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USDA REVIEW OF JAPAN: U.S. – JAPAN EQUIVALENCY ARRANGEMENT

I. REPORT DATE

- September 8, 2017

II. DATES OF ONSITE REVIEW

- July 19 – 22, 25 - 26, 2016

III. REVIEW TEAM

- Robert Yang, Accreditation Manager, Accreditation and International Activities Division, USDA AMS NOP
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IV. INTRODUCTION

On September 26, 2013, the U.S. Department of Agriculture (USDA), Agricultural Marketing Service (AMS) established an organic equivalency arrangement with Japan's Ministry of Agriculture, Forestry and Fisheries, which went into effect on January 1, 2014. From July 19 through July 26, 2016, the USDA AMS National Organic Program (NOP) conducted an onsite review of Japan's organic program. This report is an account of those activities and findings of the review.

A. REVIEW OBJECTIVES

The objectives of the review were to verify the following:

- That the Ministry of Agriculture, Forestry and Fisheries (MAFF), Food and Agricultural Materials Inspection Center (FAMIC), and domestic Registered Certifying Bodies (RCB) are carrying out the requirements of the Japanese Agricultural Standard (JAS) Organic Program;

- MAFF's and the domestic RCBs' continuing adherence with the provisions of the U.S. – Japan Equivalency Arrangement; and
- The implementation of MAFF's corrective actions in response to the USDA AMS NOP's 2013 onsite peer review.

B. REVIEW SCOPE

The scope of the review included activities related to the following:

- MAFF/FAMIC's accreditation and oversight of domestic RCBs;
- MAFF's investigation of, including enforcement actions taken against, violations of the terms of the U.S. – Japan Equivalency Arrangement by certified operations or domestic RCBs;
- Certification and oversight of domestic organic plant and processed food operations, including re-packers and importers, certified by RCBs under the JAS Organic Program and verified to be meeting the terms of the US – Japan Equivalency Arrangement.

C. LEGAL BASIS FOR THE REVIEW

The U.S. – Japan Equivalency Arrangement provides for USDA officials to conduct onsite evaluations in Japan to verify that the relevant regulatory authorities and certification bodies of Japan's organic program are carrying out the requirements of that program. The onsite evaluations are to include visits to offices of relevant regulatory authorities, certification body offices, production facilities, and farms that certification bodies have certified in Japan. Equivalency arrangements are provided for pursuant to the USDA organic regulations at 7 C.F.R. 205.500(c)(1).

The following regulations, standards, and criteria were considered in the review:

- Provisions of the 2013 U.S. – Japan Equivalency Arrangement
- Japanese Agricultural Standards for Organic Foods and Technical Criteria
- ISO/IEC 17011:2004 General requirements for accreditation bodies accrediting conformity assessment bodies
- ISO/IEC 17065:2012 Requirements for bodies certifying products, processes, and services
- USDA AMS NOP 2013 Peer Review Report

V. ONSITE REVIEW PROCESS

The onsite review was accomplished in five parts: a review of oversight and accreditation activities at MAFF's office and FAMIC's headquarters office; a review of certification activities at the offices of two RCBs accredited by MAFF to certify operations under the Japanese Agricultural Standards for Organic Plants and/or Processed Foods; an observation of FAMIC's witness audit of a processor inspection conducted by one of the two RCBs; a witness audit of a processor inspection conducted by the second RCB; and a review audit of a certified organic importer.

In selecting certification bodies to be reviewed, the USDA AMS NOP review team worked with MAFF to select two RCBs currently certifying operations in Japan that export product to the United States under the U.S. – Japan Equivalency Arrangement. The two processing operations selected for the witness audits were companies certified by the two RCBs that were currently exporting product under the equivalency arrangement. At the time of the review, 56 certification bodies in Japan were accredited by MAFF to certify operations under the Japanese Agricultural Standards for Organic Plants and/or Processed Foods. There were 56 operations reported by MAFF to be exporting products under the equivalency arrangement.

An opening meeting was conducted with MAFF and FAMIC representatives at MAFF's office in Tokyo. At MAFF's office, the USDA AMS NOP review team reviewed MAFF's accreditation process; revisions to the Japanese Agricultural Standards for Organic Plants and Processed Foods since the last onsite review; MAFF's process for investigating violations of the terms of the U.S. – Japan Equivalency Arrangement; the results of MAFF's most recent internal audit and management review; and MAFF's conflict of interest and confidentiality policies.

At FAMIC's office in Saitama City, the USDA AMS NOP review team reviewed FAMIC's process for assessing and conducting surveillance of RCBs; process for handling complaints; the results of FAMIC's most recent internal audit and management review; FAMIC's training, confidentiality and conflict of interest policies; and the most recent audit reports of the two selected RCBs on file at FAMIC.

At the offices of the two selected RCBs, the USDA AMS NOP review team reviewed each certification body's policies and process for inspecting and certifying operations under the JAS Organic Program, including the issuance of NOP import certificates and review of labeling for products exported under the U.S. – Japan Equivalency Arrangement. The review team also conducted a sample review of NOP import certificates issued by the certification bodies and

product labels approved by the certification bodies for compliance with USDA NOP organic labeling requirements.

The USDA AMS NOP review team observed FAMIC conduct a witness audit of an annual inspection conducted by one of the two RCBs at a certified JAS organic processor. The operation was manufacturing, packaging, and labeling organic green tea products for export under the equivalency arrangement. The USDA AMS NOP review team conducted a witness audit of an annual inspection conducted by the other RCB at a certified JAS organic processor manufacturing, packaging, and labeling organic rice cake products for export under the equivalency arrangement.

The review team also conducted a review audit of a certified JAS organic importer that was importing, labeling, and trading certified USDA organic products imported under the equivalency arrangement. The onsite visit included a review of the operation's facility management, product storage, transport, and labeling practices.

The USDA AMS NOP review team was accompanied by representatives of MAFF and FAMIC throughout the review. During the witness and review audits, the review team was also accompanied by at least one representative of the respective RCB.

A closing meeting of the onsite review was conducted with MAFF and FAMIC officials at MAFF's headquarters in Tokyo on July 26, 2016.

A. GENERAL OVERVIEW OF MAFF AND FAMIC

MAFF is a cabinet ministry in the government of Japan whose primary responsibilities include overseeing the agriculture, forestry and fishing industries. The ministry's functions include setting quality standards for food products and supervising commodity markets. The Food Standards Office within the Food Industry Affairs Bureau of MAFF is directly responsible for administering and implementing the JAS, which includes the standards for organic foods, and for the accreditation of certification bodies to certify products under the JAS. All oversight activities related to the U.S. – Japan Equivalency Arrangement are conducted by the Food Standards Office out of MAFF's head office in Tokyo. There are currently five full-time staff in the Food Standards Office.

FAMIC is an incorporated, administrative agency within the government of Japan. FAMIC's JAS Inspection division is responsible for conducting reviews of applications submitted from organizations seeking to become an RCB and for conducting the onsite audits of RCBs. FAMIC's system for assessing RCBs has been developed to meet the requirements of ISO/IEC 17011,

except for the requirements related to application for accreditation and decisions regarding the granting, suspension, and withdrawal of accreditation, including the issuance of a certificate for accreditation, which are activities conducted by MAFF.

FAMIC has one head office in Saitama City and five regional offices, located in Sapporo, Sendai, Nagoya, Kobe, and Fukuoka. FAMIC's auditors work out of both the head office and regional offices. There are currently 35 auditors who conduct the assessments of RCBs accredited for the JAS Standards for organic foods. All accreditation records are maintained both at the head office and in the regional offices.

Organizations seeking to become accredited as RCB submit an application for accreditation to MAFF. An application review and onsite audit to verify the organization's compliance with ISO/IEC 17065 and JAS Standards criteria is conducted by FAMIC. The results of the application review and onsite audit are reported to MAFF, who makes the final decision as to whether the organization should be accredited as an RCB. Accreditation is valid four years. During the four-year accreditation period, an RCB undergoes an annual surveillance assessment conducted by FAMIC. The surveillance assessment includes an onsite audit of the RCB's operations and certification activities, and witness audits of the RCB's onsite inspection.

FAMIC also conducts marketplace surveillance by purchasing raw and processed organic products in the marketplace. Products are analyzed for quality and verified for compliance with labeling requirements. Products may also be tested for pesticide residue. If a product tests positive, FAMIC informs the RCB who certified the product and requires the RCB to conduct an investigation.

Complaints and investigation requests from USDA AMS NOP regarding products imported/exported under the U.S. – Japan Equivalency are handled by MAFF's Food Manufacture Affairs Division. Complaints against certified organic operations are referred to FAMIC for further investigation.

VI. SUMMARY OF PREVIOUS REVIEW FINDINGS AND VERIFICATION OF CORRECTIVE ACTIONS

USDA AMS NOP's previous onsite review conducted in July 2013 resulted in six findings. In response to the findings, MAFF submitted its responses to USDA AMS NOP on August 12, 2013. The 2016 onsite review verified MAFF's responses.

A previous finding labeled as "Cleared," indicates that the response was verified.

A. FINDING 1: Cleared.

ISO 17011 5.8.1 states that the accreditation body's top management shall establish procedures to review its management system at planned intervals to ensure its continuing adequacy and effectiveness in satisfying the relevant requirements, including this International Standard and the stated policies and objectives. These reviews should be conducted normally at least once a year. MAFF indicated that although MAFF is not conducting management reviews of the JAS organic program, FAMIC is conducting management reviews on its behalf.

1. MAFF Response: MAFF has revised its Business Handling Manual for Assessment of Registered Japanese or Overseas Certifying Bodies so that MAFF is required to conduct management reviews annually pursuant to this manual. From this year, MAFF will conduct management reviews.
2. Verification: A review of information regarding internal audits and management reviews conducted by MAFF since the last onsite review indicated that MAFF has conducted annual management reviews since 2013.

B. FINDING 2: Cleared.

USDA organic regulation 205.501(a)(11) (ii) states that certifying agents must prevent conflicts of interest by excluding any person, including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. ISO 17065 section 4.2.8 states that when the separate legal entity in 4.2.7 offers or produces the certified product (including products to be certified) or offers or provides consultancy (see 3.2), the certification body's management personnel and personnel in the review and certification decision-making process shall not be involved in the activities of the separate legal entity. The personnel of the separate legal entity shall not be involved in the management of the certification body, the review, or the certification decision. The JAS law allows certified operations to be members of the board of directors of a MAFF Registered Certifying Body (RCB). One certifier had three out of seven board members who were certified operators. JAS law allows certified operators to serve as board members of the RCB as long as they do not hold a majority position on the board and they exclude themselves from involvement in decision making processes where they have a

conflict of interest. A registered certifying body cannot have a board member who sells or produces certified products (i) review or evaluate results of the RCB, (ii) make certification decisions for the RCB, or (iii) have authority for certification activities.

1. MAFF Response: MAFF clarified that the JAS organic system does not allow a board member who sells or produces certified products to be involved as personnel in the review of evaluation results, in the certification decision-making of the registered certification body, or have authority for certification activities.
2. Verification: A review of the current requirements of the JAS organic system and interviews with RCB staff indicated that certification bodies do not allow board members who sell or produce certified products to participate in certification activities, including the review of inspection results and certification decision-making.

C. FINDING 3: Cleared.

USDA organic regulation 205.301(b) states, *“Products sold, labeled, or represented as “organic.”* A raw or processed agricultural product sold, labeled, or represented as “organic” must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially available in organic form, or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to § 205.303.” Under JAS law minor agricultural ingredients that compose less than 5% of the product may be non-organic only when organic ingredients are not available. The JAS law does not include a restricted list of agricultural ingredients that may be non-organic if organic ingredients are not commercially available. However, the JAS law has a restricted list of food additives.

1. MAFF Response: MAFF clarified that due to the limited availability of organic products in Japan, ingredients that are less than 5% of the product are allowed to be non-organic only when organic ingredients are not available.
2. Verification: A review of the current JAS law, MAFF's policies, interviews with RCB staff, and a review of certification files for JAS-certified organic products at the RCBs indicated that the use of non-organic ingredients is only allowed when the processor is unable to obtain an organic form of the ingredient in an appropriate quantity or at a reasonable cost in order to fulfill an essential function in the production of the product.

D. FINDING 4: Cleared.

USDA organic regulation 205.100 states that each production or handling operation that produces or handles organic products must be certified. ISO 17065, section 7.2 Application states that the certification body shall obtain all necessary information including the general features of the client any relevant legal obligations. It was noted that the certified organic rice operation was not a legal entity. The certification was issued to a group of rice farmers that were operating under the same certification and were not individually certified. These farmers were allowed to sell organic products without obtaining individual certification. This group of farmers was certified together but did not represent any legal entity. MAFF allows non-legal entities to apply and obtain organic certification. MAFF also allows organic farmers to be covered under a processor's certification and not obtain their own individual certification.

1. MAFF Response: MAFF clarified that in Japan there are small-scale organic producers with less than .01 acre of land and also producers that farm together as a community. The JAS law allows such farmers to be certified as a group. Although the group may not be a legal entity, all organic fields and facilities of the group are inspected by the RCB. When a member of the group violates the JAS law, penal provisions, including cancelling/suspending certification, is carried out against the entire group.
2. Verification: A review of the current version of the JAS law and interviews with MAFF and RCB staff indicated that MAFF and RCB continue to allow farmers to be certified as groups, even if the group is not a legal entity. All farmers in the group undergo annual inspections by the RCB.

E. FINDING 5: Cleared.

USDA organic regulation 205.205 requires the practice of alternating the annual crops grown on a specific field in a planned pattern or sequence in successive crop years so that crops of the same species or family are not grown repeatedly without interruption on the same field. JAS organic standards do not require crop rotation.

1. MAFF Response: MAFF confirmed that the JAS organic system does not require crop rotations.
2. Verification: A review of JAS organic system requirements indicated that crop rotations continue to not be required.

F. FINDING 6: Cleared.

MAFF requires organic plants and organic processed foods of plant origin imports to be JAS certified or be imported with a government-issued (or quasi-governmental organization) import certificate under an equivalency agreement (e.g. EU, US, Australia). The US agreement currently requires the TM-11 transaction certificate for all non-JAS certified organic imports from the United States. Transaction certificates are not required for JAS labeled/certified organic products. The revised “Technical Criteria for Certifying Importers of Organic Plants and Organic Processed Foods of Plant Origin-March 29, 2013” allows grading labels to be covered under a contract with JAS certified importers.

1. MAFF Response: MAFF confirmed that under the JAS law when certified importers import organic foods that were graded under an overseas system, certificates issued by the governmental or quasi-governmental organization are required for each shipment.
2. Verification: The review of two RCBs and one certified JAS organic importer indicated that RCBs are correctly enforcing the terms of the U.S. – Japan Equivalency Arrangement, which requires organic products imported under the equivalency arrangement to be accompanied by a TM-11 certificate.

VII. SUMMARY OF REVIEW FINDINGS AND MAFF RESPONSES

The 2016 onsite review resulted in three findings. On August 31, 2017, MAFF provided responses, including descriptions of actions taken to address each finding. A finding labeled “Accepted” indicates that the response is accepted by the NOP.

A. FINDING 1: Accepted.

The terms of the U.S. – Japan Equivalency Arrangement states in Appendix 1, Section I.B, “A Japanese organic product for export to the United is expected to be labeled according to the USDA NOP organic labeling requirements.”

1. Comments: A review of two RCBs processes for verifying labels for products exported under the equivalency arrangement indicated that one RCB was not verifying product labels for compliance with USDA NOP organic labeling requirements. Interviews with RCB and MAFF representatives indicated that certifiers are not required to verify the labels of products exported under the U.S. – Japan Equivalency Arrangement for compliance with USDA NOP labeling requirements.
2. MAFF Response: MAFF notified the RCBs again that they need to verify whether product labeling meets the requirements of USDA NOP organic labeling when issuing NOP import certificates.

B. FINDING 2: Accepted.

The terms of the U.S. – Japan Equivalency Arrangement states in Appendix 1, Section 1.F.1 states, “MAFF is expected to provide to USDA’s Agricultural Marketing Service (AMS) the following documents ...: A report that contains the types of non-compliances identified by the MAFF during any oversight review or audits ...”

1. **Comments:** MAFF's most recent annual report submitted in March 2016 did not fully disclose the types of nonconformities identified by MAFF during its 2015 oversight reviews or audits. The report only included the top three nonconformities detected during its onsite audits. Information included in the March 2016 annual report and provided to the review team during the onsite review indicated that 46 nonconformities were issued to the RCBs as a result of the 2015 onsite audits.
2. **MAFF Response:** MAFF submitted the 2015 annual report and the 2016 annual report on August 23, 2017, which included nonconformities detected during the onsite audits.

C. FINDING 3: Accepted.

ISO/IEC 17011: 7.5.6 states, "The accreditation body shall establish procedures for sampling ... where the scope of the CAB covers a variety of specific conformity assessment services. The procedures shall ensure that the assessment team witness a representative number of examples to ensure proper evaluation of the competence of the CAB."

1. **Comments:** FAMIC's onsite assessment activities do not include a sample review of labels of products exported under the U.S. – Japan Equivalency Arrangement on file at the RCB. FAMIC also does not conduct a sample review of NOP import certificates issued by the RCB. As a result, FAMIC is not evaluating whether an RCB is appropriately verifying labels for compliance with USDA NOP organic labeling requirement and issuing NOP import certificates.
2. **MAFF Response:** MAFF will conduct sample reviews of labels of products exported under the equivalency arrangement between Japan and the U.S.

VIII. CONCLUSION

The implementation of MAFF's response to any finding noted as "Accepted" will be verified by USDA AMS NOP during its next onsite review of MAFF and Japan's organic program.