

USDA REVIEW OF JAPAN: U.S. - JAPAN EQUIVALENCY AGREEMENT, ALCOHOL BEVERAGES ADDITION

REPORT DATE: January 10, 2025

DATES OF ONSITE AUDIT: June 23 – July 2, 2024

AUDIT TEAM:

1. Bridget McElroy, Assistant Director, Trade Activities Division, USDA-AMS-NOP
2. Jessica Walden, International Specialist, Trade Activities Division, USDA-AMS-NOP

INTRODUCTION

On September 26, 2013, the U.S. Department of Agriculture (USDA), Agricultural Marketing Service (AMS) National Organic Program (NOP) and Japan's Ministry of Agriculture, Forestry and Fisheries (MAFF) established an organic equivalence arrangement. The arrangement allowed for organic plant and processed plant products to be sold, labeled and represented as organic in each country's respective marketplace without separate in-country certification. On July 14, 2020, the U.S.-Japan equivalence arrangement was expanded to include livestock products. As part of ongoing maintenance of this organic equivalence arrangement, USDA National Organic Program (NOP) representatives conducted an onsite review of Japan's organic accreditation, certification, and production/handling systems. This report is an account of those activities and findings of the review.

The NOP's onsite review also included a review of Japan's organic alcohol scope. Organic alcohol products are not covered under the U.S.-Japan equivalence arrangement

because Japan's organic regulations did not include alcohol when the arrangement was established. However, USDA organic alcohol products were allowed to be sold in Japan under certain conditions. On October 1, 2022, Japan expanded its organic regulations to regulate alcohol products and provided a transition period until October 1, 2025, for operations to come into compliance.

Japan and the U.S. are conducting technical reviews of each other's programs to assess the feasibility of adding alcohol to the equivalence, which would allow USDA organic alcohol products to continue to be sold in Japan and use the JAS organic seal after the transition period is over, without obtaining JAS certification.

OBJECTIVES OF REVIEW

The objectives of the review were the following:

1. To verify that MAFF, the Food and Agricultural Materials Inspection Center (FAMIC), and domestic accredited certification bodies are carrying out the requirements of the Japanese Agricultural Standards (JAS) for organic production and technical criteria, hereafter the JAS organic regulations.
2. To evaluate MAFF/FAMIC and the domestic certification bodies' continuing adherence with the provisions of the U.S. – Japan Equivalence Arrangement.
3. To verify the implementation of MAFF's three corrective actions in response to the USDA AMS NOP's 2016 onsite peer review findings.

SCOPE OF REVIEW

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

- MAFF and FAMIC accreditation and oversight of certification bodies.
- Certification and oversight of operations certified under Japan's organic program by certification bodies accredited by MAFF, including operations verified to be meeting the terms of the U.S.- Japan Organic Equivalence Arrangement.

- MAFF and FAMIC's system for conducting organic surveillance and investigations and taking enforcement actions when violations of the JAS organic regulations or the U.S.- Japan Organic Equivalence Arrangement are identified.
- MAFF's approval of organic imports and exports, including exports under the U.S.- Japan Organic Equivalence Arrangement.
- Certification and oversight of domestic processors of alcoholic beverages certified by certification bodies under the JAS organic regulations and verified to be able to meet the terms of the U.S. – Japan Equivalency Arrangement.

BASIS FOR THE PEER REVIEW

The 2013 & 2020 U.S. – Japan Equivalence Arrangement letters provide for representatives of USDA, following advance notice, to conduct onsite evaluations to verify that the relevant regulatory authorities and certification bodies of the Japan organic program are carrying out the requirements of the program. The onsite evaluations include visits to offices of relevant regulatory authorities, certification body offices, and certified production facilities and farms within Japan. On November 11, 2023, AMS NOP notified MAFF of its intent to conduct an onsite assessment of the Japan organic program as part of the ongoing requirements of the equivalence arrangement. Equivalence arrangements are provided for pursuant to USDA organic regulations at 7 CFR § 205.511.

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

- Provisions of the U.S. – Japan Organic Equivalence Arrangement
- Japanese Agricultural Standards for Organic Foods and Technical Criteria
- MAFF and FAMIC's accreditation and certification policy and procedures, including all related regulations, enforcement rules, and operating guidelines.
- ISO/IEC 17011:2017 Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies.
- ISO/IEC 17065:2012 Conformity assessment — Requirements for bodies

certifying products, processes, and services.

- U.S. Organic Foods Production Act of 1990
- U.S. Code of Federal Regulations (CFR) Part 205, National Organic Program
- USDA AMS NOP 2016 and 2019 Peer Review Reports
- 2023 MAFF Annual Report

ONSITE REVIEW PROCESS

The review was accomplished in five parts: a review of MAFF and FAMIC oversight and accreditation activities at FAMIC headquarters office in Saitama City, Japan; a review of certification activities at the offices of two certification bodies, referred to as recognized certification bodies (RCBs), accredited by MAFF to certify operations under the JAS organic regulations; an observation of FAMIC's witness audit of a handling operation inspection conducted by one of the two RCBs; a farm visit of a certified organic crop producer certified by

a second RCB; and a witness audit of a dairy inspection conducted by a third RCB whose office was not visited during the onsite review.

In selecting certification bodies and operations to be reviewed, the AMS NOP worked with MAFF to choose operations representative of the organic products produced in Japan that are being exported to the United States. One exception to this was the livestock operation; no livestock products are exported to the U.S. at this time; however, livestock and livestock products remain included under the equivalence arrangement. Additionally, since AMS NOP and MAFF are assessing whether organic alcohol products can be included under the U.S.-Japan equivalence, an alcohol producer was included in the review. To prepare for this part of the onsite review, AMS NOP and MAFF conducted a side-by-side assessment of organic alcohol requirements under the two certification schemes.

AMS NOP reviewers conducted an opening meeting with MAFF, FAMIC, and three representatives from Japan's National Taxation Agency (NTA) at the FAMIC headquarters office in Saitama, Japan, on June 23, 2024. NTA is the authority for organic alcohol production in Japan. At the FAMIC office, the NOP reviewers assessed MAFF's accreditation process and management system since the last onsite review, with input from the FAMIC staff in attendance. The AMS NOP review team reviewed various phases of the organic production, certification, and accreditation system to determine if the responsible authorities had the necessary controls in place to ensure traceability, compliance with the referenced organic standards, and compliance with the terms of the U.S.- Japan Equivalence Arrangement. At the time of the review, 51 certification bodies in Japan were accredited by MAFF to certify operations under the JAS organic regulations.

At the offices of the two selected RCBs, the AMS NOP review team reviewed each certification body's policies and procedures for inspecting and certifying operations under the JAS organic program; process for investigating complaints of operations/products exported or imported under the U.S.- Japan Organic Equivalence Arrangement; procedures for NOP import certificate issuance; label review procedures for products exported to the U.S. under the equivalence arrangement; and certification staff and inspector training requirements. 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 AMS NOP reviewers observed FAMIC's witness audit of the annual inspection of an organic sake manufacturer (handler), certified by RCB #1. This operation currently markets their organic products in Japan only. The AMS NOP reviewers conducted a farm visit and interviews with a producer of organic green tea (crops), certified by RCB #2. The green tea operation exports organic products to the U.S. The AMS NOP observed the annual inspection of a dairy operation (livestock) producing organic milk for the domestic

market in Japan. The dairy operation is certified by a third RCB.

The AMS NOP reviewers were accompanied by representatives of MAFF and FAMIC throughout the onsite review. During the observation of FAMIC's witness audit of the sake manufacturer, the reviewers were also accompanied by a representative from NTA.

The AMS NOP reviewers conducted a closing meeting of the onsite review with MAFF and FAMIC officials, and three officials from NTA, on July 2, 2024, at MAFF's headquarters office in Tokyo. At the closing meeting, the NOP reviewers presented a summary of the findings and discussed other observations from the peer review, which are included in this report.

OVERVIEW OF JAPAN ORGANIC SYSTEM

General

MAFF is the competent authority for Japan's organic system. 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 MAFF's Food Industry Affairs Bureau 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. The MAFF organic program team is within the Standards and Conformity Assessment Policy Office located at MAFF's head office in Tokyo. This team oversees all activities related to the U.S. – Japan Equivalency Arrangement. There are currently four full-time staff in the Standards and Conformity Assessment Policy Office.

FAMIC is an incorporated, administrative agency within the government of Japan.

FAMIC's JAS Conformity Assessment 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 Accreditation Service Division is responsible for making the recommendation of accreditation to MAFF for RCBs and managing the competence of the JAS Conformity Assessment Division. 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 52 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. MAFF sends the application to FAMIC, who conducts the application review and onsite audit to verify the organization's compliance with ISO/IEC 17065 and JAS Standards criteria.

During the process, FAMIC may issue the applicant corrective action requests and assess corrective actions implemented by the RCB. FAMIC reports the results of the application review and onsite audit and provides a recommendation on accreditation to MAFF. MAFF then makes the final decision as to whether the organization should be accredited as an RCB. MAFF and FAMIC maintain a close working relationship with constant communication in their accreditation and surveillance work.

Accreditation is valid for four years. During the four-year accreditation period, an RCB undergoes an annual surveillance assessment conducted by FAMIC. FAMIC typically uses one of four methods for the annual surveillance assessment, including onsite office audits of the RCB's operations and certification activities; witness audits of the RCB's

onsite inspections; validation audits (where FAMIC visits operators directly), and/or residue testing and label review of organic products. FAMIC conducts the on-site office audits of RCBs at least once every two years. FAMIC also carries out unannounced onsite office audits of RCBs based on risk. Since Japan's National Tax Agency (NTA) is the authority for organic alcoholic beverage production, FAMIC and NTA conduct joint audits organic alcoholic beverage certification activities.

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 investigate.

Complaints and investigation requests from USDA AMS NOP regarding products imported/exported under the U.S. – Japan Equivalence are handled by MAFF's Food Manufacture Affairs Division. Complaints against certified organic operations are referred to FAMIC for further investigation. Japan exported over 1,219 U.S. tons of agricultural processed products to the U.S. in 2023. The bulk of exported product was green tea and other tea products, miso, soy sauce, vinegar, natto (fermented soybeans), noodles, rice cake, rice, and green juice.

AMS NOP Observations of Certification Bodies and Operations

- Certification body #1 –The RCB (herein referred to as “CB”) has provided organic certification since 2019 and currently certifies 324 operations. At the time of the peer review, 11 of these operators were exporting to the U.S. under the equivalence arrangement. CB #1 holds accreditation from MAFF for organic certification of organic products of plant origin, organic processed foods (including organic alcohol beverages), organic feeds, organic livestock products and organic algae. CB #1 is approved to provide certification in Japan and

overseas and offers certification to other schemes under other accreditations. CB #1 does not have any overseas certification offices. CB #1 uses 34 contract inspectors from the Japan Organic Inspectors Association (JOIA) and conducts annual performance reviews of each inspector. New inspectors must apprentice under a qualified inspector for a total of four inspections before they can conduct inspections on their own. Reviewers (“certification decision makers”) receive the same training as inspectors and must have worked as an inspector first before they are eligible to review certification files. This CB, in collaboration with 21 other CBs in Japan, provides an annual training for inspectors, and each inspector must have regular performance evaluations. CB #1 has a formal process for approving organic exports to the U.S. under the U.S.- Japan Equivalence Arrangement and issuing NOP Import Certificates. Material input review is contracted out to the Organic JAS Material Evaluation Association.

- Certification body #2 – This CB has been in operation since 1999 and certifies over 400 operations. It holds accreditation from MAFF for organic certification of organic products of plant origin, organic processed foods (including organic alcohol beverages), organic feeds and organic livestock products. CB #2 does not conduct certification activities outside of Japan. CB #2, in collaboration with 21 other RCBs in Japan, provides an annual training for inspectors, and each inspector must have ongoing performance evaluations. New inspectors must apprentice under, and be observed by, a qualified inspector before they can conduct inspections on their own. Reviewers (“judges”) receive the similar training as inspectors and several reviewers are also inspectors. CB #2 has a formal process for approving organic exports to the U.S. under the U.S.- Japan Equivalence Arrangement and issuing NOP Import Certificates. Material input review is contracted out to the Organic JAS Material Evaluation Association.
- Certified Operation #1 – The operation is a sake processor that has been

producing sake for 200 years. The business has been certified for a year and produces both organic and non-organic sake. The organic sake is brewed separately, following an artisanal brewing process, which is a different process used for the non-organic sake brewing. The operation does not currently export to the U.S. or outside of Japan. While onsite, the NOP reviewers observed FAMIC's witness audit and the inspection. Following the inspection, while visiting the CB, the NOP reviewers interviewed both FAMIC and the CB regarding the inspector's performance as well as findings that FAMIC issued to the CB following the witness audit. Based on observations while onsite and during interviews with FAMIC following the inspection, the NOP Reviewers determined that the FAMIC auditors conducted a thorough witness audit.

- **Certified Operation #2** – This operation grows organic green tea for the local market and for exports mainly to the EU, but also periodically to the U.S. The producer harvests tea leaves from their own 30 hectares of land and manages multiple affiliate producers with small tea gardens who are covered under the same organic certification and organic management practices. Fresh leaves are sent to a separate certified organic processing factory for processing. The tea operation is a family business, which has been certified organic for nearly 30 years. Some tea trees are over 100 years old. This operation was a farm visit rather than a witness audit. While onsite, the NOP reviewers visited the main tea garden, the tea plant nursery site, and the compost storage area, and interviewed the operator regarding organic practices and CB oversight.
- **Certified Operation #3** – The operation is a certified dairy operation that produces organic milk for the local Japan market. To date, the operation has not exported dairy products to the U.S. At this operation, the NOP reviewers observed a routine annual inspection. The operation's records were well organized and readily available. The inspector has been inspecting organic

operations for 15 years but stated that he had not inspected a dairy operation for many years prior to this inspection. The NOP reviewers observed the inspector perform a thorough inspection, including a mass balance of feed and feed traceback audits.

SUMMARY OF PREVIOUS FINDINGS AND VERIFICATION OF CORRECTIVE ACTIONS

USDA AMS NOP's previous onsite review conducted in July 2016 resulted in three findings. In response to the findings, MAFF submitted its responses to USDA AMS NOP on September 1, 2017. The 2024 onsite review verified MAFF's responses.

A previous finding labeled as "Cleared," indicates that the response was verified. A previous finding labeled as "Outstanding" indicates that either the reviewers could not verify the response or observed ongoing evidence of the finding.

2016 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 States is expected to be labeled according to the USDA NOP organic labeling requirements."

Comments: A review of two RCBs' processes for verifying labels for products exported under the equivalence 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.

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.

2024 Onsite Verification: The NOP reviewers interviewed certification staff of two CBs and reviewed CB label verification checklists. This revealed that both CBs understood this requirement of the equivalence arrangement and that their staff do complete verification checklists during label review for products exported to the U.S. However, the NOP review team's assessment of product labels for one operation found that the placement of the "certified organic by" statement was not in compliance with the USDA organic regulations. Additionally, one CB label verification checklist lacked clarity regarding the placement of the "certified organic by" statement.

2024 MAFF Response: MAFF notified the RCBs that they must verify the compliance with the USDA organic labeling requirements prior to issuing NOP import certificates, which are required for the products exported to the U.S. under the U.S.-Japan Organic Equivalency Arrangement. MAFF sent a reminder e-mail to the RCBs on July 2, 2024, which communicated the NOP 2024 peer review findings regarding the placement of the "certified organic by" statement."

2016 Finding 2: Cleared.

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 ..."

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.

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.

2024 Onsite Verification: The NOP Review team verified that annual reports submitted by MAFF since 2017 include nonconformities detected during onsite audits.

2016 Finding 3: Cleared.

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.”

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.

MAFF Response: MAFF will conduct sample reviews of labels of products exported under the equivalency arrangement between Japan and the U.S.

2024 Onsite Verification: The review team interviewed FAMIC and MAFF who clarified that FAMIC checks labels for compliance with the terms of the organic equivalence during onsite CB audits and verification audits but does not record the results of this specific activity in the FAMIC audit checklists. To verify CBs’ label review activities, FAMIC selects samples of labels when evaluating the CBs’ issuance of NOP Import Certificates. FAMIC’s

label review procedure is included in the scope of FAMIC's audit activities of accredited Certification Bodies as per 3)-

a) of (A6-4)) of MAFF's Q&A document. This document is the main resource for CBs regarding MAFF's accreditation requirements.

SUMMARY OF REVIEW FINDINGS

The 2024 onsite review resulted in one finding.

Finding 1. ISO 17011 4.2 (Accreditation agreement) states, "The accreditation body shall establish a legally enforceable arrangement with each conformity assessment body that requires the conformity assessment body to conform to at least the following:..."

Comments: *The NOP reviewers' interview with MAFF and review of MAFF's accreditation policies and procedures found that MAFF does not establish accreditation agreements with CBs.*

MAFF Response: MAFF clarified that while the Ministry of Agriculture, Forestry and Fisheries (MAFF) does not establish accreditation agreements with CBs individually, comparable CB requirements/standards for accreditation are set forth in the provisions of Act on JAS, Section 3, Articles 14 - 29. If there is an accreditation violation, MAFF will take disciplinary actions against the CB in accordance with Act on JAS, which is considered as a legally enforceable arrangement.

OBSERVATIONS

The 2024 onsite review resulted in four observations. Observations are included as potential areas for improvement, but do not require a response.

Observation 1. Residue testing: Under Japan's organic system there is no requirement for CBs to collect samples for residue testing when there is a reason to suspect the organic product has come into contact with a prohibited substance or has been produced using

excluded methods. Even though it is not a requirement, there are no prohibitions against CBs collecting samples and conducting their own residue testing. Some CBs have collected their own samples for testing in the past and taken enforcement action against operators, but this is not standard practice. The USDA organic regulations require CBs to collect samples for testing under certain conditions, including when there is a reason to suspect contact with or use of prohibited substances.

Observation 2. Unannounced inspections: Under Japan's organic system, CB inspection procedures note that unannounced inspections are required, however there is no specific requirement for the number of unannounced inspections that CBs must conduct each year or the amount of prior notice they can give before arriving for the inspection. Both CBs interviewed stated that they conduct one unannounced inspection each year. Each CB has a different policy on notifying the operator. The USDA organic regulations and other international organic standards require that CBs conduct a certain number of unannounced inspections per year, based on the number of operations they certify. Unannounced inspections are an important tool for ensuring compliance, giving the CB the opportunity to observe the activities of a specific operation without the advance notice and serving as a deterrent to operations who may consider violating organic regulations.

Observation 3. Remote inspections: MAFF policy allows remote inspections for all programs that MAFF oversees, including organic. However, MAFF's policy does not clearly define the criteria, scope and other parameters under which remote inspections can be conducted. This allows for operations to request remote inspections without any guidelines for CBs to determine eligibility and for CBs to establish inconsistent remote inspection policies. The USDA organic regulations do not permit virtual and/or remote organic inspections.

Observation 4. Traceback/Mass Balance Exercises: Under Japan’s system, inspectors are not specifically required to conduct traceback and mass balance exercises during inspections. Certification bodies (CBs) have their own policies and some CBs work together when training certification personnel on how to conduct these exercises, but MAFF does not have specific requirements or guidelines to ensure consistency and thoroughness across all CBs. The USDA organic regulations require that CBs verify quantities and traceability of organic products produced or handled by an operation through mass-balance and traceability audits. The USDA considers these audit tools to be essential for monitoring and verifying organic integrity.

CONCLUSION

General Comments

Throughout AMS NOP’s review, representatives from MAFF, FAMIC, the certification bodies, inspectors, and certified operators were responsive, open to engage in productive conversations, and supportive to ensure that AMS NOP met its review objectives. The certification bodies demonstrated a sound grasp of the JAS requirements and the U.S.-Japan organic equivalence requirements. AMS NOP reviewers observed that MAFF and FAMIC work well together, have expert knowledge of Japan’s organic standards and agricultural industries, and have a robust system for oversight of organic CBs to ensure compliance with the JAS organic standards.

The AMS NOP invites MAFF to respond in writing to the findings in this report within 30 days of receipt.

The AMS NOP will post the final report on its website.

END OF REPORT

USDA REVIEW OF JAPAN: U.S. - JAPAN EQUIVALENCY AGREEMENT, LIVESTOCK SCOPE ADDITION

I. REPORT DATE

- November 14, 2019

II. DATES OF ONSITE REVIEW

- October 28 – November 1, 2019

III. REVIEW TEAM

- Cheri Courtney, Director, International Activities Division, USDA-AMS-NOP; attended opening and closing meetings by video
- Renée Gebault King, International Specialist, International Activities Division, USDA-AMS-NOP
- Kelly Strzelecki, Senior Trade Advisor, Foreign Agricultural Service, USDA-FAS

IV. INTRODUCTION

On September 26, 2013, the U.S. Department of Agriculture (USDA), Agricultural Marketing Service (AMS) National Organic Program (NOP) and Japan's Ministry of Agriculture, Forestry and Fisheries (MAFF) entered into an organic equivalency arrangement. This equivalency arrangement allows for organic plant and processed plant products to be sold, labeled and represented as organic in each country's respective marketplace without separate in-country certification. USDA organic livestock products were outside the scope of this arrangement but continued to have access to the Japanese marketplace. In April 2018, Japan notified the U.S. that they were expanding the scope of

their organic regulations to include livestock.

Considering Japan's regulatory change, Japan and the U.S. entered into discussions about expanding the equivalency arrangement to include organic livestock. The ongoing discussions included a side-by-side comparison of both countries' organic livestock standards and onsite reviews of certified livestock operations. This report is an account of these activities and the U.S. onsite review in Japan.

A. REVIEW OBJECTIVES

The objectives of the review were to verify Japan's organic livestock regulations through technical discussions, and a review of MAFF and the Food and Agricultural Materials Inspection Center (FAMIC) oversight of accredited certifiers for livestock certification.

B. REVIEW SCOPE

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

- Technical discussions and clarifications of the JAS organic regulations and oversight of organic livestock certification activities.
- A witness audit of a JAS-accredited certifier during an organic livestock inspection;
- MAFF and FAMIC accreditation and oversight of certifying bodies that certify organic livestock operations under the technical standards of JAS Law.

C. LEGAL BASIS FOR THE REVIEW

The review was conducted at the invitation of the Japan and was not part of a legal or regulatory enforcement function of the USDA.

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

- Conformity of the Law Concerning Standardization, etc. of Agricultural and Forestry Products,” hereafter JAS Law
- U.S. Organic Foods Production Act (OFPA) of 1990
- 7 U.S. Code of Federal Regulations (CFR) Part 205, National Organic Program
- ISO/IEC 17065 Conformity assessment – Requirements for bodies certifying products, processes and services

V. ONSITE REVIEW PROCESS

In advance of and in conjunction with the onsite audit, technical discussions about the side-by-side technical were held. During the onsite audit, the USDA team observed one witness audit of an organic beef operation and interviewed one certifier about organic livestock certification processes.

On October 28, 2019, an opening meeting was conducted with MAFF and FAMIC representatives at MAFF headquarters in Tokyo.

On October 29, 2019, the USDA review team was accompanied by members of MAFF and FAMIC for the witness audit of an inspection at an organic beef operation in Hokkaido, Japan.

On October 30, 2019, the organic inspection began with an opening meeting where the inspector introduced himself, explained the purpose of the inspection and outlined the general plan for the day. The inspector explained that this inspection is conducted during the grazing season, of which today was the last day because the cattle are being moved indoors for the winter. Prior to today’s visit, the inspector conducted inspections at this operation in 2015 and 2016. The farm has 220 animals (cows, calves, bulls) and the inspector verified numbers against records.

During the inspection, the inspector visited pastures and verified borders based on the map, including a new pasture that was added this year. The inspector documented various aspects of the facility and records with photographs. The inspector reviewed a variety of records to verify compliance per the JAS organic standards:

- Organic System Plan: verified annual updates or changes, including added pasture, maps and facilities
- Herd records: calving dates and counts, animal ID- ear tag numbers (calf, cow, bull), weaning, movement (indoors vs. pasture), medical treatments and animal identification, alterations process and age (dehorning, castration), breeding (artificial insemination vs. natural service), bum calves sold as conventional
- Health records: medical treatments (e.g. drenches, vaccines, parasiticides, antibiotics) and veterinary prescriptions, dates given, and withdrawal intervals
- Feed records: feed sources, pasture access and roughage intake (dry matter), calculations for onsite hay and silage production quantities, no external feed purchases
- Transport and truck sanitation records for livestock (to slaughter facility), ear tag numbers cross-checked against sales/shipping/receiving records, slaughter dates, transfer of ownership, JAS Seal use on carcasses
- Materials: labels and use, wood chip bedding, sanitation/cleaning, medical treatments, manure handling and composting
- Followed up on request from the certification body (CB) to obtain/verify documentation that no treatments are used in wood chips (sawdust) bedding

During the closing meeting (exit interview), the inspector summarized the information verified and items or issues where the operation needs to provide more information to the CB (animal monitoring records during confinement, grading manager reviews of

records/labels before shipping for slaughter). The inspector and farm manager agreed to timelines for information submission to the CB, which was documented on the closing meeting form and signed/dated by both parties.

A post-inspection interview with the farm manager indicated that the CB provides regulatory updates and other communications, such as approved products/materials, via fax and paper newsletter a few times per year.

On October 31, 2019, the USDA review team interviewed representatives from a JAS-accredited certification body. The USDA team interviewed the inspector from the CB to verify expertise and MAFF/FAMIC oversight related to organic livestock certification. The inspector demonstrated a thorough knowledge of the JAS organic standards and over 20 years of experience in the organic industry. The CB was formed in 1999 and has been involved in organic agriculture for over 20 years. It is an organization composed of producer members. The CB is registered by MAFF/FAMIC for organic certification to JAS organic standards. The CB vice president reported that they are audited annually by FAMIC for compliance as a certification body. FAMIC also conducts review audits of certification bodies and the frequency of review audits is based on risk-assessment (certifiers with more noncompliances receive more frequent review audits). The CB management said they have not received a noncompliance in 10 years.

The CB has a total of 170 certified operations, of which 120 are on Hokkaido. Japan currently has six certified organic livestock operations and the CB certifies three of them (1 beef, 1 dairy, 1 poultry). Operations on Hokkaido range in size from 1-50 hectares (approximately 2.5-123 acres) in size but tend to be much smaller elsewhere in Japan. Avian influenza (AI) is a prominent issue for Japan's poultry producers. The CB representatives and MAFF officials explained that producers house organic poultry in barns and provide an additional covered barn or greenhouse for exercise to meet the requirement for "open air runs" while preventing potential contact with AI-infected birds.

The CB also certifies the organic abattoir used by the organic beef operation.

The CB representatives noted that sourcing organic feed ingredients, such as corn for poultry rations, is sometimes an issue. To address this, operations import organic feed from the U.S. (under existing equivalency) or source ingredients from domestic human food supplies.

JAS Law requires that inspectors and decision makers be registered. MAFF officials provided the list from the CB showing registered inspectors and decision makers. The CB vice president is also an inspector, livestock leader and trainer. He explained that after he conducts inspections, he submits his report to the CB committee who make the certification decision. The CB provides courses and on-the-job training for organic inspectors.

The CB noted they receive regular communications from MAFF, typically via email. The CB does not currently conduct unannounced inspections. However, under the updated JAS organic regulations, certification bodies are now required to conduct unannounced inspections, and MAFF issued a directive to certifiers about this requirement. MAFF hosts annual training seminars for certification bodies and entry-level inspectors; training for ISO 17065, etc. is typically outsourced to professional entities. The CB offers regional training and information on regulatory updates to operations in Japan at least once per year.

VI. CLOSING MEETING

On November 1, 2019, technical discussions continued, and the closing meeting was held in the FAMIC office in Sapporo, Japan. (See annexes for information that was verified and/or resolved by the USDA based on the technical discussions and witness audit.)

The U.S. team obtained additional details and information during the closing meeting to ensure accurate reporting for the peer review. MAFF clarified that the “cow tracking law” in Japan is managed by an incorporated administrative agency, but it tracks every beef and dairy animal by ID (number) and DNA to ensure accurate tracking and prevent fraud. This database is publicly accessible and used by organic inspectors to verify animal movement and traceability in the supply chain. MAFF also explained that there is no organic pork production in Japan currently; organic livestock is limited to poultry, dairy and beef. MAFF confirmed that they manage and maintain the online list (Japanese only) of approved livestock veterinary drugs.

VII. CONCLUSIONS

A. GENERAL COMMENTS

Throughout the peer review, representatives from MAFF, FAMIC, the CB and the beef operation were responsive, forthright, and supportive to ensure the U.S. team was able to meet audit objectives. The scale of the organic livestock industry in Japan is small compared to the U.S., but Japan clearly has strong organic livestock regulations and is working to boost domestic production and capacity. Although there are some procedural or technical differences, the U.S. team observed that MAFF and FAMIC have a robust and thorough system for oversight of organic certification bodies to ensure compliance with the JAS organic livestock standards.

B. DIFFERENCES

Item	NOP Standard	JAS Standard
1	205.237(a) The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that are organically produced and handled...	Feeding: 5. Nonorganic feeds (limited to feeds produced without recombinant DNA technology, and free from antibiotics and synthetic antibacterials) may be provided ... only for a certain period when necessary amount of feeds for organic livestock cannot be provided in case that feeds for organic livestock are difficult to obtain.
2	205.238(c)(1) Sell, label, or represent as organic any animal or edible product derived from any animal treated with antibiotics...	Health Control: 3. In case that veterinary drugs are used, veterinary drugs other than prescribed drugs or antibiotics shall be used.

END OF REPORT