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Incorporated Administrative Agency
Food and Agricultural Materials Inspection Center

Tentative Translation

Technical Criteria for the Certification of Product Handlers for Easily Chewable and Swallowable Foods

Establishment: Notification No. 1569 of August 17, 2016

Partial revision: Notification No. 687 of March 29, 2018

[1] Technical criteria for the certification of manufacturers (including overseas manufacturers; the same applies hereinafter)

I. Facilities for manufacturing or processing, storage, quality control, and grading

1 Manufacturing facilities

(1) Workplace

The workplace shall conform to the following conditions:

- (a) broadness and brightness that would not interfere with the work;
- (b) structures that can prevent dust from falling and structures that can prevent mice and insects from entry through openings such as windows and entrances;
- (c) floor surface that is finished to form a flat surface and is easy to clean. However, in the case of a floor surface for work using water, the floor surface shall be finished to be flat with a water-proof material and have a structure that allows water to drain well;
- (d) water supply equipment that enables sufficient supply of clean water;
- (e) no sump inside the workplace.

(2) Machinery and tools

Machinery and tools shall have balanced performance and allow continuous production.

2 Storage facilities

Facilities shall have a suitable broadness to satisfactorily maintain the quality of ingredients, additives, materials, and products.

3 Quality control facilities

Facilities shall have necessary machinery and tools to conduct quality control (including outsourcing management; the same applies hereinafter) in accordance with the internal rule prescribed in II-3. When a part of manufacturing, inspection, or equipment management is outsourced to external providers, outsourcing management means the management regarding outsourcing (e.g. selection criteria of external providers, outsourced process, and outsourcing procedure).

4 Grading facilities

In addition to having the machinery and tools listed below, the facilities shall have a suitable broadness for evaluating test results and management of grade label.

- (1) thermometer;

- (2) balance (verification scale interval of 0.5 g or less);
- (3) vacuum gauge;
- (4) micrometer;
- (5) caliper;
- (6) miscellaneous apparatus/tools.

However, there are the following exclusions for this requirement:

- when the inspection of samples for grading is not conducted by the manufacturer, all of the machinery and tools listed above are not required;
- when products are other than the canned or bottled products, the machinery and tools listed in (3) are not required;
- when the products are other than canned products, the machinery and tools listed in (4) and (5) are not required.

II. Implementation methods of quality control

1 The following duties shall be performed by a quality control manager, which is prescribed in III-2:

- (1) drafting and promoting a plan for quality control;
- (2) supervision of establishment, confirmation, and revision/abolition of the internal rules;
- (3) promoting of quality control education and training for workers;
- (4) providing guidance and/or advising on handling and measures to deal with the issues occurred in the process and complaints.

2 Sensory evaluation shall be conducted by sensory evaluation personnel (a person who is in charge of sensory evaluation; the same applies hereinafter) as prescribed in III-1.

3 The internal rules shall be specifically and systematically developed to include the following matters:

- (1) the quality of ingredients and additives upon acceptance;
- (2) selection of ingredients;
- (3) treatment/process of ingredients;
- (4) the amount of ingredients and additives to use;
- (5) the temperature and time for rapid freezing;
- (6) the filling amount;
- (7) the temperature and time for sterilization and cooling;
- (8) the reference values for product hardness according to measurement;

- (9) sensory evaluation;
- (10) the conditions of the container or package;
- (11) the quality of products (including absence of contamination with foreign matters);
- (12) the management of machinery and tools for manufacturing and quality control;
- (13) handling of defective products and abnormalities occurred in the process;
- (14) the complaints handling;
- (15) the preparation and preservation of quality control records;
- (16) internal audits on the implementation status of quality control;
- (17) necessary rules for appropriate implementation of operations, e.g., confirmation about the implementation status of quality control by a certification body (meaning an accredited certification body or an accredited overseas certification body; the same applies hereinafter);
- (18) the transmission of information regarding the hardness of products;
- (19) the transmission of information regarding additives.

However, there are following exclusions for the requirement:

- the matters listed in (5) shall be required only when manufacturing frozen products;
- those listed in (6) and (7) shall be required only in the case of manufacturing canned, bottled, and/or retort pouch foods;
- those listed in (18) and (19) shall be required only in the case of manufacturing products other than those for business use.

- 4 In accordance with the internal rules, quality control shall be properly performed and records of the quality control shall be prepared and preserved.
- 5 The quality of products shall be stabilized as a result of quality control.
- 6 The internal rules shall be properly reviewed on a regular basis, and fully notified to the workers.

III. Qualifications and the number of persons in charge of quality control and sensory evaluation

1 Quality control personnel and sensory evaluation personnel

The manufacturer shall have two or more persons as quality control personnel. Such persons shall meet any one of the following requirements. Further, the manufacturer shall have two or more persons as sensory evaluation personnel. Such persons shall meet any one of the following requirements, and shall have at least one year of experience in the sensory evaluation of easily chewable and swallowable foods.

- (1) those who have graduated from a university acknowledged under the School Education Act (Act No. 26 of 1947) and acquired credits of subjects related to food manufacturing or processing or who have a qualification equal to or higher than that, and who have at least one year of experience in manufacturing or testing research on easily chewable and swallowable foods;

- (2) those who have graduated from a high school or a secondary school acknowledged under the School Education Act or who have a qualification equivalent to or higher than that, and who have at least three years of experience in manufacturing or testing research on easily chewable and swallowable foods; or
- (3) those who have at least five years of experience in manufacturing or testing research on easily chewable and swallowable foods.

2 Quality control manager

The manufacturer shall appoint a quality control manager from the quality control personnel. The quality control manager shall have completed a course related to quality control for easily chewable and swallowable foods in a training session designated by the certification body (hereinafter referred to as “training session”).

IV. Grading organization and implementation method

1 Grading organization

A department to perform grading shall be a substantially independent organization and shall have substantially independent authority from the manufacturing department and sales department.

2 Implementation methods of grading

- (1) Rules regarding the grading method (hereinafter referred to as “grading rules”) shall be specifically and systematically developed, including matters related to:
 - (a) sampling;
 - (b) sample inspection;
 - (c) the grade labeling ;
 - (d) the shipment or disposal of the lot after grading;
 - (e) the management of machinery and tools for grading;
 - (f) the preparation and preservation of grading records;
 - (g) internal audits on the implementation status of grading;
 - (h) necessary rules for appropriate implementation of operations, e.g., confirmation about the implementation status of grading by a certification body.

However, the matters listed in (b) and (e) are not required when sample inspections for grading are not performed by the manufacturer).

- (2) When the sample inspections are outsourced to a third party without internally appointing grading inspection personnel prescribed in V-1, an outsourcing contract shall be concluded with the party that has machinery and tools, and personnel, enabling appropriate implementation of sample inspections of easily chewable and swallowable foods. Here, the third party shall be limited to a party comprising executive officers, members, or personnel who will not interfere with fair implementation of sample

inspections. The grading shall be conducted based on the inspection results which the third party performs sample inspections for grading with the contract.

- (3) In accordance with grading rules, operations related to grading and grade labeling shall be properly performed, which in turn ensures appropriate grade labeling.

V. Qualifications and the number of persons in charge of grading

1 Grading inspection personnel

The manufacturer shall have two or more persons as grading inspection personnel. Such persons shall meet any one of the following requirements, have at least one year of experience in the sensory evaluation of easily chewable and swallowable foods, and regularly participate in skill training for grading inspection personnel, which is designated by a certification body:

- (1) those who have graduated from a university acknowledged under the School Education Act and acquired credits on subjects related to food manufacturing or processing or who have a qualification equivalent to or higher than that, and who have at least one year of experience in inspection or testing research on foods;
- (2) those who have graduated from a high school or a secondary school acknowledged under the School Education Act or who have a qualification equivalent to or higher than that, and who have at least three years of experience in inspection or testing research on foods; or
- (3) those who have at least five years of experience in inspection or testing research on foods.

2 Grading manager

The manufacturer shall appoint at least one grading manager from the grading inspection personnel other than the quality control personnel prescribed in III-2. Such grading manager(s) shall have completed a course related to the grading of easily chewable and swallowable foods in a training session. However, when a part of manufacturing (limited to the filling process and the packaging process) is outsourced and when it is considered that sampling is necessary at the external providers' factory or place of business, the manufacturer shall additionally have at least one person who assists the grading manager(s) at the factory or place of business. Such person(s) shall meet any one of the requirements prescribed in III-1 (1) to (3), and shall have completed a course related to the grading of easily chewable and swallowable foods in a training session.

3 Grading personnel

When sample inspections for grading are not performed by the manufacturer, the manufacturer shall have at least one person as grading personnel instead of the grading inspection personnel and the grading manager. Such person(s) shall meet any one of the requirements prescribed in III-1 (1) to (3), and shall have completed a course related to the grading of easily chewable and swallowable foods in a training session. However, when a part of manufacturing (limited to the filling process and the packaging process) is outsourced and when it is considered that sampling is necessary at the external providers' factory or place of business, the manufacturer shall additionally have at least one person who assists the grading personnel at the factory or place of business. Such person(s) shall meet any one of the requirements prescribed in III-1 (1) to (3), and shall have completed a course related to the grading of easily chewable and swallowable foods in a training session.

[2] Technical criteria for the certification of product handlers (including overseas product handlers) other than the manufacturers (hereinafter referred to as “non-manufacturers”)

I. Facilities for manufacturing or processing, storage, quality control, and grading

The facilities shall conform to the criteria prescribed in [1]-I.

II. Implementation methods of quality control

- 1 The quality control managers prescribed in III-2 shall perform the duties prescribed in [1]-II 1 at the factory or place of business (hereinafter referred to as “factory, etc.”) related to the certification of a non-manufacturer.
- 2 At the factory, etc., the manager shall perform the duties prescribed in [1]-II 3 to 6.
- 3 The sensory evaluation personnel prescribed in III-1 shall perform the duties prescribed in [1]-II 2 at the factory, etc. of the non-manufacturer.
- 4 Rules regarding the methods of management of the factory, etc. (hereinafter referred to as “management rules”) shall be specifically and systematically developed, including the matters related to:
 - (1) the confirmation of whether the facilities for manufacturing or processing, storage, and quality control conform to the criteria prescribed in [1]- I ;
 - (2) the confirmation of development of internal rules and their periodic revision(s).
 - (3) the supervision of the quality control personnel or the sensory evaluation personnel when the quality control personnel or the sensory evaluation personnel is designated from the workers of the factory, etc.;
 - (4) the supervision of persons who assist the grading personnel when sample inspections for grading are not performed by the non-manufacturer, and persons who assist the grading personnel are appointed at the factory, etc.;
 - (5) other necessary rule for the management of the factory, etc.
- 5 The management rules shall be regularly and properly reviewed, and fully notified to the workers of the management department of the non-manufacturer.

III. Qualifications and the number of persons in charge of quality control and sensory evaluation

1 Quality control personnel and sensory evaluation personnel

The non-manufacturer shall have two or more persons as quality control personnel at the factory, etc. Such persons shall meet any one of the requirements prescribed in [1]-III 1(1) to (3). Further, the non-manufacturer shall have two or more persons as sensory evaluation personnel who meet any one of the requirements prescribed in [1]-III 1(1) to (3), and who have at least one year of experience in the sensory evaluation of easily chewable and swallowable foods. Here, the quality control personnel and the sensory evaluation personnel may be designated from the workers of the factory, etc.

2 Quality control manager

The non-manufacturer shall have one person as quality control manager at the non-manufacturer. The quality control manager shall meet any one of the requirements prescribed in [1]-III (1) to (3), and shall have completed a course related to the quality control of easily chewable and swallowable foods.

IV. Grading organization and implementation method

The organization and implementation method shall conform to the criteria prescribed in [1]-IV.

V. Qualifications and the number of persons in charge of grading

1 Grading inspection personnel

The non-manufacturer shall have two or more persons as grading inspection personnel at the non-manufacturer. Such persons shall meet any one of the requirements prescribed in [1]-V 1(1) to (3), shall have at least one year of experience in the sensory evaluation of easily chewable and swallowable foods, and shall regularly participate in skill training for the grading inspection personnel, which is designated by the certification body.

2 Grading manager

The non-manufacturer shall appoint at least one grading manager from the grading inspection personnel other than the quality control manager prescribed in III-2. Such grading manager(s) shall have completed a course related to the grading of easily chewable and swallowable foods in a training session. However, when it is considered that sampling is necessary at the factory, etc., the non-manufacturer shall additionally have at least one person who assists the grading manager(s) at the factory, etc. Such persons shall meet any one of the requirements prescribed in [1]-III 1(1) to (3), and shall have completed a course related to the grading of easily chewable and swallowable foods in a training session.

3 Grading personnel

When the sample inspections for grading are not performed by the non-manufacturer, the non-manufacturer shall have at least one person as the grading personnel at the non-manufacturer instead of the grading inspection personnel and the grading manager. Such person(s) shall meet any one of the requirements prescribed in [1]-III 1(1) to (3), and shall have completed a course related to the grading of easily chewable and swallowable foods in a training session. However, when it is considered that sampling is necessary at the factory, etc., the non-manufacturer shall additionally have at least one person who assists the grading personnel at the factory, etc. Such person(s) shall meet any one of the requirements prescribed in [1]-III 1(1) to (3), and shall have completed a course related to the grading of easily chewable and swallowable foods in a training session.

(Schedule)

Notification No. 687 of Ministry of Agriculture, Forestry and Fisheries of March 29, 2018 comes into effect as of April 01, 2018.