

Tentative Translation

JAS
0014

JAPANESE AGRICULTURAL
STANDARD

Production process management for non-gluten rice flour

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Ministry of Agriculture, Forestry and Fisheries

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Food and Agricultural Materials Inspection Center, Incorporated Administrative Agency

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Foreword

This Japanese Agricultural Standard has been established by the Minister of Agriculture, Forestry and Fisheries through deliberations at the Council for the Japanese Agricultural Standards as the result of proposal for establishment of Japanese Agricultural Standard submitted by the Japan Rice Flour Association with the original bill being attached, based on the provision of Article 4, paragraph (1) of the Act on Japanese Agricultural Standards.

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Production process management for non-gluten rice flour

1 Scope

This document specifies the management for the production process for non-gluten rice flour.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

gluten

protein fraction from barley, wheat, rye, oats, *hatomugi* or their crossbred varieties and derivatives thereof and insoluble in water and in 0,5 mol/L sodium chloride solution

3.2

non-gluten rice flour

rice flour with gluten content not exceeding 1 µg/g

3.3

raw material rice

rice used as a raw material of non-gluten rice flour

3.4

traceability system

system that can trace forward and trace back the history, application, movement and location of an object through specified stage(s) of production and distribution

3.5

risk of contamination

likelihood of contamination and level of the effect

4 Facility requirements

4.1 Facilities

Facilities (including facilities for workers) shall be designed, constructed and maintained to control the risk of contamination with gluten and gluten-containing grains, etc. that arises from the premises and inside and outside the facilities.

4.2 Equipment and apparatus

Equipment and apparatus, etc. used for production shall be properly used and always maintained and stored at a proper level to prevent the contamination with gluten and gluten-containing grains, etc.

5 Management requirements

5.1 General

Points at which the contamination with gluten and gluten-containing grains, etc. can occur shall be identified and processes that require prevention of contamination with gluten and gluten-containing grains, etc. shall be managed to ensure that gluten content of the final product does not exceed 1 µg/g. The management method shall be periodically verified and improved. In verification, it shall be determined whether the management method is appropriate or not and whether the management method needs modification or not due to the circumstances such as changes in raw material rice, equipment and apparatus or production method. These determinations shall be conducted by using the methods, including but not limited to the following:

- checking records of management including monitoring;
- gluten test (see Annex A).

NOTE When developing a management method, GENERAL PRINCIPLES OF FOOD HYGIENE CAC/RCP 1-1969 Annex: Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application, set forth by the Codex Alimentarius Commission that was established by the Food and Agriculture Organization of the United Nations and the World Health Organization, is a useful reference.

5.2 Control of raw material rice and materials

5.2.1 Raw material rice and materials shall be assessed as to the risk of contamination with gluten and gluten-containing grains, etc. and be ensured that they have been controlled to prevent contamination with gluten and gluten-containing grains, etc. or that they have no likelihood of contamination with gluten and gluten-containing grains, etc. The methods considered to ensure that raw material rice has been controlled to prevent contamination with gluten and gluten-containing grains, etc. include, but not limited to the following:

- proving that the raw material rice has been controlled to prevent contamination with gluten and gluten-containing grains, etc. based on records or documentary evidence provided by the supplier of the raw material rice;
- proving that raw material rice that has been produced and harvested in-house to prevent contamination with gluten and gluten-containing grains, etc. based on production records or documentary evidence.

5.2.2 When raw material rice and materials are stored, they shall be controlled to prevent contamination with gluten and gluten-containing grains, etc.

5.2.3 When water is used in production, water for drinking that has been controlled to prevent contamination with gluten and gluten-containing grains, etc. shall be used.

5.3 Control of Shipment

5.3.1 The products shall not be shipped before they are confirmed to have been managed properly to ensure that their gluten content does not exceed 1 µg/g.

5.3.2 A method to handle cases in which the contamination with gluten is found after products are shipped shall be established, and, to ensure that the method is always effective, it shall be verified at least once a year and be maintained.

5.3.3 The traceability system that can identify the following items of the products shall be established and verified at least once a year:

- a) raw material rice and materials used in production of non-gluten rice flour;
- b) records relating to the production process management;

c) shipment destinations and distribution (processors and delivery companies, etc.).

5.3.4 Until the products are shipped, they shall be stored to prevent contamination with gluten and gluten-containing grains, etc.

5.4 Worker management

5.4.1 The workers shall be made to implement the management for the production processes for non-gluten rice flour in accordance with 5.1 to 5.3 for sure. Furthermore, they shall be provided with training in order to do so.

5.4.2 The workers and external parties (outsourcing contractors and visitors, etc.) shall be managed to prevent contamination with gluten and gluten-containing grains, etc. Such management shall include measures against their intentional contamination with gluten and gluten-containing grains, etc.

Annex A **(informative)**

Test method for Gluten

A.1 Quantitative test

A method for the quantitative test shall be ELISA which is based on the antigen-antibody reaction and shall be confirmed to satisfy the criteria of 50 % to 150 % recovery and 25 % or lower interlaboratory precision in interlaboratory validation implemented at a minimum of 8 laboratories using a minimum of 5 rice flour samples [provided, however, that the gluten concentration level in one of those samples shall be 1 µg/g (or, 1,2 µg/g as wheat protein content)] based on an international protocol (e.g., AOAC INTERNATIONAL, Appendix D: Guidelines for Collaborative Study Procedures To Validate Characteristics of a Method of Analysis). Test kits other than those listed in the Note may be used if they are confirmed to satisfy the above-mentioned criteria for validation as quantitative test methods for gluten.

NOTE Commercially available applicable quantitative test kits for gluten are as follows (in the order of Japanese syllabary):

- NH Foods Ltd.: FASTKIT ELISA Ver. III Wheat;
- Prima Meat Packers, Ltd.: Allergeneye ELISA II Wheat;
- Morinaga Institute of Biological Science, Inc.: FASPEK ELISA II Wheat (Gliadin).

A.2 Qualitative test

For qualitative test, a test method that can detect 1 µg/g wheat gluten in rice flour shall be used. When a qualitative test is used, tests using the quantitative test in A.1 shall be implemented periodically.

NOTE 1 A commercially available test kit that can detect 1 µg/g wheat gluten in rice flour is immunochromato kit for gluten detection, Gluteneye, for rice flour by Prima Meat Packers, Ltd. .

NOTE 2 Newly developed test kits are expected to satisfy the criteria of 90% or higher positive rate and 90% or higher negative rate for blank samples in interlaboratory validation implemented based on the protocol for the qualitative test method provided by the Consumer Affairs Agency [“Test method for Food Containing Allergens, which is an attachment to “Labeling Related to Allergen-Containing Food” that is attached to “On Food Labeling Standards” (Notice of Consumer Affairs Agency Vice-Commissioner No. 139 of March 30, 2015)].