



United States
Department of
Agriculture

Agricultural
Marketing
Service

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FINAL REPORT

USDA REVIEW OF MAFF – GOVERNMENT OF JAPAN

RECOGNITION AGREEMENT

DATES OF REVIEW – OCTOBER 15 – 17, 2008

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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 body for the accreditation of organic certification bodies under the USDA National Organic Program (NOP), subject to the successful completion of an onsite audit. Pursuant to the recognition agreement, representatives of the NOP conducted an onsite review of the Japanese recognition agreement in Japan on October 15 - 17, 2008.
- 1.2. At the time of the audit, MAFF had no accredited organic certification bodies certifying to the NOP standards.

2. OBJECTIVES OF AUDIT

- 2.1. The objective of the audit was to evaluate the system capabilities and performance of MAFF in controlling the proper application and enforcement of the NOP technical and conformity assessment standards for organic products labeled and exported to the United States.

3. LEGAL BASIS FOR THE AUDIT

- 3.1. The audit was conducted pursuant to a 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 assessment system when

properly notified of the review by USDA and recognition was based upon an interim onsite audit. 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 audit was accomplished in three parts; a review of operations at the MAFF headquarters office in Tokyo, Japan; a review of the Food and Agricultural Materials Inspection Center (FAMIC), the auditing and inspection body that does all auditing and evaluations of certification bodies on behalf of MAFF; and reviews of a Japanese tea farm and processing facility certified to the JAS Standards.

4.2. In selecting certifiers and operations to be reviewed, the audit team and U.S. Embassy staff based in Tokyo worked with MAFF officials to select operations representative of those producing the types of products that Japan would like to export to the United States.

4.3. The audit 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.

4.4. At MAFF and FAMIC, the NOP audit team reviewed processes used to evaluate the competence of the certifying bodies. The auditors reviewed procedures relating to the certification of organic operations according to JAS in order to determine how compliance with the NOP regulations would be carried out. The auditors also interviewed MAFF and FAMIC personnel to determine their knowledge of the NOP regulations and their qualifications with respect to their duties and responsibilities.

4.5. The audit team visited two 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 audit team interviewed farmers and other

responsible parties at each site, and participated in a follow-up meeting with the farmer, production managers and the certifying body.

4.6. The audit team was accompanied by a representatives of MAFF and FAMIC throughout the audit. At each of the certified organic operations visited, the team was also accompanied by at least one representative of the certifying body. Any issues of concern or perceived noncompliance's were immediately brought to the attention of the accompanying MAFF or FAMIC official.

4.7. Unless otherwise noted in this report, conformity assessment practices and technical performance observed was considered to be in compliance with the NOP regulations.

5. SUMMARY OF PREVIOUS AUDITS

5.1. This was the initial onsite audit of the Japanese government program for the purpose of reviewing the ability to apply the NOP regulations. There were no previous onsite audit findings to consider for corrective actions.

6. OBSERVATIONS

6.1. MAFF administers the Japanese Agricultural Standard System (JAS) in Japan. Further analysis showed that within MAFF, the actual organizational structure consisted of the Food Safety and Consumer Affairs Bureau, the Standards and Labeling Division and finally, several Teams exist to facilitate day to day operations such as the Organic Foods Team, International Affairs Team, and Labeling and Standards Specialists. Complaints are handled by the Food Labeling and Standards Surveillance Office.

6.2. MAFF collaborates with FAMIC, an incorporated administrative agency, for all audit evaluations, processing of applications and all assessments and testing for Registered Certifying Bodies (RCB's). As stated previously, there are as yet no Registered Certifying Bodies accredited to certify to the NOP Standards by MAFF.

6.3. RCB's will conduct certification of organic operations in Japan as they are accredited by MAFF.

6.4. MAFF, through its collaboration with FAMIC, will review RCB's to ensure they comply with ISO/IEC Guide 65, JAS Law, and the NOP Regulations each separately.

6.5. Accreditation is based upon a recommendation and evaluation by FAMIC with an evaluation by a technical expert from MAFF, Food Labeling Division, Organic Food Team.

6.6. Qualifications of accrediting body personnel. Review of qualifications of MAFF and FAMIC personnel revealed substantial education, training and experience relevant to the certification of organic production according to JAS. Persons assigned to review various aspects of certifying body operations are qualified to assess those particular types of production and handling operations.

6.7. Quality system management. A review of the quality management system in place at MAFF 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 in place at MAFF, including the qualifications of management and staff, provide confidence in the system of controls in place for organic certification.

7. INTRODUCTION TO FINDINGS

7.1. Comments will be with the consideration that no accreditations have taken place at the time of this audit.

7.2. Findings discussed in this report are a summary of work to be completed prior to full implementation and issues to be aware of once accreditation work has begun.

8. FINDINGS

8.1. Translation of the NOP technical standards. There are currently no NOP regulations translated into Japanese for use in Japan. Before work goes forward, arrangements need to be made to ensure that all certifiers that do work for the NOP have complete, current copies of the NOP regulations available for use in Japanese and that all NOP certified operations have access to the complete and correct standards. Paragraph 205.501 (a) (8) of the NOP regulations state that certifiers must *provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulation*”

- 8.2. Competency of Certifying Bodies (RCB's). NOP and MAFF agree that qualifications of certifying bodies are critical to the successful application of a conformity assessment standard. Discussions with MAFF revealed that MAFF expects RCB's to become fully versed in the referenced specifications for organic certification. It is the RCB's duty to develop this specialized competence. MAFF should ensure that RCB's are fully trained and competent prior to issuing accreditation.
- 8.3. Continued Competency of MAFF/FAMIC. MAFF/FAMIC are expected to take positive steps to ensure that staff assigned to conduct accreditation and NOP inspections have a combination of education, training, and experience necessary to do NOP work. We have accepted MAFF/FAMIC's policy that training be offered annually for inspectors and that inspectors must attend at least once every 3 years for JAS accreditation work. We would reasonably expect the same level of assurance to be provided for NOP accreditation work.
- 8.4. Recognition vs. Equivalence. During our review, we discussed similarities and differences between recognition agreements and standards equivalence. In many respects, what AMS refers to as a "recognition" agreement is similar to what MAFF considers "equivalence." It should be noted that products that enter Japan certified as organic by way of equivalence arrangements with other countries are not necessarily in compliance with the NOP requirements and no assumption of such should be made by MAFF for the purposes of this recognition agreement.
- 8.5. Companies seeking JAS certification in conjunction with NOP. We have noted that certification to the NOP standards goes beyond simply certifying to the JAS standards and then assuring that no materials prohibited in the United States are included in the NOP product. Certification to the NOP is a process based certification and as such requires things such as crop rotation, verification of buffer zones, and minimizing soil erosion; all as a part of the technical requirements to be verified by MAFF accredited certifying bodies. After further clarification from MAFF, we understand that the certification process for NOP will not be done at the same time as JAS certification, but will be separated completely.

9. CLOSING MEETING

- 9.1. The audit team conducted a closing meeting with MAFF officials in Tokyo on

October 17, 2008. At the meeting, the NOP audit team provided a complete summary and discussion of all findings in this report.

10. CONCLUSIONS AND RECOMMENTATIONS

- 10.1. With consideration given to the above findings, MAFF and FAMIC have the processes in place necessary for accreditation of NOP certifying bodies.
- 10.2. MAFF is considered competent to conduct accreditation to the NOP, based upon an ISO 17011 framework for an accrediting body.
- 10.3. A follow-up review is recommended once a number of certifying agents have been accredited to apply the NOP regulations.
- 10.4. 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.