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General good manufacturing practice for food packaging containers and materials factory

食品包装容器及材料生产企业通用良好操作规范

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Foreword

This Standard references to European Union's "*General Good Manufacturing Practice for Food Contact Materials and Articles*" (2023/2006/EC).

This Standard was proposed by and shall be under the jurisdiction of China National Institute of Standardization.

Drafting organizations of this Standard: China National Institute of Standardization, National Quality Supervision and Testing Centre of Plastic Product, National Quality Supervision and Testing Centre of Environmental Product, China National Pulp and Paper Research Institute, Hebei University of Science & Technology, and Beijing Haidian District Product Quality Supervision and Testing Institute, etc.

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General good manufacturing practice for food packaging containers and materials factory

1 Scope

This Standard specifies food packaging containers and materials factories' basic requirements of factory environment, workshop and facilities, equipment, personnel, production process and control, hygienic management, quality management, documents and records, complaint handling and product recall, product information, propaganda-guidance, etc.

This Standard is applicable to food packaging containers and materials factories.

2 Normative references

The articles contained in the following documents have become part of this Standard when they are quoted herein. For the dated documents so quoted, all the modifications (excluding corrections) or revisions made thereafter shall not be applicable to this Standard. For the undated documents so quoted, the latest editions shall be applicable to this Standard.

GB 5749 Standards for drinking water quality

GB 9685 Hygienic standards for uses of additives in food containers and packaging materials

3 Terms and definitions

For the purpose of this Standard, the following terms and definitions apply.

3.1

Food packaging containers and materials

The paper, bamboo, wood, metal, enamel, ceramic, plastic, rubber, natural fiber, chemical fiber, and glass products that are used to pack or contain food; or they are used as the food additives. And the painting that directly contact with food or food additives.

3.2

Workshop

All or part of buildings and facilities that are used for or relevant to the processing, fabrication, packaging, and storage of food packaging containers and materials.

3.3

Materials

The general term of all articles that need to be listed in the plan, control inventory and control costs for product sales.

3.4

Products

The general term of semi-finished products and finished products of food packaging containers and materials.

3.5

Semi-finished products

The intermediate products in any fabrication process of finished products. It can be produced into finished products through subsequent fabrication process.

3.6

Finished products

The products that are ready for selling, after undergoing complete processing and fabricating, and being packaged and marked.

3.7

Buffer area

The buffer place that is set up at the entrance to avoid the controlled operating zone to directly connect with the outside area, when the raw materials or semi-finished products enter into the controlled operating zone.

3.8

Purchased parts

The parts of food packaging containers and materials that are processed by other manufacturers.

4 Factory environment

4.1 The factory shall keep a certain safe distance from the poisonous and harmful

5.2.5 A buffer area or buffer measures shall be set up at the entrance of the workshop as required; the workshop shall also be equipped with de-dusting and disinfection facilities; and regular sterilization shall be conducted.

5.2.6 Dressing room shall be set up near the workshop. The size of the dressing room shall be suitable for the number of production personnel. The dressing room shall be equipped with lighting facilities.

5.2.7 The storehouse shall be equipped with leakage-proof, damp-proof, dustproof, insect-prevention, bird-prevention, rat-prevention and other harm-prevention facilities as required.

5.2.8 Proper cleaning and disinfection facilities shall be set up at necessary places as required.

5.2.9 Appropriate and convenient toilets shall be provided for the staffs. The toilets shall be separated from the workshop.

5.2.10 Waste treatment facilities shall be provided to avoid pollution produced due to the production of food packaging containers and materials.

5.2.11 Proper water supply and water drainage system shall be provided.

6 Equipment

6.1 Product equipment AND analytical and detecting instruments or equipment that comply with the production requirements shall be provided.

6.2 The design, type-selection, layout, and installation of production equipment shall comply with the production requirements; be easy to clean; be convenient for production operations, maintenance, and repair, so as to ensure safety production.

6.3 Production equipment shall be regularly repaired and maintained.

6.4 The application scope and precision of instruments, meters, measuring tools and weighing apparatuses that are used for production and inspection shall comply with the production and quality inspection requirements, and shall have obvious status marks and be calibrated regularly.

6.5 For production and inspection equipment (including spare pieces and parts), the equipment files shall be set up to record the actual condition of use, repair and maintenance; and shall be managed by specially-assigned personnel.

7 Personnel

7.1 The enterprise shall be equipped with enough personnel suitable for product fabrication.

8.5 Quality inspection or quality verification shall be conducted in accordance with relevant regulations for the raw and auxiliary materials and parts purchased; the inspection/verification certificate shall be kept for more than two years.

8.6 After entered into the storehouse, the raw and auxiliary materials shall be marked with an obvious "waiting for inspection"; after successfully passing the inspection and verification conducted by the quality management department, they can be used. After the inspection, the raw and auxiliary materials shall be used on the principle of "first-in first-out". Unqualified raw and auxiliary materials shall not be used and shall be timely disposed and recorded in accordance with relevant regulations with the approval of authorizing personnel.

8.7 Raw and auxiliary materials shall be stored separately in appropriate storage conditions according to their physical and chemical properties. Poisonous, harmful, flammable, and combustible materials shall be stored separately with obvious marks, and shall be safeguarded by specially-assigned personnel.

8.8.Waiting-for-inspection, qualified and unqualified raw and auxiliary materials shall be stored in separated areas by different batches, and shall have easily identifiable marks.

8.9 Raw and auxiliary materials shall be weighed by precise quantitative instruments when used.

9 Control of production process

9.1.1 The enterprise's production personnel shall strictly conduct production operations in accordance with technical management system, operating rules and regulations, operation instructions, and other technical documents. Each link shall be performed in certain production technical conditions to reduce the possibility of the product quality safety being affected as much as possible.

9.1.2 For products with special production requirements (e.g. aseptic packaging), the air quality in their production area shall be monitored; the monitoring results shall be written down for filing.

9.1.3 The water directly contacting the products in the production process shall comply with the requirements of GB 5749.

9.1.4 Effective measures shall be taken to prevent cross contamination in the production process.

9.1.5 Production equipment and tools shall be properly operated and maintained to prevent products being contaminated during the processing.

9.1.6 Carrying tools shall be properly used according to products' characteristics.

9.2 Requirements of packaging, storage and transportation

production process, the enterprise shall promptly seek the reasons and conduct proper disposal.

11.4 A trial-produce shall be conducted for raw and auxiliary materials, new process and new formulation that are used for the first time; testing for main control indexes shall be conducted. After successfully passing the testing, trial products can be launched into mass production.

11.5 Process inspection shall be carried out according to the provisions; and process specifications shall be inspected in accordance with relevant parameter requirements of technical procedures; corresponding records shall be made.

11.6 Type test shall be conducted for products according to standard requirements. Entrusted inspection items shall be conducted by agencies with legal inspection qualifications.

11.7 Exit-factory inspection shall be conducted for products through random sampling in accordance with corresponding standard requirements; original records shall be made; and product inspection qualification certificate shall be issued.

11.8 Unqualified products after the inspection shall be disposed correspondingly in accordance with unqualified product management system.

11.9 Storage plan for finished product's reserved-samples shall be formulated; the storage period shall not be less than the quality guaranteed-period marked on the finished products.

11.10 Batch production records shall be filed according to batch numbers or production date; the records shall be kept till one year after the products' expiration date. Production records shall be kept for at least three years for products with no specified expiration date.

12 Documents and records

12.1 There shall have systems and records relevant to the use, repair, maintenance, and overhaul of facilities and equipment.

12.2 Management systems in terms of procurement, storage and use of raw and auxiliary materials required in production shall be established, including raw and auxiliary materials' procurement plan, procurement list, procurement agreement, procurement contract and other relevant procurement documents and use standing book, etc.

12.3 There shall have systems and records relating to material acceptance, production operating, inspection, issuing, finished production sales, users' complaints, product recall, etc.

12.4 There shall have systems and records relevant to unqualified product management, cancelling stocks and scrapping of raw and auxiliary materials, disposal of emergency

circumstances, etc.

12.5 There shall have hygienic management systems and records regarding environment, workshop, equipment, personnel, etc.

12.6 Documented procedure shall be set up to monitor personnel's personal hygienic status; and related records shall be preserved.

12.7 There shall have systems and records relating to this Standard, specialized technical training, etc.

12.8 If there are purchased-parts procedure and other entrusted service items, quality safety management and control methods shall be formulated correspondingly.

12.9 There shall have production technical procedures, post operation methods or standard operating procedures.

12.10 There shall have batch production records, including product name, batch number, production date, signature of operator and checker, related operations and equipment, product quantity of relevant production stages, calculation of material balance, control records of production process, records of special problems, etc.

12.11 There shall have quality standards and inspection operating instructions for materials, semi-finished products and finished products.

12.12 There shall have batch inspection records.

12.13 Management systems relating to document drafting, revision and review, approval, canceling, printing and safekeeping shall be established.

13 Complaint handling and production recall

13.1 All complaints, received in oral or written form, shall be recorded and investigated in accordance with written procedures. Head of quality management (coordinate other relevant departments when necessary) shall make timely investigation and properly solve the problems.

13.2 The management shall implement effective working procedures to deal with product safety problems, and ensure that all questionable batches of products can be quickly recalled from the market. The recalled products shall be properly kept under supervision until being destroyed, or used for other purposes other than food packaging, or be reprocessed with ensured safety.

14 Product information and propaganda-guidance

14.1 Outgoing products shall have certificate of quality and product labels. Product label identification shall include product name, place of origin, manufacturer's name and

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