

## Measures for the Administration of Food Production Licenses

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Order of General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China

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The Measures for the Administration of Food Production Licenses, which were deliberated and adopted at the executive meeting of the General Administration of Quality Supervision, Inspection and Quarantine on March 10, 2010, are hereby promulgated, and shall come into force on June 1, 2010.

Director General Wang Yong

April 7, 2010

## Measures for the Administration of Food Production Licenses

### Chapter I General Provisions

Article 1 These Measures are formulated according to the Food Safety Law of the People's Republic of China and the regulation for the implementation thereof and the laws and regulations on product quality, production licenses, etc. in order to ensure food safety, strengthen the supervision of food production and regulate the food production licensing activities.

Article 2 The enterprises engaging in food production activities and the quality and technical supervision departments granting food production licenses within the territory of the People's Republic of China must comply with these Measures.

Article 3 No enterprise may engage in food production activities without a food production license.

Article 4 The General Administration of Quality Supervision, Inspection and Quarantine (hereinafter referred to as the "AQSIQ") shall be responsible for the nationwide administration of food production license within the scope of its functions.

The local quality and technical supervision departments at the county level and above shall be responsible for the administration of food production license within their respective administrative regions according to their functions.

Article 5 The granting of food production licenses shall be in strict accordance with the procedures and requirements as prescribed by laws, regulations and rules, and shall observe the principles of openness, fairness, impartiality, and convenience for the people.

## Chapter II Procedures

Article 6 To establish a food production enterprise, a food production license shall be obtained in accordance with the laws and regulations on food safety and the relevant requirements of these Measures after the enterprise's name is pre-approved by the industrial and commercial department.

Article 7 The local quality and technical supervision departments at the county level and above shall be the organs responsible for granting food production licenses, except for those that should be granted by the AQSIQ according to the relevant provisions.

A provincial quality and technical supervision department shall, in accordance with the relevant laws and regulations and relevant provisions of the AQSIQ, determine the scope of varieties to be licensed respectively by the quality and technical supervision departments within its administrative region.

Article 8 In addition to meeting the food safety standards, the following requirements shall also be met to obtain a food production license:

(1) having places for treating food raw materials and food processing, packaging and storage, which are in keeping with the varieties and quantities of the food for which a production license is applied for, keeping the environment of the said places tidy and clean, and ensuring that they are at a prescribed distance from toxic and hazardous sites and other pollution sources;

(2) having production equipment or facilities, which are in keeping with the varieties and quantities of the food for which a production license is applied for, and having the corresponding equipment or facilities for disinfection, changing clothes, toilet, day-lighting, illumination, ventilation, anti-corrosion, anti-dust, anti-fly, rat proof, mothproof, washing, disposal of waste water, and storage of garbage and waste;

(3) having reasonable equipment layout and technical flowchart which are in keeping with the varieties and quantities of the food for which a production license is applied for, so as to prevent cross pollution between the food to be processed and ready-to-eat food, and between raw materials and finished products, and to prevent the food from contacting with toxic substances or unclean articles;

(4) having professional food safety technicians and managerial personnel which are in keeping with the varieties and quantities of the food for which a production license is applied for; and

(5) having food safety management systems with respect to health management such as health examination and health records of trainers and employees, and with respect to checking records of the purchased goods, ex-factory inspection records, check and acceptance of raw materials, production process, etc. to ensure the food safety, which are in keeping with the varieties and quantities of the food for which a production license is applied for.

If there are any other requirements in laws, regulations and the national industrial policies for food production, such requirements shall be met.

Article 9 Where a to-be established food production enterprise applies for a food production license, it shall apply to the quality and technical supervision department of the place of production (hereinafter referred to as the “licensing authority”), and submit the following materials:

- (1) an application for food production license;
- (2) a photocopy of the identity certificate or qualification certificate of the applicant;
- (3) a Notice of Pre-approval of Name of the food production enterprise to be established;
- (4) the plans of the food production and processing places and the surrounding environment, and the layout plan of each production and processing functional area;
- (5) a list of the food production equipment and facilities;
- (6) the food production process flowchart and the equipment layout;
- (7) a list of the professional food safety technicians and managerial personnel;
- (8) documents of the food safety management regulations and rules;
- (9) the food safety standards implemented on the products; if the products implement enterprise standards, it shall provide the enterprise standards filed with the health administrative department; and
- (10) other evidential materials that should be submitted as prescribed by the relevant laws and regulations.

The materials submitted for applying for a food production license shall be authentic, legal and effective. The applicant shall sign the written application for a food production license and other materials for confirmation.

Article 10 A licensing authority shall treat the applications received according to Article 32 of the Administrative License Law of the People's Republic of China and other relevant provisions.

If it decides to accept an application, it shall issue a Decision on Acceptance. If it decides not to accept an application, it shall issue a Decision on Rejection, give the reasons for rejection, and inform the applicant of the rights to apply for administrative reconsideration or initiate an administrative lawsuit according to law.

Article 11 A licensing authority shall, after accepting an application, organize an inspection on the application materials and the production places (hereinafter referred to as the "on-site inspection") according to the relevant provisions.

The on-site inspection shall be conducted according to the relevant provisions of the AQSIQ by an inspection team composed of two to four inspectors as designated by the licensing authority, and the enterprises shall provide cooperation.

Article 12 A licensing authority shall, according to the inspection results, make the following decisions within the time limit as prescribed by laws and regulations:

(1) If the production conditions are found to meet the requirements through the on-site inspection, it shall make a decision on approval of production according to law, issue a Decision on Granting a Food Production License to the applicant, and issue a food production license for a food production enterprise to be established within 10 days from the date on which the decision is made.

(2) If the production conditions are found to fail to meet the requirements through the on-site inspection, it shall make a decision on not granting a production license according to law, and issue a Decision on not Granting a Food Production License to the applicant and give reasons.

Except for force majeure, if the on-site inspection can not be carried out within the prescribed time limit due to the applicant, it shall be deemed that the applicant has failed the on-site inspection.

Article 13 A food production enterprise to be established may organize the trial production of food according to the requirements for production license inspection only after it has obtained a food

production license and handled the formalities for industrial and commercial registration of business license.

Article 14 A newly established food production enterprise shall apply for production license inspection according to the varieties of food subject to license as prescribed.

A licensing authority shall, after receiving an application for production license inspection, timely select and seal up samples according to the relevant provisions, and ask the applicant to submit the samples to an inspection institution with corresponding qualifications within seven days after the samples are sealed up.

Article 15 After receiving the samples, an inspection institution shall conduct an inspection according to the prescribed requirements and standards, and accurately and timely issue an inspection report.

Article 16 If the inspection is passed, the licensing authority shall determine the scope of varieties in the food production license according to the inspection report, and indicate it on the auxiliary page of the food production license.

Before the licensing authority determines the scope of varieties in a food production license, no food under trial production may be delivered from the factory for sale.

Article 17 If the inspection is failed, the enterprise may apply for re-inspection according to the relevant provisions.

If some varieties of food fail the re-inspection, the scope of production license of such kind of food shall not be determined, and shall not be indicated on the auxiliary page of the food production license; and such kind of food shall be forbidden to leave the factory for sale.

If all the varieties of food fail the re-inspection, the food production license shall be deregistered according to the relevant provisions. All these varieties of food shall be forbidden to leave the factory for sale.

Article 18 Where an established enterprise applies for a food production license, it shall go through the application formalities for a license upon the strength of its legal and valid business license according to the relevant conditions and requirements as prescribed in this Chapter.

A licensing authority shall, according to the relevant conditions and requirements of this Chapter, accept the application for a food production license submitted by an established enterprise, and decide whether to grant a license, determine the scope of varieties in the food production license and issue a food production license according to the on-site inspection results and the inspection report.

Article 19 A food production license shall be valid for three years.

Upon expiry of the term of validity of the food production license, if an enterprise that has obtained a food production license needs to continue the production of food, it shall, six months before the expiry of the term of validity of the food production license, make an application for renewing the license to the original licensing authority. If the application is approved, the serial number of the food production license shall remain unchanged.

If an enterprise fails to have the license renewed upon expiry of the term of validity, it shall be deemed as having no license; and if the enterprise intends to continue the production of food, it shall make an application anew for a new license, which shall be renumbered and the term of validity thereof shall be calculated anew from the date the license is issued.

Article 20 Where an enterprise falls under any of the following circumstances within the term of validity of the food production license, it shall make an application for modification to the original licensing authority:

- (1) the name of the enterprise changes;
- (2) the name of its domicile or production address changes;
- (3) the production place is relocated;

(4) the surrounding environment of the production place changes;

(5) the equipment layout and the process flowchart change;

(6) the production equipment or facilities change; or

(7) other circumstances under which modification shall be applied for as prescribed by laws and regulations.

Where an enterprise falls under any of the circumstances as prescribed in items (3) to (6) of the preceding Paragraph, the original licensing authority shall, according to these Measures, organize check and inspection. If the conditions are met, it shall handle the formalities for modification according to law.

Article 21 Where an enterprise makes an application for modification of the food production license, it shall submit the following application materials:

(1) an application for modifying the food production license;

(2) the original and duplicate of the food production license; and

(3) the evidential materials relevant to the modification of the food production license.

The materials submitted for applying for the modification of the food production license shall be authentic, legal and valid, and meet the provisions of the relevant laws and regulations. The applicant shall sign the application for modification of the food production license and other materials for confirmation, and be responsible for the legitimacy and authenticity of the contents thereof.

Article 22 Within the term of validity of a food production license, if the relevant laws, regulations, food safety standards or technical requirements change, the original licensing authority may reorganize check and inspection according to the relevant provisions of the state.

Article 23 Under any of the following circumstances, the original licensing authority shall handle the formalities for deregistration of the food production license according to law:

(1) the production licensing is withdrawn or cancelled according to law or the production license is revoked according to law;

(2) the enterprise applies for deregistering the license or the production license fails to be renewed upon expiry of the term of validity;

(3) the enterprise is terminated according to law;

(4) the issues under production licensing can not be implemented due to force majeure; or

(5) other circumstances under which the production license shall be deregistered as prescribed by laws and regulations.

Article 24 Where an enterprise applies for deregistering a food production license, it shall submit the following application materials to the original licensing authority:

(1) an application for deregistering the food production license;

(2) the original and duplicate of the food production license; and

(3) other evidential materials relevant to the deregistration of food production license.

Chapter III License and Marks

Article 25 A food production license shall include an original and a duplicate, and the format of the license and its auxiliary page shall be uniformly stipulated by the AQSIQ.

Article 26 An enterprise shall properly keep the food production license, and hang or place it on an eye-catching position of its production place.

If the food production license is lost or damaged, the enterprise shall make a declaration on the media at or above the provincial level, and timely apply for issuing a new license.

Article 27 An enterprise shall put the serial number and sign of the food production license on the food or its packaging, otherwise the food shall not leave the factory for sale.

Article 28 The serial number and sign of the food production license both belong to the mark of a food production license that an enterprise has obtained. The numbering rules of the food production licenses and the format of the signs shall be uniformly stipulated by the AQSIQ.

Article 29 No enterprise may lease, lend or transfer in any other form the food production license and the serial number thereof. It is forbidden to forge or alter food production licenses, serial numbers of food production licenses and signs of food production licenses.

#### Chapter IV Supervision and Inspection

Article 30 An enterprise shall engage in food production activities within the scope of varieties in the food production license, and shall not produce food beyond the scope of varieties in the license.

Article 31 An enterprise shall ensure that the production conditions continuously meet the prescribed requirements, and be responsible for the safety of the food it produces.

Article 32 The quality and technical supervision departments at all levels shall regularly or irregularly supervise and inspect the food production activities of enterprises within their respective functions in accordance with law.

Article 33 The quality and technical supervision departments at all levels shall establish a management system for the files on food production license and supervision and inspection thereof. The term for keeping the files shall be governed by the relevant provisions of the state.

Article 34 The quality and technical supervision departments at all levels shall establish an information platform for food production license and supervision and inspection thereof so as to facilitate the inquiry by citizens, legal persons and other social organizations.

## Chapter V Legal Liabilities

Article 35 Where an enterprise violates Article 3, Paragraph 2 of Article 16, Paragraph 2 of Article 17, Paragraph 3 of Article 17, or Article 30 of these Measures, or has its food production license deregistered according to law, it shall be punished according to Article 84 of the Food Safety Law of the People's Republic of China.

Article 36 Where an enterprise violates Article 20, Article 27, or Article 29 of these Measures, and constitutes any illegal act as prescribed by the relevant laws and regulations, it shall be subject to administrative punishment according to the relevant laws and regulations.

Article 37 Where any of the quality and technical supervision departments at all levels or any of their staff members or inspectors, or any inspection institution or any of the inspectors thereof abuses its (his) powers, neglects its (his) duties or practices favoritism in the administration of food production license, it or he shall be subject to legal liabilities according to law.

Article 38 A local quality and technical supervision department at or above the county level shall determine and implement the administrative punishment as prescribed in these Measures within the scope of its power. If it decides to revoke a food production license, it shall report the decision level by level to the licensing authority for approval before making a decision on the administrative punishment.

Article 39 Where any party concerned is against the administrative license and administrative punishment implemented according to these Measures, it or he may apply for administrative reconsideration or initiate an administrative lawsuit according to law.

## Chapter VI Supplementary Provisions

Article 40 The term “food” as mentioned in these Measures shall refer to the food as prescribed in Article 99 and other provisions of the Food Safety Law of the People’s Republic of China, excluding the edible agriculture products and the food claimed to have the function of health protection.

If there are otherwise provisions in laws and administrative regulations on the food production license for dairy, genetically modified food, live pig slaughtering, alcohol and salt, such provisions shall prevail.

Article 41 The classification of the varieties of food subject to production license as prescribed by these Measures shall be governed by the laws and regulations and the relevant provisions of the AQSIQ.

Article 42 The catering service providers that have obtained the catering service license shall not be required to obtain a food production license as prescribed by these Measures for making and processing food at their catering service places.

Article 43 Small workshops and other food producers engaging in food production activities shall be governed by the relevant laws and regulations.

Article 44 The qualification and management of the inspectors and inspection institutions as prescribed by these Measures shall be governed by the relevant provisions.

Article 45 The power to interpret these Measures shall remain with the AQSIQ.

Article 46 These Measures shall come into force on June 1, 2010. If there is any discrepancy between the relevant rules and regulatory documents on food production license promulgated before the implementation of these Measures by the AQSIQ and these Measures, these Measures shall prevail.