

Notice of the State Administration of Quality Supervision, Inspection and Quarantine on Printing and Distributing the “General Principles for the Examination of Food Quality Safety for Market Access (2004)”

Promulgation date: 12-23-2004
Effective date: 01-01-2005
Department: STATE GENERAL ADMINISTRATION OF QUALITY SUPERVISION, INSPECTION AND QUARANTINE
Subject: QUALITY ADMINISTRATION

Notice of the State Administration of Quality Supervision, Inspection and Quarantine on Printing and Distributing the “General Principles for the Examination of Food Quality Safety for Market Access (2004)”

(No. 558 [2004] of SAQSIQ; Date of Promulgation: December 23, 2004)

The quality and technical supervision bureaus of all provinces, autonomous regions, and municipalities directly under the Central Government:

In order to meet the demand for performing the duties of supervising the quality and sanitation in food production and processing, improve and deepen the work on food quality safety for market access, the State Administration of Quality Supervision, Inspection and Quarantine (SAQSIQ) has amended the “General Principles for the Examination of Food Quality Safety for Market Access”, which shall come into force on January 1, 2005. The General Principles are hereby printed and distributed to you. Please implement them carefully and earnestly. The Letter No. 515 [2003] of the SAQSIQ shall be repealed simultaneously.

Annex:

General Principles for the Examination of Food Quality Safety for Market Access (2004)

I. These General Principles are formulated in accordance with the “Product Quality Law of the People’s Republic of China”, the “Food Sanitation Law of the People’s Republic of China”, the “Regulation on Production Permits for Industrial Products (for Trial Implementation)”, other relevant laws and regulations, and relevant provisions on market access systems on food quality safety, so as to earnestly strengthen the supervision and administration of food quality safety from the source, regulate food enterprises’ production and processing, and improve the level of food quality safety in China.

II. A “food production or processing enterprise” mentioned in these General Principles shall mean an enterprise that has its fixed production or processing place, corresponding production or processing equipment and process flows, and makes or sells food products, excluding the food processing sites making on the spot or making in a mobile way, etc. These General Principles shall apply to the verification of the indispensable conditions for food production or processing enterprises to guarantee the product quality and to the inspections of food quality safety, etc. The application of these General Principles shall be combined with the Detailed Rules for Examination of Corresponding Food Production Permits (hereinafter referred to as Detailed Rules for Examination).

III. A food production or processing enterprise shall be established in accordance with the law, conform to the industrial policies of the State, and meet the following indispensable conditions for guaranteeing product quality safety (hereinafter referred to as indispensable conditions):

(1) Environment sanitation requirements. There shall be no harmful gas, soot, dust, radioactive substances or other diffusible sources of pollution around the enterprise. The sanitary conditions of the enterprise’s factory area, production and processing workshops, raw materials and auxiliary

ones, storerooms for finished products, means of storage and transport, as well as the enterprise's environmental protection measures shall all meet the requirements as prescribed by the State.

(2) Production resource requirements. A food production or processing enterprise must have the production facilities and equipment suitable for guaranteeing the product quality safety, and the places for treatment of raw materials, for production and processing, for storage of raw materials and finished products. If it uses any special equipment to produce or process food, it shall meet the requirements of relevant laws and regulations, in addition.

(3) Requirements on raw materials and auxiliary ones. The raw materials and auxiliary ones used in food production or processing must meet corresponding national standards, trade standards and other relevant provisions. No non-food-purpose raw materials or auxiliary ones shall be used to produce food. The water directly used for food production and processing must meet the requirements in GB 5749 "Sanitary Standards for Drinking Water". The enterprise shall, when purchasing any product under production permit administration and using it as production raw materials or auxiliary ones, ask for a photocopy of the production permit for this product and verify its validity.

(4) Production and processing requirements. The food processing flows should be scientific and reasonable. The course of production and processing shall be controlled strictly so as to prevent biotic, chemical or physical pollution or cross pollution between raw materials and semi-finished products or finished products. It is strictly prohibited to use the production techniques or equipments banned by the State from use or explicitly ordered by the State to be eliminated.

(5) Product requirements. The enterprise must arrange for production according to the effective product standards. The enterprise's products must meet the national standards, trade standards, the compulsory provisions in the Detailed Rules for Examination, and the quality requirements explicitly indicated by the enterprise itself. The food additives and nutrition enhancers must meet the GB 2760 "Sanitary Standards on the Use of Food Additives" and the GB 14880 "Sanitary Standards on the Use of Food Nutrition Enhancers". It is strictly prohibited to use excessive food additives or nutrition enhancers in food.

(6) Staff requirements. The enterprise's person-in-charge shall have good knowledge of the product quality laws and regulations, and the enterprise's product quality responsibilities and obligations. The enterprise's production technicians shall have relevant professional knowledge. The enterprise's production operators and inspectors shall, before taking their posts, accept trainings and examination. Each inspector shall have acquired a coresponding certificate before taking. The staff engaging in food production and processing shall be healthy, and have no infectious disease. The various employees of a food production or processing enterprise shall have necessary knowledge on food quality safety.

(7) Inspection requirements. The enterprise shall make inspections during the course of production and when the products leave the factory. The enterprise shall be capable of inspecting the items of products under ex-factory inspection as prescribed in the Detailed Rules for Examination. The inspection equipment must be used by the enterprise within the duration of validity after it is checked and adjusted to be qualified. The enterprise's inspection department shall be entitled to exercise the inspection power independently.

(8) Requirements on packing, label and mark. The food packing materials must conform to the laws and regulations of the State, and meet the requirements of compulsory standards. The net content of the food with quantified packing shall conform to corresponding product standards and the "Provisions for the Measurement Supervision of Commodities with Quantified Packing". The labels and marks of food must conform to the laws and regulations of the State and meet the requirements in food label standards and relevant product standards.

(9) Storage and transport requirements. The conditions of an enterprise's storerooms shall be meet the storage requirements and production scale of relevant food. The storerooms for finished products shall, as a general rule, be used for the storage of the targeted foods. The vehicles and means of food transport must be clean, and no finished product may be transported along with any pollutant. For the food which needs to be refrigerated (frozen) during the process of transport, the food production enterprise shall have the refrigerating (freezing) vehicles and means of transport.

(10) Quality management requirements. The enterprise shall, in accordance with relevant laws and regulations, set up and improve its quality management system. It shall conduct quality management in the whole process from raw materials to final products, rigorously enforce the post-related quality responsibility sytem, and strengthen quality assessment.

IV. Any food production or processing enterprise having a business license must apply for the food production permit independently. The food production or processing enterprise shall, when applying for the production permit, submit the following materials:

- (1) 3 copies of the "Application Letter for Food Production Permit" (see Annex 1 for specimen of the application letter);
- (2) photocopies of the industrial and commercial business license, the sanitation permit, and the enterprise code certificate (unless no code certificate is required) within the valid term, with 3 copies for each document;
- (3) 3 photocopies of the identity certificate of the enterprise's legal representative or person-in-charge;
- (4) 3 photocopies of the drawing on the layout of the enterprise's production place;
- (5) 3 photocopies of the drawing on the enterprise's production process flows, which is marked with key equipment and parameters;
- (6) 1 photocopy of the enterprise's quality management document;
- (7) 1 photocopy of the full text of the enterprise's standard (for enterprises to which enterprise standards are applied);
- (8) The enterprises which have obtained the HACCP certificate or the sanitation registration certificate for the export of food shall provide 3 photocopies of the certificate;
- (9) Other materials required by the Detailed Rules for Examination to be provided.

V. The verification of the indispensable conditions of food production or processing enterprises shall comply with the following requirements:

- (1) Rationality examination of enterprise standards. The verification team shall examine the rationality of the enterprise standards. The main contents to be examined include: whether or not the enterprise standards are archived, whether or not they meet the requirements of the compulsory standards, and whether or not the indexes lower than the requirements of recommended national or trade standards are reasonable.
- (2) On-site verification. The quality and technical supervision department at the provincial or municipal (prefectural) level shall be responsible for organizing the verification team, and shall appoint 1 observer. The verification team shall usually be composed of 2 or 3 persons. Each verifier undertaking the enterprise's on-site verification tasks (excluding experts) must pass the examination and obtain a verifier's qualification. The chief of the verification team must have been approved by the quality and technical supervision department at the provincial level, and be reported to the SAQSIQ for archival purposes. A team chief's responsibility system shall be applied to the enterprise's on-site verification.

The quality and technical supervision department at the provincial or municipal (prefectural) level shall notify the enterprise 5 days prior to the verification, and inform the enterprise of the staff information of the verification team. The enterprise shall have the right to request a certain verifier to withdraw.

The verification team shall make an on-site verification plan before conducting a verification, and fill out the “Form of Plan on On-site Verification of the Indispensable Conditions of the Food Production or Processing Enterprise” (Annex 2). The on-site verification shall be conducted in accordance with these General Principles, the “Form on On-site Verification of the Indispensable Conditions of the Food Production or Processing Enterprise” (Annex 3) and the Detailed Rules for Examination, and records shall be made as well. A clear verification conclusion shall be made from the on-site verification, and the “On-site Verification Report on the Indispensable Conditions of the Food Production or Processing Enterprise” (Annex 4) and the “Form on Improving the Unqualified Items of the Food Production or Processing Enterprise” (Annex 5) shall be filled out. The enterprise is also requested to carefully fill out the “Form on the Clean and Incorrupt Information Feedback from Verification of the Indispensable Conditions of the Food Production or Processing Enterprise” (Annex 6).

Where an enterprise has two or more branch factories or production or processing sites which have no business license, the verification team shall use the “Form on On-site Verification of the Indispensable Conditions of the Food Production or Processing Enterprise” to conduct on-site verification, and shall accumulate the ordinary unqualified items and the severely unqualified ones.

(3) Exception from on-site verification. An enterprise that has passed HACCP certification and sanitation registration for the export of food may be exempted from on-site verification, provided that such materials as the eligibility of the certification institution, the certification testimonial, registration certificate, records of unqualified items, and information on improving the unqualified items, etc., which are submitted by the enterprise, shall be verified, so as to confirm whether the enterprise has the capability of ex-factory inspection. In addition, the verification conclusion shall be made by filling in the “Report on On-site Verification of the Indispensable Conditions of the Food Production or Processing Enterprise”.

(4) Requirements for separate packing enterprises. For the food allowed to be produced and processed in separate packs, the separate packing enterprise shall have the production environment, warehouses for raw materials and auxiliary ones, and the storerooms for finished products, which are the same as those of the production enterprise. The separate packing enterprise shall also have the separate packing equipment as prescribed in the Detailed Rules for Examination, have the capability of ex-factory inspection, and have other indispensable conditions suitable for the separately packed products as required by the Detailed Rules for Examination. If the separately packed food originates within China, a photocopy of the supplier’s food production permit must be provided; while if the separately packed food originates from outside China, there must be a quality testimonial issued by the entry and exit inspection and quarantine institution.

(5) Improvement unqualified items. The verification team shall fill the enterprise’s unqualified items in the “Form on Improving the Unqualified Items of the Food Production or Processing Enterprise”, and require the enterprise to improve such unqualified items within the prescribed time.

(6) Sampling. Where an enterprise is found to be qualified after on-site verification, the verification team shall select samples in the sampling method prescribed in the relevant detailed rules for food examination, and fill out the sampling list (Annex 7). The basic number of samples and the quantity of samples shall conform to the corresponding Detailed Rules for Examination, and the sampled products shall be the product varieties which are large quantity and are difficult to be produced and processed or from which quality problems are liable to arise. The verification team shall seal up the samples, and attach a sealing strip at the opening. The samples for inspection and standby samples shall, within 7 days after the sampling (samples of food with short quality guaranty period shall be delivered in a timely manner), be safely delivered by the enterprise (or by the verification team upon entrustment) to the designated inspection institution for inspection.

VI. The inspection of food quality safety shall comply with the following requirements:

(1) Items under inspection. Inspection on certificate issuance is the inspection on all the items of the products. The items under inspection shall be inspected in accordance with the relevant detailed rules for food examination. Regular supervision and inspections of the items under inspection shall be conducted in accordance with the relevant detailed rules for food examination. Ex-factory inspection is the inspection conducted according to the standards before the products leave the factory. The items under inspection shall include the ex-factory items under inspection which are prescribed in the relevant detailed rules for food examination.

(2) Inspection on certificate issuance. The inspection of certificate issuance shall be conducted by the inspection institution designated by the SAQSIQ or the quality and technical supervision department at the provincial level. The inspection institution shall, after receipt of the enterprise's samples, check whether the packing and the sealing strip are intact, and whether the samples conform to the provisions. The inspection institution shall inspect the samples which conform to the provisions, reject those which do not and notify the quality and technical supervision department that accepted the application to deal with the matter. The standby samples for inspection on certificate issuance shall be kept for no less than 3 months (except for special circumstances). During the inspection of certificate issuance, the inspection institution shall inspect all the explicit indexes marked by the enterprise on the food label, and shall list the specific inspected contents of the label of the food in detail on the certificate issuance inspection report.

The inspection institution shall, within 15 days as of receipt of the samples, finish the inspection, and issue an inspection report in quadruplicate after the inspection (of which four copies shall be kept by the SAQSIQ, the quality and technical supervision department at the provincial level, the quality and technical supervision department at the municipal (prefectural) level, and the production enterprise, respectively, and the other copy shall be kept by the inspection institution for archival purposes).

The inspection institution shall guarantee that all work in the process of inspecting products (such as treatment, custody, inspection and determination of samples, and compilation, review, approval and sending of the inspection report) conform to the requirements, and shall be responsible for the inspection report.

(3) Determination of inspection on certificate issuance. The inspection on certificate issuance shall be determined according to the national and trade standards. If there are no national standard or trade standard, it may be determined according to the local standards, or may, in special circumstances, be determined according to the enterprise's standards as confirmed by the verification team. If the enterprise's explicit quality requirements are higher than national standards or trade standards, the inspection on certificate issuance shall be determined according to the enterprise's requirements. The inspection of products, etc. from the place of origin shall be determined according to corresponding product standards.

Where all the inspection items conform to the provisions, it shall be determined that they meet the conditions for certificate issuance; if, among the inspection items, there is one or more items which do not conform to the provisions, it shall be determined that they do not meet the conditions for certificate issuance (unless it is otherwise prescribed by the Detailed Rules for Examination). If the enterprise uses a certain kind of food additive, but fails to mark this additive on the food label according to the provisions on food label standards, it shall be determined that the enterprise has failed the conditions for certificate issuance.

(4) Ex-factory inspection. A production enterprise shall have indispensable ex-factory inspection equipment as prescribed in the Detailed Rules for Examination, and qualified laboratories and inspectors, as well, so as to be able to inspect the ex-factory items as prescribed in the Detailed Rules for Examination. An enterprise shall conduct ex-factory inspections by production batches. An

enterprise's products of the same group of materials, the same production line and the same shift shall be one production batch. An enterprise may use other testing equipment and inspection methods to conduct ex-factory inspections, provided that it is able to prove that its inspection methods are in good consistency and relevancy with the standard inspection methods. An enterprise that conducts ex-factory inspections by itself shall attend the ex-factory inspection capability comparison test organized by the quality and technical supervision department once each year.

(5) Inspection of the inspection items which are marked with an asterisk *. An enterprise shall inspect the items marked with "*" (unless it is otherwise prescribed in the "Detailed Rules for Examination") for no less than twice a year. An enterprise capable of inspecting the items with "*" may conduct inspections by itself; if it has no such inspection capability, it shall entrust an eligible inspection institution to conduct the inspections. If the supervision and inspection on an enterprise include the items marked with "*" and such items are found to be "qualified" upon inspection, the times of inspections conducted by the enterprise itself or upon entrustment on the items marked with "*" may be adequately reduced.

VII. The responsibility to interpret these General Principles shall remain with the State Administration of Quality Supervision, Inspection and Quarantine.

Annex:

1. Application Letter for the Food Production Permit (omitted)
2. Form of Plan on On-site Verification of the Indispensable Conditions of the Food Production or Processing Enterprise (omitted)
3. Form on On-site Verification of the Indispensable Conditions of the Food Production or Processing Enterprise (omitted)
4. On-site Verification Report on the Indispensable Conditions of the Food Production or Processing Enterprise (omitted)
5. Form on Improving the Unqualified Items of the Food Production or Processing Enterprise (omitted)
6. Form on the Clean and Incorrupt Information Feedback from Verification of the Indispensable Conditions of the Food Production or Processing Enterprise (omitted)
7. Sampling List on Inspection on the Issuance of Food Production Permits (omitted)