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#### Tentative Translation

## Technical Criteria for the Certification of Production Handlers for Soy sauce (Shoyu)

#### 1 Scope

This document specifies technical criteria for the certification, which accredited certification body and accredited overseas certification body perform, pursuant to the provisions of Article 10, paragraph (1) and Article 30, paragraph (1) of the Act on Japanese Agricultural Standards (Act No. 175 of 1950), of product handlers and overseas product handlers for soy sauce.

### 2 Technical criteria for the certification of manufacturers (including overseas manufacturers; the same applies hereinafter)

#### 2.1 Facilities for manufacturing or processing, storage, quality control and grading

#### 2.1.1 Manufacturing facilities

#### **2.1.1.1** Workplace

The workplace shall conform to the following conditions that:

- a) the size and brightness that would not interfere with the work;
- b) at places where operations from preparing to placing bottles (including cans, barrels, etc.) are carried out, the structures that can prevent dust, etc. from falling, and at places to open such as windows and entrances, the structures that can prevent mice and insects from entering;
- c) the floor surface that is finished with a flat surface and is easy to clean; provided, however, that, in the case of a floor surface for work using water, the floor surface is to be finished to be flat with a water-proof coating and have a structure that allows water to drain away well;
- d) having water supply equipment that enable sufficient supply of clean water;
- e) no sump inside the workplace;
- f) the place for *koji morikomi* has a structure that can maintain the state of cleanliness, when producing *kiage*.

#### 2.1.1.2 *Koji* room (limited to the cases when producing *kiage*)

The *koji* room shall have a structure that allows temperature, moisture, ventilation, etc. to be adjusted to carry out the production of *koji* sufficiently.

#### 2.1.1.3 Storage of *moromi* (limited to the cases when producing *kiage*)

The storage of *moromi* shall have a structure capable of carrying out fermentation and aging of *moromi* sufficiently.

#### 2.1.1.4 Machinery and tools

The machinery and tools shall have balanced performance and shall be capable of carrying out continuous production.

#### 2.1.2 Storage facilities

The storage facilities shall have a suitable size to maintain the quality of ingredients, additives, materials, and products in good condition.

#### 2.1.3 Facilities for quality control

The facilities shall have necessary machinery and tools to conduct quality control [including outsourcing management (when a part of manufacturing, inspection or equipment management is outsourced to external providers, outsourcing management means the management regarding outsourcing such as criteria for selecting external providers, outsourced process, and outsourcing procedure); the same applies hereinafter] in accordance with the internal rules prescribed in 2.2.2.

#### 2.1.4 Grading facilities

In addition to having the machinery and tools listed below, the grading facilities shall have a suitable size for evaluating test results and managing grade label; provided, however, that a) to g) are excluded from the cases when the inspection of the samples for grading is not conducted by the manufacturer, c) is excluded from the cases when producing the normal grade products of *koikuchi shoyu*, *usukuchi shoyu*, *tamari shoyu*, and *saishikomi shoyu*, and e) is excluded from the cases when the soluble solids without salt are not measured with a potentiometric titrator:

- a) a set of standard colors;
- b) apparatus for determining the nitrogen by the Kjeldahl method or apparatus for measuring the total nitrogen by the combustion method;
- c) sugar refractometer;
- d) balance (with a reciprocal sensibility of 0.1 mg or less when weighing the sample for measuring the total nitrogen content by mass, and with a reciprocal sensibility of 0.01 mg or less when measuring the total nitrogen content with apparatus for measuring the total nitrogen by the combustion method, and the amount of the sample is to be 40 mg to less than 100 mg);
- e) potentiometric titrator;
- f) glass apparatus;
- g) miscellaneous apparatus and tools.

#### 2.2 Methods of implementing quality control

- **2.2.1** The manufacturer shall order the person responsible for quality control prescribed in 2.3.2 to perform the following duties:
- a) drafting and promoting a plan for quality control;
- b) supervising the establishment, confirmation, and revision or repeal of internal rules;
- c) promoting training on quality control for workers;
- d) providing guidance and advising on actions and measures to deal with abnormalities occurred in the process, complaints, etc.
- **2.2.2** The manufacturer shall develop internal rules on the following matters specifically and systematically; provided, however, that b) is limited to the cases when not using processed wheat for production of *shoyu koji* and producing *kiage*, c) to e) are limited to the cases when producing *kiage*, f) is limited to the cases when carrying out blending, g) is limited to the cases when carrying out the heating of *kiage*, h) is limited to the cases when carrying out sterilisation or disinfection, and p) is limited to the cases when manufacturing products other than those for business use:
- a) matters relating to the quality of ingredients and additives;
- b) matters relating to the treatment and processing of wheat;
- c) matters relating to the treatment and processing of soybeans;
- d) matters relating to the production of *koji*;
- e) matters relating to the fermentation and aging of *moromi*;

- f) matters relating to blending;
- g) matters relating to the heating of *kiage*;
- h) matters relating to sterilisation or disinfection;
- i) matters relating to the quality of products (including absence of contamination with foreign matter);
- j) matters relating to the management of machinery and tools for manufacturing and quality control;
- k) matters relating to actions for defective items and abnormalities occurred in the process;
- l) matters relating to complaints handling;
- m) matters relating to the preparation and preservation of quality control records;
- n) matters relating to internal audits on the implementation status of quality control;
- o) necessary matters relating to the appropriate implementation of operations, such as confirmation of the implementation status of quality control by the certification body (meaning an accredited certification body or an accredited overseas certification body; the same applies hereinafter);
- p) matters relating to providing information on additives;
- q) matters relating to the cleaning of facilities, etc., drainage and waste disposal;
- r) matters relating to the health management, work clothes, etc. and handwashing of workers;
- s) matters relating to the prevention of insects and mice;
- **2.2.3** In accordance with the internal rules, the manufacturer shall perform the quality control properly and shall prepare and preserve records thereof.
- **2.2.4** The quality of products shall be stabilized as a result of quality control.
- **2.2.5** The manufacturer shall review the internal rules properly on a regular basis, and shall fully disseminate the internal rules to the workers.

#### 2.3 Qualifications and number of persons who take charge of quality control

#### 2.3.1 Person in charge of quality control

The manufacturer shall have at least two persons who meet any of the following requirements as the person in charge of quality control:

- a) those who graduated from a university acknowledged under the School Education Act (Act No. 26 of 1947) as having acquired credits for subjects relating 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 manufacturing or testing research on fermented foods;
- b) those who 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 fermented foods;
- c) those who have at least five years of experience in manufacturing or testing research on fermented foods.

#### 2.3.2 Person responsible for quality control

The manufacturer shall appoint one person who has completed a course relating to quality control for soy sauce in a training session designated by the certification body (hereinafter referred to as "training session") as the person responsible for quality control from among the person in charge of quality

control.

#### 2.4 Grading organization and implementation method

#### 2.4.1 Grading organization

The manufacturer shall ensure that the organization and authority of the department that performs grading are substantially independent from those of the manufacturing department and the sales department.

#### 2.4.2 Methods of implementing grading

- **2.4.2.1** The manufacturer shall develop rules of grading (hereinafter referred to as "grading rules") on the following matters specifically and systematically; provided, however, that b) and e) are excluded from the cases when the manufacturer does not conduct the inspection of samples for grading by itself:
- a) matters relating to sampling;
- b) matters relating to sample inspection;
- c) matters relating to grade labeling;
- d) matters relating to the shipment or disposal of lots after grading;
- e) matters relating to the management of machinery and tools for grading;
- f) matters relating to the preparation and preservation of grading records;
- g) matters relating to internal audits on the implementation status of grading;
- h) necessary matters relating to the appropriate implementation of operations, such as confirmation of the implementation status of grading by the certification body.
- **2.4.2.2** When the manufacturer does not have someone who meets either 2.5.1 a) or b), and regularly participates in skill training for persons in charge of grading inspection designated by the certification body and outsources the sample inspections to a third party, the manufacturer shall conclude a contract with a party that has machinery and tools, and personnel, that can appropriately conduct sample inspections of soy sauce (limited to parties whose composition of executive officers, members, or personnel have no likelihood of interference with the fair implementation of sample inspections), and shall order the third party to conduct the sample inspection for grading and shall conduct the grading based on the actual inspection results of relevant samples.
- **2.4.2.3** In accordance with the grading rules, the manufacturer shall conduct the operations relating to grading and grade labeling properly, and as a result, it shall be confirmed that the grade label is affixed appropriately.

#### 2.5 Qualifications and number of persons who take charge of grading

#### 2.5.1 Person in charge of grading inspection

The manufacturer shall have at least one person who meets any of the following requirements, and regularly participates in skill training for persons in charge of grading inspection designated by the certification body as the person in charge of grading inspection:

- a) those who graduated from a university acknowledged under the School Education Act as having acquired credits for subjects relating 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;
- b) those who 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.

#### 2.5.2 Person responsible for grading

The manufacturer shall appoint at least one person who has completed the course relating to the grading of soy sauce in a training session as the person responsible for grading, from among the person in charge of grading inspection and the person other than the person responsible for quality control prescribed in 2.3.2, provided, however, when a part of the manufacturing (limited to the filling process and the packaging process) is outsourced and when it is recognized that a part of the grading (sampling, etc.) needs to be carried out at an external provider's factory or place of business, the manufacturer shall have at least one person who meets any of the requirements prescribed in 2.3.1 a) to c), and who has completed a course relating to the grading of soy sauce in a training session as the person who supports the person responsible for grading at the external provider's factory or place of business.

#### 2.5.3 Person in charge of grading

When the manufacturer does not perform the sample inspections for grading by itself, the manufacturer shall have at least one person who meets any of the requirements prescribed in 2.3.1 a) to c), and who has completed a course relating to the grading of soy sauce in a training session as the person in charge of grading instead of the person in charge of grading inspection and the person responsible for grading, provided, however, when a part of the manufacturing (limited to the filling process and the packaging process) is outsourced and when it is recognized that a part of the grading (sampling, etc.) needs to be carried out at an external provider's factory or place of business, the manufacturer shall have at least one person who meets any of the requirements prescribed in 2.3.1 a) to c), and who has completed a course relating to the grading of soy sauce in a training session as the person who supports the person in charge of grading at the external provider's factory or place of business.

# 3 Technical criteria for the certification of product handlers (including overseas product handlers) other than manufacturers (hereinafter referred to as "non-manufacturers")

#### 3.1 Facilities for manufacturing or processing, storage, quality control and grading

The facilities for manufacturing or processing, storage, quality control and grading shall conform to the criteria prescribed in 2.1.

#### 3.2 Methods of implementing quality control

- **3.2.1** The non-manufacturer shall order the person responsible for quality control prescribed in 3.3.2 to conduct the duties prescribed in 2.2.1 at the factory or the place of business (hereinafter referred to as "factory, etc.") relating to the certification of the non-manufacturer.
- **3.2.2** The non-manufacturer shall order the person responsible for the factory, etc. to conduct the duties prescribed in 2.2.2 to 2.2.5 at the factory, etc.
- **3.2.3** The non-manufacturer shall develop rules concerning the method of implementing management of the factory, etc. (hereinafter referred to as "management rules") on the following matters specifically and systematically:
- a) matters relating to confirming that the facilities for manufacturing or processing, storage, and quality control conform to the criteria prescribed in 2.1;
- b) matters relating to confirming that the internal rules are developed and periodically reviewed;
- c) matters relating to supervising the person in charge of quality control when the non-manufacturer designates such person from among the workers of the factory, etc.;
- d) matters relating to the supervising the persons who support the person in charge of grading

when the non-manufacturer does not perform sample inspections for grading by itself and has such person for support at the factory, etc.;

- e) other necessary matters required for the management of the factory, etc.
- **3.2.4** The non-manufacturer shall review the management rules properly on a regular basis, and shall fully disseminate the internal rules to workers of the management department of the non-manufacturer.

#### 3.3 Qualifications and number of persons who take charge of quality control

#### 3.3.1 Person in charge of quality control

The non-manufacturer shall have at least two persons who meet any of the requirements prescribed in 2.3.1 a) to c) as the person in charge of quality control at the factory, etc. In this case, the non-manufacturer may designate the person in charge of quality control from among the workers of the factory, etc.

#### 3.3.2 Person responsible for quality control

The non-manufacturer shall have one person who meets any of the requirements prescribed in 2.3.1 a) to c), and has completed a course relating to the quality control of soy sauce in the training session as the person responsible for quality control at the non-manufacturer.

#### 3.4 Grading organization and implementation method

The grading organization and the implementation method shall conform to the criteria prescribed in 2.4.

#### 3.5 Qualifications and number of persons who take charge of grading

#### 3.5.1 Person in charge of grading inspection

The non-manufacturer shall have at least one person who meets either 2.5.1 a) or b), and regularly participates in skill training for persons in charge of grading inspection designated by the certification body as the person in charge of grading inspection at the non-manufacturer.

#### 3.5.2 Person responsible for grading

The non-manufacturer shall appoint at least one person who has completed a course relating to the grading of soy sauce in a training session as the person responsible for grading from among the person in charge of grading inspection and other than the person responsible for quality control prescribed in 3.3.2., provided, however, when it is recognized that a part of grading (sampling, etc.) needs to be carried out at the factory, etc., the non-manufacturer shall have at least one person who meets any of the requirements prescribed in 2.3.1 a) to c), and who has completed a course relating to the grading of soy sauce in a training session as the person who supports the person responsible for grading at the factory, etc.

#### 3.5.3 Person in charge of grading

When the non-manufacturer does not perform the sample inspections for grading by itself, the non-manufacturer shall have at least one person who meets any of the requirements prescribed in 2.3.1 a) to c), and who has completed a course relating to the grading of soy sauce in a training session as the person in charge of grading instead of the person in charge of grading inspection and the person responsible for grading at the non-manufacturer, provided, however, when it is recognized that a part of grading (sampling, etc.) needs to be carried out at the factory, etc., the non-manufacturer shall have at least one person who meets any of the requirements prescribed in 2.3.1 a) to c), and who has completed a course relating to the grading of soy sauce in a training session as the person who supports the person in charge of grading at the factory, etc.