thus caused any regional food safety risk, the relevant responsible persons shall be imposed the liabilities according to the provisions of the Food Safety Law.

In case of any major food safety wrongdoing or food safety incident due to any cause of a food producer or dealer, and there is evidence proving that the employees of the competent food and drug administration, quality supervision, agricultural administration, and health administration have duly performed their duties regarding food safety supervision and administration, the administrative liabilities of the relevant employees shall be released.

## **Chapter Ten Supplementary Provisions**

**Article 204** The following terms used herein shall have the meaning defined below:

Edible agricultural product shall refer to any plant, animal or microorganism without change of its basic natural character and chemical nature, which is gained from the agricultural activities such as planting, cultivation, harvesting, fishing, greenhouse agriculture and bio-engineering, or formed through preliminary processing such as sorting, peeling, shelling, grinding, washing, cutting, freezing, waxing, grading and packaging, as well as the products of such plant, animal or microorganism.

Catering service shall refer to the service activities of directly providing foods to consumers through instant making and processing.

Food safety risk assessment shall refer to the scientific assessment of possible harmful effect on human health caused by biological, chemical and physical hazards in the foods, food additives and food related products, including hazard identification, depiction of hazard characteristics, exposure assessment and depiction of risk characteristics.

Food safety risk communication shall refer to the process where the food safety stakeholders exchange information and opinions concerning the food safety risks, risk related factors and risk perception involved in the relevant works.

Health food shall refer to a kind of food which claims any health function or is for supplementing nutrients such as vitamins and minerals, or can regulate body function, but is not for treating any disease, and which contains certain specific functional ingredients, and is suitable for specific group of people, and which has prescribed dosage.

Bulk food shall refer to the food without package of a fixed quantity and sold by specific measurement, including the food without package or with package of non-fixed quantity.

Initially imported health food shall refer to the health food from a different country, different producer or with different formula, as compared to any existing health food.

Rapid food test method shall refer to the technologies and products suitable for testing the relevant items of food safety, and such technologies and products shall be rapid, simple and sensitive.

Food safety professional and technical personnel shall refer to the persons who have the specialized education and practical background in the food safety related natural science such as food, biology, chemistry and medicine, have the professional knowledge and skill in food related biological, chemical and physical properties, food production process, characteristics of food production facilities and equipment, sources of food contamination, food safety risk control requirements and food safety test technologies, and have the ability to identify and control relevant food safety risks.

Food of quantitative and special dosage form shall refer to a kind of foods which use special dosage forms such as capsule, oral liquid, tablet, granule (pelletized granule) or pellet, and which need to eat with quantitative dosage or shall be administered at a predetermined quantity every day.

Toxic or harmful non-food ingredient shall refer to any substance prohibited from being adding or using in food production and marketing under the laws and regulations; any substance listed in the List of Non-Food Substances Which Might Be Illegally Added in Foods and the List of Substances Which Might Be Illegally Added in Health Foods promulgated by the relevant ministries under the State Council; any pesticide, veterinary drug or any other toxic or harmful substance prohibited by the relevant ministries under the State Council; and any other substance which is harmful to human health.

Flaw in label or instruction of food or food additive shall refer to the situation that the character spacing, font size, punctuation, simplified or traditional Chinese characters, rounding interval or any other non-essential content of the label or instruction of any food or food additive does not conform to the food safety standards, but it will not affect food safety nor mislead the consumers with respect to the food safety issues.

Food sub-packaging shall refer to the food production activity, during which the food producer or dealer splits the pre-packed foods that are directly released to the market into several smaller packages, packs the foods in the packages with smaller contents of such foods, through certain process control, without affecting the food safety. If the foods in large packages are split in bulk sales during the marketing of the foods, without being processed to pre-packed foods, it shall not be deemed as food sub-packaging.

Unannounced inspection shall refer to any surprise supervisory inspection conducted by the food and drug administration on the administrative subject without prior notice.

Recycled food shall refer to the food which has been sold but was recalled or returned by the food producer or dealer due to violation of any law, regulation or food safety standard or expiration of the shelf life, except any flaw in the label or instruction.

Value of involved products shall refer to total amount of market price of the food, food additive or food related product illegally produced or sold by the party concerned, or of the primary edible agricultural product being illegally marketed. For the ingredients and food additives, the value shall be counted at the purchase price; for the semi-finished products, the value shall be counted at the price of ingredients plus other costs; for the finished products, the value shall be counted at the selling price. The selling price of a single produced product shall be the unit price expressly indicated in the sales; the selling price of a single sold product shall be the unit price indicated by the seller. Where the producer or seller does not indicate the price, it shall be the average unit price of the market retailing prices of such product in the region at the time of being investigated and confiscated.

Illegal gains shall refer to all revenues received by the concerned party from illegal production and sale of foods, food additives and food related products. Where the food producer did not commit any intentional misconduct and performed the statutory duties such as purchase inspection, asking for the certificates and vouchers, and there is evidence proving that it did not know the purchased materials or the foods being marketed do not meet the food safety standard, and it has not caused any harmful

consequence, the purchase price of the sold goods or materials shall be deducted in calculating the illegal gains.

**Article 205** The "filing" used herein shall refer to the processes that the administrative subject registers, files, makes public or records the relevant documents with or to the competent authority according to the relevant regulations.

With respect to the filing of enterprise standards and the filing of health foods and infant formulas, the competent authority shall not implement administrative licensing in a disguised form such as formal deliberation, determination or approval.

Where these Rules do not have express provision regarding food additives, the provisions here regarding foods shall apply *mutatis mutandis*.

**Article 206** The "frontier port" used herein shall refer to the international gateway where passengers, luggage, cargoes, containers, transportation vehicles, items and postal parcels enter or exit the border. Food safety supervision and administration at any place other than the international gateway or border such as port, airport, railway station, land frontier, and border river shall be taken charge of by the food and drug administration.

**Article 207** In order to satisfy the needs for registration of special foods, the applicants who apply for registration of the product formulation of health foods, FSMP and infant formula powders shall pay the registration fee and the inspection fee. The rates of such fees shall be determined by the fiscal authority, the price administration, together with the CFDA.

**Article 208** These Rules shall enter into force as of \_\_\_\_\_ (date).

## **END OF TRANSLATION**

Note: full text of the Revised Draft Implementing Rules could be downloaded at:  
<http://www.chinalaw.gov.cn/article/cazjgg/201610/20161000481908.shtml>