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Final Food Safety Law Implementation Measures

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Approved By:

William Westman

Prepared By:

Mark Petry and Wu Bugang

Report Highlights:

On February 28, China's National People's Congress (NPC) Standing Committee passed the first comprehensive Food Safety Law (FSL) after five years of drafting. The FSL went into effect on June 1, 2009. On April 24, the State Council published the first draft implementation regulation for public comment. On July 20, the final implementing regulation incorporating public comments was published as an Order by the State Council. This report is an UNOFFICIAL translation of this regulation.

General Information:

Executive Summary: On February 28, China's National People's Congress (NPC) Standing Committee passed the first comprehensive Food Safety Law (FSL) after five years of drafting; the first draft was read in December 2007. The FSL went into effect on June 1, 2009. On April 24, the State Council published the first set of implementation regulations related to the new law (CH9040). Following a public comment period, the final implementation regulations were published on July 20, 2009 to go into force immediately.

Many other regulations and implementing measures have been released following the publication of the final food safety law (CH9019). The following reports touches on various measures relating to trade that have been released as unofficial English translations from the Office of Agricultural Affairs Beijing: Food Safety Law and its implementation regulations (CH9018, CH9019, CH9040), Ministry of Health draft regulations (CH9051) and quarantine regulations on import food and feed (CH9065).

Neither the Food Safety Law nor any associated regulations have been notified to the World Trade Organization.

This report is an UNOFFICIAL translation of this implementing regulation.

BEGIN TRANSLATION

Order of State Council of the People's Republic of China No. 557

Implementation Rules of Food Safety Law of the People's Republic of China have been adopted at the 73rd Standing Committee Meeting of the State Council on July 8, 2009, and are now published and shall be effective from the date of issuance.

Prime Minister:
Wen Jiabao

July 20, 2009

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

Chapter 1 General Provisions

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

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

Article 3. Food manufacturers and traders shall conduct production and trading activities according to laws, regulations and food safety standards, establish and improve the food safety management system, and take effective management measures to ensure food safety. Food manufacturers and traders shall be responsible for the safety for food manufactured or traded, for public safety, and shall assume the social responsibility.

Article 4. Food safety regulatory authorities shall publish food safety information according to the Food Safety Law and the Regulations, provide convenience to the public regarding consultation and complaints about and any organization or individual as entitled under the food safety information from relevant departments.

Chapter 2 Food Safety Risk Surveillance and Assessment

Article 5. The Ministry of Health (MOH), in conjunction with the Administration for Quality, Supervision, Inspection and Quarantine (AQSIQ), State Administration for Industry and Commerce (SAIC), State Food and Drug Organization (SFDA), Ministry of Commerce and Trade (MOFCOM) and other authorities under the State Council, shall prepare the national food safety risk surveillance plan specified in Article 11 of Food Safety Law, according to preparation and revision of food safety risk evaluation, food safety standards, food safety regulation, etc.

Article 6. The health administrative authorities of provinces, autonomous regions and central municipalities ("the Provincial health administrative authorities") shall coordinate with AQSIQ, SAIC, SFDA, MOFCOM and other departments at the same level to prepare the local food safety risk surveillance program, according to Article 11 of Food Safety Law, and report to MOH for filing. MOH shall inform AQSIQ, SAIC, SFDA, MOFCOM and other departments under the State Council.

Article 7. MOH, in conjunction with other relevant departments, shall make adjustments to the national food safety risk surveillance program, according to Article 12 of Food Safety Law, and if necessary, adjust the national food safety risk surveillance program based on the disease information reported by medical institutions. After adjustment of the national food safety risk surveillance program, provincial health administrative authorities shall make the appropriate adjustment to the local food safety risk surveillance program according to the actual local condition.

Article 8. The medical institution, upon finding any patient with food borne diseases, food poisoning, or suspected food borne diseases or food poisoning among admitted patients, shall report it to the health authorities under the People's Government at or above the county level in a timely manner. The health administrative authorities receiving the report shall summarize and analyze the disease information and report to the People's Government at the same level and report to the higher level health administrative authorities in a timely manner. If necessary, it should directly report to the health administration authorities under the State Council and report to the People's Government at the same level and the higher level health administrative authorities.

Article 9. The health administration authorities at or above provincial level shall, in conjunction with the technical institution appointed by the AQSIQ, SAIC and SFDA at the same level, conduct the food safety risk surveillance. The technical institution responsible for food safety risk surveillance shall perform surveillance according to the food safety risk surveillance plan and the monitoring program to ensure the true and correct data is obtained. The authorities shall submit the monitoring data and analysis results to the health administration authorities at or above provincial level and the authorities assigning the monitor task, according to the food safety risk surveillance plan and the monitor program. The personnel for food safety risk surveillance shall collect the samples and relevant data and can enter the facility of the edible agricultural product planting/raising, food production, food distribution or catering services. The samples collected shall be paid according to the market price.

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

Article 11. MOH shall gather and summarize the data and analysis results of food safety risk surveillance and inform AQSIQ, SAIC, SFDA, MOFCOM and other authorities under the State Council.

Article 12. Under any of the following circumstances, MOH shall arrange the food safety risk evaluation:

- 1) The risk assessment is required for providing scientific basis in preparing or revising the national food safety standard;
- 2) When a risk assessment is required to determine the key areas and key types for supervision and management;
- 3) When any new factor likely to affect the food safety is found;
- 4) When it is necessary to judge whether any factor becomes the potential problem to the food safety;
- 5) Other cases that MOH deems necessary to conduct the risk assessment.

Article 13. The Ministry of Agriculture (MOA), AQSIQ, SAIC and state SFDA and other authorities under the State Council shall provide recommendations on food safety risk evaluation to MOH according to Article 15 of Food Safety Law, including:

- 1) Source and nature of risks;
- 2) Data and conclusions of relevant test;

3) Scope of risk;

4) Other information.

The local agricultural administration, AQSIQ, SAIC, SFDA and other departments at or above county level shall assist to gather the information on food safety risk evaluation specified in the above paragraphs.

Article 14. The health administration and agricultural administration under the provincial People's Government or above shall mutually inform the public on food safety risk surveillance, edible agricultural product quality safety risk surveillance, etc. The health administration and agricultural administration under the State Council shall timely distribute the results of food safety risk evaluation, edible agricultural product quality safety risk evaluation, etc. to each other.

Chapter 3 Food Safety Standard

Article 15. MOH shall, in conjunction with MOA, AQSIQ, SAIC, SFDA, MOFCOM and other authorities under the State Council, prepare the planning and implementation plan of the national food safety standard, for which the opinions shall be gathered from the public.

Article 16. MOH shall select the units with the appropriate technical ability to draft the national food safety standard, jointly consisting of research institutions, education institutions, academic organizations, and industrial associations, etc. MOH shall publish the draft of the national food safety standard to the public and gather the opinion from the public.

Article 17. MOH is responsible for organizing the National Food Safety Standard Review Committee as specified in Article 23 of Food Safety Law. The National Food Safety Standard Review Committee is responsible for review the scientific level, applicability and others of the drafts of national food safety standard.

Article 18. The provincial health administrative authorities shall transmit the enterprise standards submitted by companies according to Article 25 of Food Safety Law to MOA, AQSIQ, SAIC, SFDA, MOFCOM and other departments at the same level.

Article 19. MOH and the provincial health administrative authorities shall, in conjunction with MOA, AQSIQ, SAIC, SFDA, MOFCOM and other departments at the same level, track and evaluate implementation of the national and local food safety standards and make appropriate revisions according to the evaluation results.

MOA, AQSIQ, SAIC, SFDA, MOFCOM and other departments under the State Council or the provincial People's Government shall gather and summarize the problems found during implementation of the food safety standards and inform the health administrative authorities at the same level. Food manufacturers, traders and food industry associations, upon finding any problem in implementing the food safety standard, shall immediately report to the food safety regulatory authorities.

Chapter 4 Food Manufacture and Trade

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

Other food manufacturers and traders shall first obtain the food production permit, food distribution permits and catering service permit according to law, handle the business registration. Small food workshops and food peddlers, when there are specific requirements of laws and regulations, shall be handled accordingly. The effective period of the food production permit, food distribution permit and catering service permit shall be three years.

Article 21. When there is any change in the production or trading conditions of a food manufacturer or trader and the conditions no longer meet the requirements, the food manufacturer or trader shall take immediate correction measures; when there occurs any food safety incident with potential risk, the facility should stop food production or trading activities immediately and report to the local county level AQSIQ, SAIC or SFDA and when new formalities for permit are required, handle accordingly.

The AQSIQ, SAIC and SFDA at or above county level shall strengthen the routine supervision and inspection of the food production and trading activities of the food manufacturer and trader; when finding any case not meeting the requirements for food production and trading requirements, the order for correction and punishment shall be according to law; when it still fails to meet the conditions for the production and trading permit, cancellation of the relevant permit shall be according to the law.

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

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

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

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

Article 25. For the food manufacture group adopting centralized material purchase, the headquarters may centrally examine the license and product compliance certificate of the suppliers, conduct the incoming product inspection and keep the records; for food materials unable to provide the compliance certificate, inspection should be according to the food safety standard.

Article 26. The food manufacturer shall establish and implement the material acceptance, production process safety management, storage management, equipment management, non-conforming product management and other food safety management systems and continuously improve the food safety assurance system to ensure the food safety.

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

- 1) Purchase, acceptance, loading and other aspects of materials;
- 2) Production techniques, equipment, storage, packaging and other key production procedures;
- 3) Inspection of materials, semi-finished products or shipment of finished products, etc.;
- 4) Transport and delivery.

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

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

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

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

Article 31. The catering service provider shall prepare and implement the material purchase control requirements in order to ensure all the materials meet the food safety standard. The catering service provider shall not process or use any food or material to be processed after finding corruption, deterioration, or abnormal condition of the sensory aspect or appearance during the process of preparation or processing.

Article 32. The catering service provider shall undertake regular maintenance of the facilities and equipment for food processing, storage, display, etc. and regular cleaning and calibration of the heat preservation facilities and cold storage and refrigeration facilities. The catering service provider shall clean and sterilize the tableware and drink ware according to requirements and not use the tableware and drink ware not cleaned or sterilized.

Article 33. The food manufacturer shall treat or destroy foods recovered from callback according to Article 53 of Food Safety Law to avoid them from returning to the market. For the foods for callback due to the label, mark or instruction not conforming to the food safety standard, the food manufacturer can continue to sell the foods after remedying the situation and the food safety can be ensured. The remedy shall be notified to customers when selling such foods. AQSIQ, SAIC and SFDA at or above county level shall record the callback foods of the food manufacturer not conforming to the food safety standard, the foods stopped for trading of the food traders not conforming to the food safety standard, and place in the food safety files of the food manufacturers and traders.

Chapter 5 Food Inspection

Article 34. The applicant shall apply for re-inspection from the food inspection institutions responsible for re-inspection (“re-inspection institution”) according to Article 60 of Food Safety Law indicating the reasons. The list of re-inspection institutions shall be jointly published by the certification and approval administration, health administration, agricultural administration and other authorities under the State Council. The re-inspection results issued by the re-inspection institutions shall be final. The applicant can select the re-inspection institution at its own discretion. The re-inspection institution and the preliminary inspection institution shall not be the same.

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

Chapter 6 Food Import and Export

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

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

requirements of MOH.

Article 38. When finding any substance in imported foods not specified in the national food safety standard and possibly endangering human health, AQSIQ shall report to MOH according to Article 12 of the Food Safety Law.

Article 39. The foreign food manufacturer exporting foods to China shall register according to Article 65 of Food Safety Law and the registration shall be effective for 4 years. When discovering the registered foreign food manufacturer providing falsified documents or any serious food safety incident, AQSIQ shall cancel its registration and publish the information.

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

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

Article 42. AQSIQ shall establish the information gathering network and gather, summarize and report the following information according to Article 69 of Food Safety Law:

- 1) The food safety information obtained by the exit-entry inspection and quarantine authorities during inspection and quarantine of the import/export foods;
- 2) The import food safety information provided by the industrial associations and customers;
- 3) The food safety information and risk warning information issued by international organizations and foreign governmental authorities and the food safety information provided by foreign industrial associations and other organizations and customers; and
- 4) Other food safety information.

The authorities shall take appropriate measures upon receiving such notice. The food safety regulatory authorities shall report the import/export food safety information received to AQSIQ in a timely manner.

Chapter 7 Response to Food Safety Incidents

Article 43. Upon any food safety incident, the concerned entity shall immediately take control measures (such as sealing up the foods and materials, tools, equipment) against the likely cause of the food safety incident and report to the health administrative authorities under the People's Government at the county level within 2 hours upon occurrence of the incident.

Article 44. A food safety incident shall be investigated in a realistic and scientific manner to timely and correctly find out the nature and reasons and determine the responsibilities and propose corrective measures. The departments participating in investigation of the food safety incidents shall perform the respective duty and cooperate with each other under the coordination of the MOH to improve the efficiency of investigation and treatment of the incident. The measures for investigation and treatment of the food safety incident shall be prepared by MOH with other relevant departments under the State Council.

Article 45. The departments participating in investigation of the food safety incident shall have the right to inquire about the incident from the relevant entities and individuals and require documents and samples. The relevant entities and individuals shall cooperate in the investigation and treatment of the food safety incident and shall not refuse to provide the documents and samples as required.

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

Chapter 8 Supervision and Administration

Article 47. The local People's Government at or above county level shall prepare the annual food safety supervision and management plan according to Article 76 of Food Safety Law, including sampling inspection of foods; sampling inspection shall be intensified for the staple and supplementary foods dedicatedly for infants, old people, patients and other specific populations. MOA, AQSIQ, SAIC and SFDA at or above county level shall conduct the sampling inspection according to the annual food safety supervision and management plan and the costs for buying the samples, the inspection fees, and other factors for the sampling inspection shall be paid for by the financial authorities of the same level.

Article 48. The county level People's Government shall centrally organize and coordinate MOH, MOA, AQSIQ, SAIC and SFDA at the same level to conduct the supervision and management of the food manufacturers and traders in the region according to the law. For the food manufacturers and traders with the higher risk of food safety incident, the supervision and management shall be intensified.

After MOH publishes the food safety risk warning information or the health administrative authorities of the provincial People's Government publish the food safety risk surveillance information according to Article 10, the cities (with districts) and the county level People's Government shall organize MOH, MOA, AQSIQ, SAIC and SFDA at the same level to take the appropriate measures so as to avoid further occurrence of the food safety incident.

Article 49. MOH shall publish the list and test methods of non-food chemical substances and other substances possibly endangering human health that are added or possibly added to foods, according to disease information, information on supervision and management, and other factors. AQSIQ, SAIC and SFDA shall take the appropriate regulatory measures.

Article 50. AQSIQ, SAIC and SFDA authorities can adopt quick testing methods validated by AQSIQ, SAIC and SFDA for preliminary screening during food safety supervision and management; for the food possibly not conforming to the food safety standard indicated in the results of the preliminary screening, the test shall be conducted according to Article 60 of Food Safety Law. The results of the preliminary screening shall not be taken as the basis for enforcement.

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

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

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

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

Article 53. MOH, MOA, AQSIQ, SAIC and SFDA shall disclose the email or telephone number to the public, to receive the suggestions, complaints; upon receiving the suggestions or complaints the authorities should reply, verify and handle

the incident according to Article 80 of Food Safety Law and record the reply, handling, and records.

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

Chapter 9 Legal Liability

Article 55. When the food manufacturer or trader fails to handle, according to Article 21, any change of the production or trading conditions, the relevant authorities shall order it to take corrective action or give warning; when serious consequence is caused punishment should be according to Article 85 of Food Safety Law.

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

The catering service provider failing to inspect foods or materials to be processed, according to Article 31 (2), or finding deterioration, abnormal conditions or appearance but continue to process using these materials shall be punished according to Article 85 of Food Safety Law.

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

- 1) The food manufacturer fails to establish and implement the food safety management system according to Article 26;
- 2) The food manufacturer fails to establish and implement the production process control system according to Article 27 or fails to take corrective measures when discovering any condition not conforming to control requirements during the food production process;
- 3) The food manufacturer fails to record safety management during the food production process and keep the relevant records according to Article 28;
- 4) A food wholesale business trader fails to record sales information or keep record of sales instruments according to Article 29 herein;
- 5) The catering service provider fails to conduct regular maintenance, cleaning and calibration of the equipment and facilities according to Article 32 (1) herein;
- 6) The catering service provider fails to clean and sterilize the tableware and drink ware according to Article 32 (2) or uses the tableware and drink ware not cleaned or sterilized. Imported food additives not meeting the requirements of Article 40 herein shall be forfeited to the entry-exit inspection and quarantine authorities; when the value of the imported illegal food additives is less than RMB10,000 a fine of RMB 2,000 – 50,000 shall be impose; and when the amount is more than RMB10,000 a fine of 2 – 5 times of the value of the goods shall be imposed.

Article 59. Any medical institution failing to report disease information according to Article 8 shall be ordered to take corrective action and given a warning by the health administrative authorities.

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

Article 61. When the local People's Government at or above county level fails to perform its statutory duty for food safety supervision and management and gives rise to severe food safety incident or causes serious social impact in the region, the responsible officer and other directly responsible personnel shall be punished by a special demerit, demotion, removal from office or dismissal.

When MOH, MOA, AQSIQ, SAIC and SFDA at or above county level or other administrative departments fail to perform a statutory duty for food safety supervision and management, fails to make proper routine supervision and inspection, abuses its authority through derelicts of duty, or practices favoritism, the responsible officer and other directly responsible personnel shall be given the punishment by a special demerit, demotion, removal from office or dismissal; the chief principal shall also acknowledge blame and resign.

Chapter 10 Miscellaneous

Article 62. The following are definitions of terms:

Food safety risk evaluation: the scientific evaluation of the possible adverse effect on human health from biological, chemical or physical hazards of food and/or food additives, including identification of the hazard, description of hazard features, exposure evaluation, description of risk features, etc. Catering service: the service activities of providing food and consumption sites and/or facilities to customers, through the prompt preparation, processing, marketing, service labor, etc.

Article 63. MOA at or above county level is responsible for the quality safety risk surveillance and risk assessment of edible agricultural products according to Law of the People's Republic of China on Agricultural Product Quality. The exit-entry inspection and quarantine authorities shall be responsible for supervision and administration of foods at the border port, according to Food Safety Law and other rules and regulations. SFDA shall execute the strict control of the food with the claim for specific healthcare functions and its measures shall be prepared separately by the State Council.

Article 64. These regulations become effective upon issuance.

END TRANSLATION