

FINAL REPORT – November 21, 2011

USDA ASSESSMENT OF MAFF – GOVERNMENT OF JAPAN

RECOGNITION AGREEMENT

DATES OF REVIEW – OCTOBER 3 – 7, 2011

REVIEW TEAM: Ruihong Guo, National Organic Program

1. INTRODUCTION

- 1.1. On May 19, 2008, the U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) recognized the Government of Japan's Ministry of Agriculture, Forestry and Fisheries (MAFF) as a competent authority for the accreditation of organic certification bodies under the USDA National Organic Program (NOP). Pursuant to the recognition agreement, the NOP was to conduct regular onsite assessments of MAFF.
- 1.2. Representatives of the NOP conducted the first onsite review of the recognition agreement in Japan on October 15 - 17, 2008. At the time of the assessment, MAFF had not accredited any organic certification bodies certifying to the NOP standards.
- 1.3. Since the last assessment, MAFF has accredited two organic certification bodies: Japan Organic and Natural Foods Association (JONA; accredited on April 6, 2010) and Center of Japan Organic Farmers Group (CJOFG; accredited on April 26, 2010).

2. OBJECTIVES OF ASSESSMENT

- 2.1. The objective of this assessment was to evaluate MAFF's systems and processes for accrediting organic certification bodies under the NOP regulations, and to assess MAFF's capabilities and performance in controlling the proper application and enforcement of the NOP standards for organic products that are produced in Japan, then labeled and exported to the United States.

3. LEGAL BASIS FOR THE ASSESSMENT

- 3.1. The assessment was conducted pursuant to the recognition agreement between AMS and MAFF completed by the AMS Administrator on May 19, 2008. The agreement provides for USDA to conduct onsite reviews of the Japanese conformity system when properly notified of the review by USDA. Recognition agreements are provided for pursuant to NOP regulations at 7CFR 205.500 (c)(1).
- 3.2. The following statutes, regulations, and standards were considered in the review:

- 3.2.1. Organic Foods Production Act of 1990
- 3.2.2. U.S. Code of Federal Regulations (CFR) Part 205, National Organic Program
- 3.2.3. ISO/IEC 17011:2004(E) Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies.

4. PROTOCOL

- 4.1. The assessment was accomplished in three parts; a review of operations at the MAFF headquarters office in Tokyo, Japan, and a review of the Food and Agricultural Materials Inspection Center (FAMIC), the audit and inspection body that conducts all audits and evaluations of certification bodies on behalf of MAFF; review of the two MAFF-accredited certification bodies; and reviews of a tea handler, tea producer/handler, and miso processor, all certified to the NOP standards. The assessment team reviewed each phase of the Japanese production, certification, and accreditation system to determine if the competent authority had the necessary controls in place to ensure traceability and compliance with the NOP regulations.
- 4.2. In selecting certified operations to be visited, the assessment team worked with MAFF officials to select operations representative of those producing the types of products that Japan exports to the United States.
- 4.3. At MAFF and FAMIC, the NOP assessment team was provided a presentation including,
 - a. The MAFF and FAMIC organizational structure in terms of their roles and responsibilities in administering the organic program and the accreditation of agents under the NOP standards;
 - b. The accreditation process, monitoring activities, enforcement procedures, complaint process, appeals process;
 - c. Brief overview of statistical data of Japanese organic agricultural products under the NOP; and
 - d. Brief description of Japan's organic standards in comparison to the NOP standards.

MAFF's processes and procedures for evaluating the competence of the certification bodies were reviewed. MAFF and FAMIC personnel were interviewed to determine their knowledge of the NOP regulations and their qualifications with respect to their duties and responsibilities. Files for the two accredited certification bodies were reviewed.

- 4.4. During the review of the two certification bodies, the assessment team received a presentation on bodies' operation and activities: such as roles and responsibilities, scope and size of operation, and number of clients, and processes of certification, monitoring activities, and complaint handling. Documents on Staff qualifications and training, and statements of conflict of interest and confidentiality were reviewed. Certification files, including the three operations to be visited, were reviewed.
- 4.5. The assessment team visited three organic production and handling operations to observe production, handling and labeling practices in order to determine the level of compliance

accomplished by the certified operations. The assessment team interviewed farmers and other responsible parties at each site.

4.6. The assessment team was accompanied by representatives of MAFF/FAMIC throughout the assessment. At each of the certified organic operations visited, the team was also accompanied by at least one representative of the certifying body. At least one professional interpreter was present at all the meetings.

4.7. The USDA Foreign Agriculture Service (FAS) staff based in Tokyo provided assistance and facilitation for the assessment. Two FAS staff members attended the opening meeting. One member accompanied the assessment team, attended the entire assessment, and provided interpretation service for many discussions on technical issues.

5. SUMMARY OF PREVIOUS ASSESSMENTS

5.1. During the previous assessment, the NOP team clarified the requirements of the NOP under the recognition agreement. The assessment report summarized MAFF's responsibility in ensuring that (1) staff assigned to conduct accreditation and NOP inspections have a combination of education, training, and experience necessary to do NOP work; (2) certification bodies are fully trained and competent before acquiring accreditation; and (3) the certification process for NOP be a separate process from the JAS certification process.

6. OBSERVATIONS

6.1. MAFF administers the Japanese Agricultural Standard System (JAS) and the NOP program in Japan. Within MAFF, the Standards and Labeling Division of the Food Safety and Consumer Affairs Bureau manages organic certification. Several teams and offices, such as Food Standards, Organic Food, Food Labeling and Standards Surveillance, facilitate day-to-day operation. The Food Labeling and Standards Surveillance Office handles complaints and consumer inquiries. Consumers can contact the office by phone or email to report concerns and complaints. The office conducts investigations. If technical assistance is needed, FAMIC inspectors may accompany the investigations. The office also conducts monitoring activities. One proactive monitoring activity has involved 1500 consumers who were hired to check food labels in supermarkets.

6.2. MAFF authorizes FAMIC, an incorporated administrative agency under MAFF, to process applications for accreditation and conduct all document reviews and onsite assessments to evaluate capabilities and performance of organic certification bodies. FAMIC's performance is evaluated annually by MAFF and the Ministry of Internal Affairs and Communications, and its staff members have official government status. FAMIC conducts inspections at various stages of the food chain, based on eight laws covering food quality, labeling, safety, and the quality and safety of fertilizers, chemicals, animal feed and feed additives, and soil improvement materials. Its approximate 700 employees are located in the Saitama headquarters, and 5 regional centers in Sapporo, Sendai, Nagoya, Kobe and Fukuoka.

FAMIC's NOP-related role and activities consist of receiving and evaluating accreditation applications and conducting onsite assessments of certification bodies. Upon receipt of an application, FAMIC conducts a formal document review and submits a report to MAFF. After MAFF's approval, accreditation is granted. Accreditation has a 5-year cycle. An onsite assessment is conducted when a certification body starts certification activities. Follow-up assessments are conducted annually. The assessment contains three parts: office audit, witness of organic inspections, and residue testing for products destined for export. FAMIC completed the accreditation document reviews and assessments for two applicants in 2010. The 2011 annual assessment has been completed for one certification body and scheduled for the other. The assessments have not identified any noncompliances. FAMIC has only run into one product destined for export; therefore, one residue sample was tested and the result was negative. Generally speaking, when there is a positive result, FAMIC initiates an investigation to identify the cause. If there is deliberate violation of the regulations, adverse actions are taken to resolve the violations; if there is no wrongdoing uncovered, product can be sold as organic, unless the residue level exceeds the allowed level for the product. FAMIC conducts random testing on about 10% of JAS certified products. FAMIC laboratories are accredited to ISO 17025.

FAMIC has established detailed requirements for its inspectors and maintains documentation of satisfaction of these requirements. It provides regular training to its inspectors. The first NOP training was provided during 2009/2010 and was conducted by IOIA. Annual NOP and ISO/IEC Guide 65 training is provided by headquarters staff.

- 6.3. MAFF staff review the document review report submitted by FAMIC and follow administrative procedures to grant accreditation.
- 6.4. Review of qualifications of MAFF and FAMIC personnel revealed substantial education, training and experience relevant to agriculture and organic production.
- 6.5. A review of the quality management system in place at MAFF and FAMIC with regards to application of the NOP technical standards revealed a detailed system in place addressing all NOP technical program and conformity assessment system requirements. Document control is closely observed by the MAFF staff persons responsible for maintaining the system. The documented quality management system provides confidence in the system of controls in place for organic certification. Accreditation files are complete and well organized.
- 6.6. The Center for Japan Organic Farmers Group (CJOFG) was established in 1998 as a non-profit certification body, and accredited to the NOP in April 2010. It conducts certification activities under eight programs, including the NOP and JAS. Certification decisions are made by a certification committee. The certification process conforms to NOP regulations. Qualification requirements for inspections and certification staffs include a combination of practical experience, university degree and ongoing training. Currently, CJOFG only certifies one NOP operator – a tea processor. No product has been exported yet. CJOFG certifies over 50 organic producers and processors.

6.7. Japan Organic and Natural Foods Association (JONA) started as an organic certifier in 1993, and was accredited to the NOP in April 2010. It is also accredited to ISO Guide 65, COR, IFOAM and JAS. JONA certified about 500 organic operations, of which about 50 are NOP operations. Certification process is consistent with NOP regulations. Staff qualifications are established and well documented. Certification files are complete. The file for a rice grower group was reviewed. All the five members in the group are inspected each year and all the production sites are inspected every three years.

6.8. Of all organic products, Green tea is Japan's most exported product. A certified organic tea handler and a tea producer/handler were reviewed. The tea handler, certified by CJOFG, is located in the Shizuoka area and processes 3000 tons of tea annually, about 1% of which is organic. It receives organic tea from two farmers certified to the NOP. The facility has an OSP in place and staff members are familiar with NOP requirements on the prevention of commingling and contamination. All machines are thoroughly cleaned with high-pressure air before organic tea is processed. Sticky traps are used to trap insects and rodents. Storage areas for organic ingredients and products are separate. The last inspection did not indicate any noncompliances. Currently, no products are sold to the US, but are sold to the EU from which products may be exported to the US.

A tea farm located in the same area was reviewed. The operation is certified as a producer and handler by JONA. It produces about 60,000 tons of tea leaves on 11 parcels and expects to be all organic in two years. The operator reported no use of pesticides, and uses seed cake, fish meal and palm cake as fertilizers. The operator maintains a daily log of production, fertilizer applications and harvests. Operator demonstrates good knowledge of the NOP regulations. The last inspection did not find any noncompliances.

6.9. A miso processing facility, located in the Kanazawa area and certified by JONA, was reviewed. The operation produces 1500 tons of miso products annually and only one ton is organic. Equipment is washed with water and organic products are always processed first at the beginning of the week. Organic ingredients and products are stored separately from other products. A miso product certified in the "organic" category was recently exported to the US. The product contains yeast, salt, organic rice and soy beans certified by JONA. There are no other inputs. The operator explained in detail the ratio of ingredients to make miso. A complete tracing of one batch of product from the transaction of incoming ingredients to final finished products was conducted, and indicated total transparency and consistency with the stated ratios. The operator maintained photographs (with dates) of the starting and end of the production cycle, the clean machines, and the adding of the ingredients.

7. FINDINGS

7.1. The NOP regulations at 7CFR Section 205.670(c) states that "the preharvest or postharvest tissue test sample collection pursuant to paragraph (b) of this section must be performed by an inspector representing the Administrator, applicable State organic

program's governing State official, or certifying agent." Under the recognition agreement, this can be interpreted to refer to an inspector representing MAFF/FAMIC or a MAFF accredited certification body. FAMIC reported that sample for testing is collected by the certified operator and sent in to the FAMIC laboratory. This practice is inconsistent with NOP regulations.

- 7.2. The NOP regulations at 7CFR Sections 205.680 and 205.681 specify the procedures for certified operations and accredited certification bodies to appeal adverse actions taken by certification bodies and the NOP to the Administrator of the Agriculture Marketing Service. Under the recognition agreement, MAFF is responsible for administering the NOP program, including appeals, in Japan. Currently, MAFF has not established procedures for handling appeals.

8. CLOSING MEETING

- 8.1. The assessment team conducted a closing meeting with MAFF/FAMIC officials in Kobe on October 7, 2011. At the meeting, the NOP assessment team provided a complete summary and discussion of all findings in this report. A complete tour of the FAMIC lab facility was conducted.

9. CONCLUSIONS AND RECOMMENDATIONS

- 9.1. With consideration given to the above findings, MAFF and FAMIC have the processes in place necessary for accreditation of NOP certification bodies.
- 9.2. MAFF is considered competent to conduct accreditation to the NOP, based upon an ISO 17011 framework for an accrediting body.
- 9.3. MAFF should prepare formal responses to the FINDINGS portion of this report, proposing actions to be taken to address any inconsistencies between the operations of the MAFF and the USDA National Organic Program.
- 9.4. It is recommended that MAFF/FAMIC and the NOP continue technical discussions on subjects such as interpretation of residue results and adverse actions procedures to ensure consistent application and enforcement of the NOP standards.
- 9.5. It is recommended that MAFF/FAMIC and the NOP conduct continued dialogue to increase understanding of each other's system and appreciation of the challenges encountered in facilitating the trade of organic products.