# Measures for the Administration of Food Production Licensing

Dan Young Business Consultancy — www.danyoungcpa.com

Unofficial English translation prepared for reference only. The official Chinese text prevails.

## Contents


Table of Contents . . . . . 1

Chapter I — General Provisions . . . . . 1

Chapter II — Application and Acceptance . . . . . 2

Chapter III — Examination and Decision . . . . . 3

Chapter IV — Administration of Licenses . . . . . 4

Chapter V — Alteration, Renewal, and Reissuance . . . . . 4

Chapter VI — Supervision and Inspection . . . . . 4

Chapter VII — Legal Liability . . . . . 5

Chapter VIII — Supplementary Provisions . . . . . 5



Issued by the State Administration for Market Regulation on January 3, 2020 (Order No. 24 of the State Administration for Market Regulation)

Effective: March 1, 2020

Replaces the Measures for the Administration of Food Production Licensing issued by the former China Food and Drug Administration on August 31, 2015


### Table of Contents


- Chapter I — General Provisions
- Chapter II — Application and Acceptance
- Chapter III — Examination and Decision
- Chapter IV — Administration of Licenses
- Chapter V — Alteration, Renewal, and Reissuance
- Chapter VI — Supervision and Inspection
- Chapter VII — Legal Liability
- Chapter VIII — Supplementary Provisions


## Chapter I — General Provisions

Article 1 — These Measures are formulated in accordance with the Food Safety Law of the People's Republic of China, the Administrative Licensing Law of the People's Republic of China, and other laws and regulations, for the purpose of regulating the food production licensing activities, strengthening the




Source: https://www.danyoungcpa.com/measures-administration-food-production-licensing-prc-2020/

supervision and administration of food production, and safeguarding food safety.

Article 2 — Entities engaged in food production activities within the territory of the People's Republic of China shall obtain a food production license in accordance with law. The application, acceptance, examination, decision, supervision and inspection of food production licenses shall be governed by these Measures.

Article 3 — Food production licensing shall follow the principles of legality, openness, fairness, impartiality, and convenience for the people.

Article 4 — Food production licensing shall be subject to the principle of one enterprise, one license. A food producer engaged in food production activities shall obtain one food production license that is valid throughout the country.

Article 5 — The State Administration for Market Regulation shall be responsible for guiding and supervising the national food production licensing administration. The market regulation departments of the people's governments at or above the county level shall be responsible for the food production licensing administration within their respective administrative regions.

Article 6 — The State Administration for Market Regulation shall accelerate the development of information technology and implement information sharing and convenient licensing services in relation to food production licensing.

## Chapter II — Application and Acceptance

Article 7 — The food production license applicant of a people's government at the provincial level shall be determined by the market regulation department of the people's government of each province, autonomous region, or municipality directly under the Central Government, based on the risk level of the food category and its own working capacity. The food production license shall be accepted and examined by the market regulation department of the local people's government at or above the county level where the applicant is located.

Article 8 — The State Administration for Market Regulation shall be responsible for formulating the classification catalogue of food production licenses, and shall adjust it in due course based on changes in the risk level of the food category and in the supervision and administration work.

Article 9 — The market regulation departments of the people's governments at or above the county level shall disclose the procedures for the handling of food production licenses on their official websites or in their service halls.

Article 10 — An applicant for a food production license shall meet the following conditions: (1) having premises for the processing of food raw materials and the processing, packaging, and storage of food, which are suitable for the varieties and quantities of the food produced, and keeping such premises clean and tidy, and at a prescribed distance from toxic and harmful sites and other sources of contamination; (2) having production equipment or facilities suitable for the varieties and quantities of the food produced, with corresponding equipment for disinfection, changing clothes, washing, lighting, ventilation, anti-corrosion, dust-proofing, fly-proofing, rodent-proofing, insect-proofing, washing, and wastewater treatment, and equipment for the storage of garbage and waste; (3) having food safety management personnel and rules and regulations to ensure food safety; (4) having a reasonable equipment layout and process flow to prevent cross-contamination between food to be processed and ready-to-eat food, raw materials and finished products, and to ensure that food does not come into contact with toxic or unclean substances; and (5) other conditions prescribed by laws and regulations.

Article 11 — An applicant for a food production license shall submit the following materials to the market regulation department at the place where the applicant is located: (1) an application form for the food production license; (2) a copy of the food producer's business license; (3) a diagram of the layout of the food



Source: https://www.danyoungcpa.com/measures-administration-food-production-licensing-prc-2020/

production and processing premises and its surrounding environment, a diagram of the functional layout of each process area, and a diagram of the layout of the process equipment; (4) a list of food production process equipment and facilities; (5) a food safety management system such as the rules and regulations relating to the management of purchase inspection, production process control, factory inspection, and food safety self-inspection, and the employment training and health management of employees; and (6) other materials required by laws and regulations.

Article 12 — The market regulation department shall, in accordance with the following circumstances, make the following dispositions in respect of the application for a food production license received: (1) if the application matter does not require a license according to law, inform the applicant of the rejection of acceptance on the spot; (2) if the application matter does not fall within the functions and powers of the department, make a decision to reject acceptance on the spot and inform the applicant of the competent authority to which the application should be made; (3) if there are errors in the application materials that can be corrected on the spot, allow the applicant to make corrections on the spot, and the applicant shall sign or affix a seal to confirm the corrections; (4) if the application materials are incomplete or do not conform to the statutory form, inform the applicant on the spot or within five working days of all the contents requiring supplementation and correction, failing which the application shall be deemed accepted as of the date of receipt of the application materials; or (5) if the application materials are complete and conform to the statutory form, or the applicant has submitted all the supplementary and corrected application materials as required, the application shall be accepted.

Article 13 — The market regulation department shall, when accepting an application for a food production license, issue a notice of acceptance stamped with the special seal of the department and dated.

## Chapter III — Examination and Decision

Article 14 — After accepting an application for a food production license, the market regulation department shall organize an on-site verification of the premises of the applicant. The on-site verification shall be conducted by no fewer than two food safety supervisors, who shall present their valid administrative law enforcement certificates. On-site verification shall be conducted in accordance with the relevant laws, regulations, rules, national food safety standards, and the requirements of the food production license review rules.

Article 15 — The on-site verification personnel shall prepare an on-site verification report based on the verification record. The on-site verification report shall be verified and signed by the applicant. If the applicant refuses to sign, the verification personnel shall note the circumstances. The on-site verification report shall serve as a basis for the food production license examination.

Article 16 — Where the on-site verification finds that the applicant's production conditions do not comply with the requirements, the market regulation department shall notify the applicant of the matters requiring rectification in writing. The applicant shall complete the rectification within the time limit prescribed by the market regulation department and submit a rectification report.

Article 17 — The market regulation department shall, within 10 working days from the date of acceptance of the application, make a decision on whether to grant the license based on the examination of the application materials and the on-site verification. If an on-site verification is required, the time required for on-site verification shall not be counted in the time limit for the food production license. If the applicant's conditions comply with the statutory requirements, the market regulation department shall make a written decision to grant the license and issue a food production license to the applicant within five working days from the date of the decision. If the applicant's conditions do not comply with the statutory requirements, the market regulation department shall make a written decision to reject the license, explain the reasons, and inform the applicant of the right to apply for administrative reconsideration or bring an administrative lawsuit in accordance with law.



Source: https://www.danyoungcpa.com/measures-administration-food-production-licensing-prc-2020/

Article 18 — The food production license shall specify: the name of the licensee, the legal representative (person in charge), domicile, production address, food category, license number, issuing authority, date of issuance, and validity period. The food production license shall clearly specify the food category in the remarks column.

Article 19 — The validity period of a food production license is five years.

Article 20 — The format of the food production license shall be uniformly prescribed by the State Administration for Market Regulation.

## Chapter IV — Administration of Licenses

Article 21 — Food producers shall properly keep the original of the food production license and shall hang the original or a duplicate of the food production license in a conspicuous place at their production premises.

Article 22 — Food producers shall carry out production within the scope of the food categories specified in the food production license and shall not produce food beyond the permitted scope.

Article 23 — Food producers shall not forge, alter, lend, lease, transfer, or sell food production licenses.

Article 24 — Where a food producer needs to produce new food categories, it shall apply for an alteration of the food production license in accordance with law.

## Chapter V — Alteration, Renewal, and Reissuance

Article 25 — Where the name, legal representative (person in charge), domicile, production address, food category, or other matters specified in the food production license change, the food producer shall apply to the original issuing authority for an alteration of the food production license within 10 working days after the change.

Article 26 — When applying for an alteration of the food production license, the food producer shall submit the following materials: (1) an application form for the alteration of the food production license; (2) a copy of the original food production license; and (3) materials related to the matters of the alteration.

Article 27 — Where a food producer needs to continue production after the expiration of the food production license, it shall apply to the original issuing authority for renewal 30 working days before the expiration of the validity period of the food production license. The procedures and time limits for renewal shall be the same as those for the initial application. Where the food producer's production conditions have not changed and it has good daily administrative management records, the issuing authority may decide to exempt it from on-site verification.

Article 28 — Where a food production license is lost or damaged, the food producer shall apply to the original issuing authority for reissuance. If the application materials comply with the requirements, the original issuing authority shall reissue the license within 10 working days from the date of acceptance of the application. Where the food production license is lost, the food producer shall declare it lost on the website of the market regulation department at or above the county level or on other public media designated by the market regulation department at or above the county level. Where the food production license is damaged, the damaged original food production license shall be submitted at the time of reissuance.

## Chapter VI — Supervision and Inspection

Article 29 — The market regulation departments of the people's governments at or above the county level shall, in accordance with laws and regulations and in accordance with their functions and duties, carry out supervision and inspection of the food production license matters of food producers.

Article 30 — The market regulation departments at or above the county level and their staff shall, when performing the supervision and inspection duties of food production licenses, have the right to take the following measures: (1) entering the production and business premises of the food producer to conduct on-site inspections; (2) conducting sampling and testing of the food produced and operated by the food producer; (3) consulting and copying relevant contracts, bills, account books, and other materials; and (4) sealing up and seizing food or food additives that are proven to be non-compliant with food safety standards, or that there is evidence to show may endanger human health, and the premises where such food and food additives are produced.

Article 31 — Where a food producer no longer meets the conditions required for a food production license due to changes in its production conditions and refuses to make rectifications, the original issuing authority shall revoke its food production license.

Article 32 — Food producers shall, in accordance with law, cooperate with the market regulation departments in carrying out supervision and inspection and shall truthfully provide the relevant information and materials.

## Chapter VII — Legal Liability

Article 33 — Where a food producer engages in food production activities without obtaining a food production license, the market regulation department of the local people's government at or above the county level shall impose penalties in accordance with the provisions of Article 122 of the Food Safety Law of the People's Republic of China.

Article 34 — Where a food producer forges, alters, lends, leases, transfers, or sells a food production license, the market regulation department of the local people's government at or above the county level shall impose penalties in accordance with the provisions of the Food Safety Law.

Article 35 — Where food producers produce food beyond the scope specified in the food production license, or use food additives beyond the scope, or use food additives beyond the limit, the market regulation department of the local people's government at or above the county level shall impose penalties in accordance with the provisions of the Food Safety Law.

Article 36 — Where market regulation departments and their staff, in violation of the provisions of these Measures, commit any of the following acts in the administration of food production licenses, the competent authority at a higher level shall order them to make corrections; and the directly responsible persons in charge and other directly responsible persons shall be given sanctions in accordance with law: (1) accepting an application that does not meet the statutory requirements; (2) granting a license to an applicant that does not meet the statutory requirements beyond the statutory authority; (3) failing to grant a license to an applicant that meets the statutory requirements; or (4) failing to perform supervision and administration duties in accordance with law after the issuance of the license.

## Chapter VIII — Supplementary Provisions

Article 37 — Food additives and formula foods for special medical purposes shall be subject to food production licensing administration in accordance with these Measures.

Article 38 — The production of food in small workshops, food vendors, and other food production and operation activities shall be subject to the specific measures formulated by the standing committees of the people's congresses of provinces, autonomous regions, and municipalities directly under the Central Government in accordance with the Food Safety Law.

Article 39 — The market regulation departments of the people's governments of provinces, autonomous regions, and municipalities directly under the Central Government may, in accordance with the actual circumstances, formulate specific implementation measures for food production licensing administration in



Source: https://www.danyoungcpa.com/measures-administration-food-production-licensing-prc-2020/

light of these Measures.

Article 40 — These Measures shall be effective as of March 1, 2020. The Measures for the Administration of Food Production Licensing issued by the former China Food and Drug Administration on August 31, 2015 (Order No. 16 of the China Food and Drug Administration) shall be repealed simultaneously.

Disclaimer: This English translation is provided for informational and reference purposes only. It is not an official translation and has no legal effect. In the event of any discrepancy between this translation and the official Chinese text, the Chinese version shall prevail. Users should consult qualified legal professionals for advice on specific legal matters. While every effort has been made to ensure accuracy, no warranty is made as to the completeness or accuracy of this translation.



Source: https://www.danyoungcpa.com/measures-administration-food-production-licensing-prc-2020/