Public Notice of the Ministry of Health, Labour and Welfare No. 121

The Ministry of Health, Labour and Welfare hereby sets forth the standards for manufacturing or processing of the foods containing the designated ingredients, etc., pursuant to the provisions of the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370 of 1959) as follows, and starts to apply those standards as from June 1, 2020.

March 27, 2020

KATO Katsunobu, Minister of Health, Labour and Welfare

Standards for Manufacturing or Processing of the Foods Containing the Designated Ingredients, Etc.

(Application)

Article 1 The standards for manufacturing or processing of the foods containing the designated ingredients, etc. (which means the foods containing the designated ingredients, etc., provided for in Article 8, paragraph (1) of the Food Sanitation Act (Act No. 233 of 1947); the same applies in Article 3, paragraph (1)) provided for in Part I, Section B, subsection 10 of the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370 of 1959) shall be specified by this Public Notice.

(Definitions)

Article 2 (1) The term “base raw materials” as used in this Public Notice means animals and plants or their specific parts, microbes, chemical substances, minerals or other materials to be used to manufacture raw materials.

(2) The term “products” as used in this Public Notice means finished products that have completed all processes of manufacturing or processing (hereinafter referred to as “manufacturing, etc.”).

(3) The term “partly finished products” as used in this Public Notice means those made in the intermediate process of manufacturing, etc., of products.

(4) The term “controlled ingredients” as used in this Public Notice means the ingredients contained in the base raw materials, of which the chemical composition is clarified and which are to be analyzed to verify that the designated ingredients, etc., contained in the raw materials, products and partly finished products conform to the standards.

(5) The term “products, etc.” as used in this Public Notice means raw materials, containers and packaging, products, and partly finished products.

(6) The term “lot” as used in this Public Notice means a group of products, etc., of which manufacturing, etc., is conducted in a series of processes to have homogeneity within a single run of manufacturing, etc.

(7) The term “controlled unit” as used in this Public Notice means a group of containers and packaging, and labeling, of which identity is confirmed.
(8) The term “validation” as used in this Public Notice means validating and reducing to writing that methods of controlling the structures and equipment of facilities conducting manufacturing, etc., of products and of controlling procedures, processes and other matters of manufacturing, etc., (hereinafter referred to as “manufacturing control”), as well as methods of quality control (these methods are hereinafter referred to as “manufacturing procedures, etc.”) will produce expected results.
(9) The term “calibration of measuring instruments” as used in this Public Notice means finding a relation between a value indicated by a measuring instrument and a real value by taking into consideration the required accuracy and using appropriate standard instruments, standard samples, and other items.
(10) The term “quality information” as used in this Public Notice means information concerning inferior quality or another fact that may have a material impact on the quality of products, etc.

(Supervising Manager, etc.)
Article 3 (1) A person engaged in manufacturing, etc., of the foods containing the designated ingredients, etc. (hereinafter referred to as “manufacturer, etc.”) must appoint a supervising manager at each of the facilities conducting such manufacturing, etc. (hereinafter referred to as “manufacturing facilities, etc.”).
(2) A manufacturer, etc., must appoint a manufacturing control manager from persons who have five or more years of experience of engaging in manufacturing control practice, and a quality control manager from persons who have five or more years of experience of engaging in quality control practice, under the supervising manager.
(3) A manufacturing control manager must not concurrently serve as a quality control manager, and a quality control manager must not concurrently serve as a manufacturing control manager, respectively.

(Product Standard Code, etc.)
Article 4 (1) A manufacturer, etc., must prepare the product standard code for each of the products stating the following particulars for each of the manufacturing facilities, etc., to which the manufacturing, etc., of the relevant product pertains and keep it at each of the manufacturing facilities, etc.:

(i) name and brand name of the product;

(ii) ingredients and quantity of the product;

(iii) standards, and test and inspection methods, of raw materials, products and partly finished products;

(iv) standards, and test and inspection methods, of containers and packaging;

(v) methods and procedures of manufacturing, etc., of the product;

(vi) standard amount of preparation and grounds thereof;

(vii) storage conditions of partly finished products;

(viii) storage conditions and use-by date or best-before date of the product;

(ix) recommended daily intake, and precautions concerning use or precautions concerning handling;

(x) documents by which the terms of the agreement with a contractor to whom the manufacturer, etc., entrusts part of manufacturing, etc., of the product; and

(xi) other necessary matters.

(2) A manufacturer, etc., must prepare the manufacturing control standards stating the particulars concerning manufacturing control, and the quality control standards stating the particulars concerning quality control, for each of the manufacturing facilities, etc., to which the manufacturing, etc., of products pertains, and keep them at each of the manufacturing facilities, etc.

(3) A manufacturer, etc., must prepare procedure manuals stating the following particulars for each of the manufacturing facilities, etc., to which the manufacturing, etc., of products pertains, and keep them at each of its manufacturing facilities, etc.:

(i) procedure for management of shipment from facilities conducting manufacturing, etc., of products;

(ii) procedure for validation of the manufacturing procedures, etc.;

(iii) procedure for management of changes of the manufacturing procedures, etc.;

(iv) procedure for management of deviations from the manufacturing procedures, etc.;

(v) procedure for product quality information and handling of inferior quality, etc.;

(vi) procedure for self-inspection;

(vii) procedure for the methods of preparation and management of documents and records; and

(viii) other procedure necessary for proper and smooth implementation of manufacturing control and quality control.

(Manufacturing Control and Quality Control of Raw Materials)

Article 5 (1) For raw materials to be used for manufacturing, etc., of products, a manufacturer, etc., shall use the raw materials that conform to the standards of the product standard code.

(2) A manufacturer, etc., must properly store raw materials and track incoming and outgoing raw materials for each lot, and prepare and retain records thereof, in accordance with the product standard code, the manufacturing control standards, the quality control standards, and procedure manuals (hereinafter referred to the “product standard code, etc.”).

(3) A manufacturer, etc., must store the amounts of raw materials of products necessary for the

designated test and inspection for each lot, according to the following product category, for the period set forth in each item below:

(i) products for which a day is established as necessitating that tests and inspections be conducted once again to see, among others, whether the products conform to the standards, after the expiration of a certain period from the date on which manufacturing, etc., was conducted: 3 years from the date on which shipment of those products is completed;

(ii) products other than those set forth in the preceding item: use-by date or best-before date, plus one year.

(Manufacturing Control of Products)

Article 6 A manufacturer, etc., must appropriately perform the following operations relating to the manufacturing control of the following products, etc., in accordance with the product standard code, etc.:

(i) to prepare manufacturing instructions stating instructions, precautions, etc., in the process of manufacturing, etc., of products, and manufacture products in accordance with those manufacturing instructions;

(ii) to homogenize controlled ingredients in raw materials and partly finished products, control them within the scope specified in the standards of the product standard code, and also homogenize controlled ingredients in finished products to secure the range of concentration specified in the relevant standards;

(iii) to prepare and retain records on manufacturing, etc., of products for each lot;

(iv) to verify for each lot that containers and packaging, and labeling, of products are adequate, and prepare and retain records thereof;

(v) to properly store products and track incoming and outgoing products for each lot, and store containers and packaging and track incoming and outgoing containers and packaging for each controlled unit, and prepare and retain records thereof;

(vi) to periodically inspect and maintain structures and equipment and calibrate measuring instruments, and prepare and retain records thereof;

(vii) to verify from records on manufacturing and storage of products and handling of incoming and outgoing products, as well as on hygiene management involving products, etc., that manufacturing control is appropriately conducted; and

(viii) to conduct other necessary manufacturing control.

(Quality Control of Products)

Article 7 A manufacturer, etc., must have its quality control manager appropriately perform the following operations relating to quality control of products, etc., in accordance with the product

standard code, etc.:

(i) to collect samples of products, etc., for each lot, and those of containers and packaging, and labeling for each controlled unit that are necessary for tests and inspections, and prepare and retain records thereof;

(ii) to conduct tests and inspections of samples collected for each lot or for each controlled unit, and prepare and retain records thereof;

(iii) to homogenize controlled ingredients for each lot and verify that those ingredients secure the range of concentration specified in the relevant standards;

(iv) to periodically inspect and maintain facilities and apparatus for tests and inspections and calibrate the measuring instruments, and prepare and retain records thereof;

(v) to designate the expiration date for reagents, standard items and other items to be used for tests, and appropriately manage them; and

(vi) to otherwise conduct necessary quality control.

(Shipment Management)

Article 8 A manufacturer, etc., must appropriately evaluate results of manufacturing control and quality control in accordance with the product standard code, etc., and determine whether or not products can be shipped from the manufacturing facilities, etc.

(Implementation of Validation, etc.)

Article 9 (1) In the following cases, a manufacturer, etc., must conduct the validation:

(i) when it starts manufacturing, etc., for the first time at its facility conducting manufacturing, etc., of products;

(ii) when there are changes in its manufacturing procedures, etc., that will have a large impact on the quality of products; or

(iii) when it otherwise deems it necessary to properly conduct manufacturing control and quality control of products.

(2) If it is necessary to improve the manufacturing control or quality control based on results of the validation under the provisions of the preceding paragraph, the manufacturer, etc., must take the required measures, and prepare and retain records on those measures.

(Management of Changes of the Manufacturing Procedures, etc.)

Article 10 When a manufacturer, etc., makes changes to its manufacturing procedures, etc., that may affect the quality of products, the manufacturer, etc., must have a predesignated person carry out the following matters in accordance with the product standard code, etc.:

(i) to evaluate possible effects of those changes on the quality of products, obtain the approval

of a quality section for making changes based on results of such evaluation, and prepare and retain records thereof; and

(ii) when making changes with the approval of the quality section, to revise the related documents, educate and train employees concerned, and take other required measures.

(Management of Deviations from the Manufacturing Procedures, etc.)

Article 11 When there has been any deviation from the manufacturing procedures, etc. (hereinafter in this Article referred to simply as "deviation"), a manufacturer, etc., must take the following measures in accordance with the product standard code, etc.:

(i) to record details of the deviation; and

(ii) to evaluate possible effects of a material deviation, if critical deviation occurs, on the quality, and take measures based on the content of such evaluation.

(Management of Quality Information)

Article 12 When a manufacturer, etc., has obtained quality information on products, the manufacturer, etc., must take the following measures in accordance with the product standard code, etc., except where it is evident that the matter to which such quality information pertains does not result from the facility conducting such manufacturing, etc.:

(i) to investigate the causes of the matters to which such quality information pertains and, if it is necessary to improve the manufacturing control or quality control, to take the required measures; and

(ii) to prepare and retain records on details of the matters to which such quality information pertains, results of investigations into the causes, and improvement measures.

(Self-inspection)

Article 13 (1) A manufacturer, etc., must periodically conduct a self-inspection of the manufacturing control and quality control of its manufacturing facilities, etc.

(2) If it is necessary to improve the manufacturing control or quality control based on results of the self-inspection, the manufacturer, etc., must take the required measures, and prepare and retain records of such measures.

(Methods of Preparation, and Management, of Documents and Records)

Article 14 In conducting manufacturing, etc., of products, a manufacturer, etc., must appropriately manage documents and records in accordance with the product standard code, etc., as follows:

(i) when preparing documents or revising the existing documents, to obtain the approval of a person responsible for management of the relevant documents, and distribute or otherwise retain the

documents so prepared or revised;

(ii) when preparing a product standard code, etc., or revising the existing product standard code, etc., to describe the date of preparation or revision on the relevant product standard code, etc., and keep earlier revision histories; and

(iii) to retain records on manufacturing, etc., and storage of products, and tracking of incoming and outgoing products for three years from the date of preparation of those records or one year from the use-by date or best-before date of the relevant products.