

Provisions on the Supervision and Administration of Production of Food Additives

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The Provisions on the Supervision and Administration of Production of Food Additives, which were deliberated and adopted at the executive meeting of the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China on March 10, 2010, are hereby promulgated and shall come into force on June 1, 2010.

Director General Wang Yong

April 4, 2010

Provisions on the Supervision and Administration of Production of Food Additives

Chapter I General Provisions

Article 1 These Provisions are formulated according to the Product Quality Law of the People's Republic of China, the Food Safety Law of the People's Republic of China and the regulation on the implementation thereof, the Regulation of the People's Republic of China on the Administration of Production License for Industrial Products and other relevant laws and regulations in order to ensure food safety and strengthen the supervision and administration of the production of food additives.

Article 2 These Provisions shall be applicable to the production of food additives within the territory of the People's Republic of China, granting of production license and supervision and administration thereof.

The term "food additives" as mentioned in these Provisions shall refer to the synthetic or natural substances, which may be added to foods to improve food quality and color, smell or taste and to meet the needs of the technology of preservation, fresh-keeping and processing and which are announced in the form of standards, announcement or by other means upon approval of the health administrative department of the State Council.

Other substances except for those as prescribed by the preceding paragraph shall not be manufactured as food additives and shall not obtain production license as food additives.

Article 3 The General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (hereinafter referred to as the "AQSIQ") shall take charge of the nationwide supervision and administration of production quality of food additives.

The provincial quality and technical supervision departments shall take charge of the supervision and administration of production quality of food additives within their respective administrative regions, and be responsible for granting production licenses for food additives.

The quality and technical supervision department at the city or county level shall be responsible for the supervision and administration of production quality of food additives within its administrative region.

Article 4 A producer shall produce food additives according to the laws, regulations, rules and the relevant standards, keep the product quality stable and qualified, be responsible to the society and the general public, and accept the supervision of the public.

Article 5 The supervision and administration of production of food additives shall observe the principle of scientificity, impartiality, convenience for the people and efficiency.

Chapter II Production License

Article 6 No producer may engage in the production of food additives until it obtains a production license.

To obtain a production license, a producer shall possess the following conditions:

(1) it has a legal and valid business license;

(2) it has professional technicians who can satisfy the production of food additives;

(3) it has production sites, factories and facilities which can satisfy the production of food additives; and its hygiene management meets the requirements for hygiene and safety;

(4) it has production equipment or facilities and other production conditions which can satisfy the production of food additives;

(5) it has technical documents and technique documents meeting the relevant requirements which can satisfy the production of food additives;

(6) it has a sound and effective quality management and responsibility system;

(7) it has the ex-factory inspection capability which can satisfy the production of food additives; and its products meet the relevant standards and the requirements for ensuring human health and personal safety;

(8) it complies with the industrial policy of the state, and has no such conditions as backward technique, high energy cost, pollution of environment, and waste of resources, which are expressly eliminated by the state and prohibited from being invested in and constructed; and

(9) other conditions as prescribed by laws and regulations.

Article 7 To produce food additives, an applicant shall submit an application for production license to the provincial quality and technical supervision department of the place where the food additives are to be produced (hereinafter referred to as the “licensing authority”).

Article 8 To apply for a production license for food additives, an applicant shall submit the following materials:

(1) an application for a food additive production license;

(2) a photocopy of the business license of the applicant;

(3) the relevant production technology documents of the food additives for which a production license is applied for;

(4) the materials proving the legal rights to use the production sites which satisfy the production of the food additives for which a production license is applied for, and the photocopies of the plan of the surrounding environment and the layout plan of factories, facilities and equipment;

(5) the materials proving the legal rights to use the production equipment and facilities which can satisfy the production of the food additives for which a production license is applied for and the list thereof, and the materials proving the legal rights to use the inspection equipment and the list thereof;

(6) the documents of the quality management and responsibility system which satisfies the production of the food additives for which a production license is applied for;

(7) a list of professional technicians which can satisfy the production of the food additives for which a production license is applied for;

(8) the documents of the standards for food additives implemented in the production thereof; and

(9) other materials as prescribed by laws and regulations.

Article 9 A licensing authority shall handle the applications for a production license submitted by applicants according to the following circumstances respectively:

(1) If no production license is required for the application matters according to law, it shall timely inform the applicant that it will not accept the application;

(2) If the application matters are not subject to the administration of the quality and technical supervision department according to law, it shall immediately decide not to accept the application and notify the applicant of the relevant administrative organ to whom it shall make the application;

(3) If an applicant falls under any of the circumstances as prescribed in Articles 78 and 79 of the Administrative License Law of the People's Republic of China, it shall immediately decide not to accept the application;

(4) If the application materials contain errors that can be corrected on the spot, it shall permit the applicant to correct them on the spot;

(5) If the application materials are incomplete or do not meet the statutory form, it shall, on the spot or within five days, inform the applicant of all the materials to be supplemented or corrected and the requirements, and issue a notice on supplement and correction of application materials for a production license to the applicant. If it fails to inform the applicant within a prescribed time limit, the application shall be deemed as having been accepted; or

(6) If the application matters fall under the scope of authority of the quality and technical supervision department, and the application materials are complete and conform to the statutory form or the applicant has submitted all the application materials supplemented and corrected as required, it shall accept the application for a production license, and issue a written decision on acceptance of the application for administrative license to the applicant.

When the licensing authority accepts or refuses to accept an application for license, it shall issue a written certificate affixed with its special seal and dated.

Article 10 A licensing authority shall, after accepting an application, organize an examination on whether the applicant has the necessary production conditions for continuously producing qualified products.

The examination shall cover the on-site inspection of the application materials and production sites and the inspection on the product quality.

Article 11 A licensing authority shall organize an inspection team to conduct on-site inspection on an applicant. The inspection team shall be composed of two to four eligible inspectors, and a team leader responsibility system shall be applied, and the inspection team shall accept the supervision of the local quality and technical supervision department according to the relevant provisions.

Article 12 A licensing authority shall work out an on-site inspection plan when conducting an on-site inspection on an applicant, and shall issue a notice on on-site inspection to the applicant five days before the inspection.

The on-site inspection shall not exceed two days in general.

Article 13 The inspectors shall not create difficulties for the enterprises, and shall not demand or accept property or seek for any other illegitimate interests when conducting on-site inspection.

An applicant shall cooperate with the inspection team in the on-site inspection. If the inspection needs to be extended due to any force majeure, an application for extension shall be timely made to the licensing authority.

Article 14 An inspection group shall, according to the inspection plan and the prescribed licensing conditions and procedures and other requirements, conduct an on-site inspection on an applicant and handle the issue as follows according to the inspection results:

(1) If the applicant passes the on-site inspection, it shall select and seal up samples according to the relevant provisions, and the applicant shall submit them to an inspection institution meeting the prescribed requirements for inspection;

(2) If the applicant fails to pass the on-site inspection, inspection of the samples of the products is unnecessary.

If the applicant refuses the inspection or does not provide cooperation without any justified reason, and thereby causing the on-site inspection unable to be implemented within the prescribed time limit, it shall be deemed that the applicant fails to pass the on-site inspection.

Article 15 For an on-site inspection, the leader of the inspection team shall fill in the on-site inspection records, which shall be signed by the inspectors and confirmed by the applicant.

Article 16 A licensing authority shall, within 30 days from the date of acceptance of an application, complete the on-site inspection and sample inspection of products of the applicant, and issue a notification on the conclusion of on-site inspection to the applicant. If the applicant fails to pass the inspection, it shall give reasons.

Article 17 An inspection institution undertaking the inspection on license issuance shall inspect the food additives according to the relevant standards, and complete the inspection within the prescribed time limit.

An inspection institution undertaking the inspection on issuance of a food additives production license shall possess statutory qualifications and the directory thereof shall be uniformly announced by the AQSIQ.

Article 18 An inspection institution shall, after completing the inspection, issue a product inspection report in triplicate, with one copy delivered to the applicant, one to the licensing authority and one kept by the inspection institution itself for archival filing.

Article 19 If an applicant has any objection to the inspection results, it may, within five days upon receipt of the inspection report, apply for re-inspection to the original licensing authority.

The re-inspection shall be carried out by an eligible inspection institution other than the original inspection institution, and the conclusion of re-inspection shall be final.

If the conclusion of the re-inspection is consistent with the original inspection conclusion, the applicant shall pay the fees for re-inspection, and if the conclusion of the re-inspection is inconsistent with the original inspection conclusion, the original inspection institution shall pay the fees for re-inspection.

Article 20 A licensing authority shall, within 60 days upon acceptance of an application, handle the issue as follows according to the examination results:

(1) If the applicant meets the conditions for granting a license, it shall make a written decision on granting a production license according to law, and issue a food additive production license to the applicant within 10 days from the date on which it makes the decision; and

(2) If the applicant fails to meet the conditions for granting a license, it shall make a written decision on not granting a production license, and give reasons, and inform the applicant of the rights to apply for administrative reconsideration or initiate an administrative lawsuit according to law.

The time for product inspection shall be excluded from the licensing period.

Article 21 A provincial quality and technical supervision department shall timely file the name list of the producers who obtain the food additive production licenses with the AQSIQ, and announce it to the general public.

Article 22 If a producer that has obtained a food additive production license needs to increase varieties of products, it shall make an application according to these Provisions. The original licensing authority shall, according to these Provisions, organize an examination on the applied-for varieties of products to be increased.

Article 23 If, within the valid term of a food additive production license, the production conditions, inspection methods, production technologies or techniques of the producer change significantly, the producer shall timely make an examination application to the original licensing authority, and the latter shall organize a new examination according to these Provisions.

Article 24 If the name of a producer changes but the production conditions, inspection methods, production technologies or techniques do not significantly change, the producer of food additives shall make an application for modification of the production license to the original licensing authority within one month after the change occurs. The original licensing authority shall handle the formalities for modification according to the relevant provisions.

Article 25 If, within the valid term of a production license, the relevant laws, regulations, product standards or technical requirements of the state change significantly, the AQSIQ may, according to needs, formulate corresponding provisions, and the original licensing authority may organize a new examination according to such provisions.

Article 26 A licensing authority shall timely archive the relevant materials for handling the food additive production licenses. The archives shall be kept for five years.

Article 27 A food additive production license shall be valid for five years.

If, upon expiry of a production license, the producer needs to continue the production of food additives, it shall, six months before the expiry of the production license, make an application for renewing the license to the original licensing authority.

If a producer fails to apply for renewing the license within a prescribed time limit or its application is disapproved, the food additive production license shall be invalidated upon expiry.

Article 28 There shall be an original and a duplicate of a food additive production license.

The license shall indicate the name and domicile of the producer, production address, the name of food additives, serial number of the license, issuance date of the license, valid term, the authority issuing the license (affixed with the official seal), etc.

Article 29 The AQSIQ shall uniformly formulate the format and numbering rules of the food additive production licenses.

Article 30 Where a food additive production license is lost or damaged, the producer shall timely make an application to the original licensing authority for issuing a new production license, and make a declaration on loss and invalidation of the original production license on the media at or above the provincial level at the same time. The original licensing authority shall handle the formalities for issuing a new license according to the relevant provisions.

Article 31 If, before a decision on granting a license is made, an applicant makes a request for withdrawing the application for a food additive production license, it shall give reasons, and submit an application. If the application for license is withdrawn, the licensing authority shall confirm it in written form, and the licensing shall be terminated naturally.

Article 32 Where a producer makes a request for terminating the food additive production license, it shall give reasons, and submit an application to the original licensing authority. The original licensing authority shall handle the formalities for deregistration according to the relevant provisions.

Article 33 The cancellation, revocation and deregistration of food additive production licenses shall be governed by the relevant provisions.

Article 34 No entity or individual may forge or alter a food additive production license and the serial number thereof.

A producer of food additives that has obtained the production license shall not lease, lend or transfer in any other form the production license and the serial number thereof.

Chapter III Obligation of Producers for Ensuring the Quality of Products

Article 35 A producer shall conduct an ex-factory inspection on the food additives leaving factories for sale, and can not sell the food additives until they pass the inspection.

Article 36 When producing food additives, the producers shall use the raw and auxiliary materials, packaging materials and production equipment meeting the relevant quality and safety requirements.

Article 37 A producer shall establish a quality management system with respect to purchase of raw materials, control of production process, product ex-factory inspection and sale, etc., and keep well the following production management records:

(1) the training and assessment records of the employees of the producer;

(2) the records on the use, maintenance, examination and repair, cleaning and disinfection of the workshops, facilities and equipment; and

(3) the operation records of the quality management system of the producer, including the check and acceptance records on the purchased raw and auxiliary materials, records on controlling the production process, product ex-factory inspection records, product sales records, etc.

The aforesaid records shall be authentic and complete and the producer shall be responsible for the authenticity and completeness thereof. The records shall be kept for at least two years. If the shelf life of the products exceeds two years, the records shall be kept for a period not shorter than the shelf life of the products.

Article 38 The food additives shall have labels and instructions, and the words “food additives” shall be indicated on the labels.

The labels and instructions shall indicate the following issues:

(1) the name, specifications, and net content of the food additives;

(2) the name, address and contact information of the producer;

(3) the components or list of ingredients;

(4) the production date, shelf life or period of safe use;

(5) storage conditions;

(6) the product standard code;

(7) the serial number of the production license;

(8) the scope, dosage and methods for using the additives as stipulated by the food safety standards and announced and approved by the health administrative department of the State Council; and

(9) other issues that must be indicated as prescribed by laws, regulations or the relevant standards.

Article 39 The labels and instructions of food additives shall not contain unauthentic and exaggerated contents, and shall not involve information on functions as disease prevention and treatment.

The labels and instructions of food additives shall be clear and eye-catching, and easy to be identified and understood.

The food additives which have use taboos or safety precautions shall have warning marks or warning statements in Chinese.

Article 40 The food additives shall be packaged to ensure that they are not to be polluted.

Article 41 Where a producer is entrusted with the processing of food additives, it shall have a food additive production license covering the scope of entrusted production.

For the food additives processed under entrustment, in addition to the signs and indications of food additives marked according to the laws and regulations on product quality and food safety and the requirements of these Provisions, the name, address and contact information of the entrusted producer shall be indicated.

Article 42 Where there are potential safety risks in food additives produced, the producer shall recall them according to law.

The producer shall report the information on the recall of food additives and the disposal of the recalled products to the quality and technical supervision department.

Article 43 A producer shall establish a self-examination system of the production management, and conduct self-examination on the production management such as quality and safety control of food additives according to the relevant provisions.

Chapter IV Supervision and Administration

Article 44 A quality and technical supervision department shall set up files on the producers of food additives within its administrative region who have obtained production licenses, record the information on production licensing or supervision and inspection results, handling of violations of laws, etc. in detail.

Article 45 A quality and technical supervision department shall, according to the work plan for supervision and administration, supervise and inspect the producers of food additives within its administrative region and keep well the relevant records according to the provisions.

Article 46 There shall be two or more staff members to conduct the on-site supervision and inspection on a producer. The supervisor and inspector shall produce valid certificates when conducting supervision and inspection.

Article 47 The supervisor and inspector shall, when supervising and inspecting a producer, mainly check the operation records of the quality management system of the producer, and verify the doubtful points reported in the self-examination report of the producer; and shall conduct supervision and administration on the implementation of recall by the producer according to law.

A producer under supervision and inspection shall designate its staff members to cooperate with the quality and technical supervision department in supervision and inspection and faithfully provide the relevant materials.

Article 48 Any entity and individual may complain about and report the violations of laws and regulations committed by the examiners of production license, inspection institutions and the staff members thereof or the supervisors and inspectors to the quality and technical supervision departments at all levels.

The quality and technical supervision departments at all levels shall timely investigate and handle the complaints and reports received and timely feed back the handling results to the complainants and reporters.

Chapter V Legal Liabilities

Article 49 Where a producer violates Paragraph 1 of Article 6, Article 22, Article 23, Article 24, Article 34, Article 35, Article 38, Article 39, Article 40, Article 41, etc. of these Provisions, and constitutes a violation of the Food Safety Law of the People's Republic of China, the Product Quality Law of the People's Republic of China, the Regulation of the People's Republic of China on the Administration of Production License for Industrial Products, or other relevant laws or regulations, it shall be punished according to the relevant laws and regulations.

Article 50 Where a producer violates Paragraph 3 of Article 2, Article 36, Article 37, Article 42, etc. of these Provisions, and constitutes a violation of the relevant laws and regulations, it shall be punished according to the relevant laws and regulations, and if its acts do not constitute a violation of the relevant laws and regulations, the local quality and technical supervision department at or above the county level shall order it to make rectifications within a prescribed time limit, and impose a fine of not more than 30,000 yuan.

Article 51 Where any staff member of a quality and technical supervision department at or above the county level violates these Provisions, or abuses his power, neglects his duties, or practices favoritism, he shall be subject to legal liabilities according to law.

Article 52 Where a party concerned has any objections to the administrative punishment imposed by the administrative organ according to these Provisions, he may apply for administrative reconsideration or lodge an administrative lawsuit according to law.

Chapter VI Supplementary Provisions

Article 53 The classification of the varieties of food additives subject to production license as prescribed by these Provisions shall be governed by the relevant laws and regulations and the relevant provisions of the AQSIQ.

Article 54 The power to interpret these Provisions shall remain with the AQSIQ.

Article 55 These Provisions shall come into force on June 1, 2010. Where there is any discrepancy between the relevant rules or regulatory documents on supervision and administration of production of food additives promulgated by the AQSIQ before the implementation of these Provisions and these Provisions, these Provisions shall prevail.