



United States Department of Agriculture

Agricultural Marketing Service
National Organic Program

MONTANA DEPARTMENT OF AGRICULTURE

302 North Roberts Street, Helena, Montana, 59601, U.S.A.

meets all the requirements prescribed in the USDA National Organic Program Regulations

7 CFR Part 205

as an Accredited Certifying Agent

for the scope of

Crops, Handling, Livestock, Wild Crops Operations

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CERTIFICATE OF ACCREDITATION





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NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

GENERAL INFORMATION

- **Certifier Name** Montana Department of Agriculture, (MTDA)
- **Physical Address** 302 North Roberts Street, Helena, Montana 59601, U.S.A.
- **Audit Type** Renewal Audit
- **Auditor(s) & Audit Dates** Sherry Aultman, Judith Bradley, Owen Brown, Steven Cabral, 08/28/2023 to 09/01/2023
- **Audit Identifier** NOP-337-23

CERTIFIER OVERVIEW

The National Organic Program (NOP) conducted an onsite Renewal Audit of Montana Department of Agriculture (MTDA)'s USDA organic certification program covering the period of March 5, 2021, to September 1, 2023. The purpose of the audit was to verify MTDA's compliance with the Organic Foods Production Act of 1990 (OFPA), the USDA organic regulations (7 CFR Part 205), and the NOP Handbook. Audit activities included a review of certification activities, interviews with MTDA personnel, a records audit, and two on-site witness audits. The two witness audits consisted of one annual on-site inspection of a handling operation and one annual on-site inspection of a crops and livestock operation; both operations are in Montana.

MTDA is a government entity initially accredited on April 29, 2002. MTDA is accredited to the crops, wild crops, livestock, and handling scopes. MTDA's office is in Helena, Montana. MTDA certifies 273 operations and offers certification services in Montana and Idaho. Certification activities are performed by 2 program staff, 8 staff inspectors, 3 contract reviewers, and 5 contract inspectors.

NOP DETERMINATION:

NOP reviewed the audit results to determine whether MTDA's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the audit.

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Accepted**" indicates acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next audit.

Noncompliances from Prior Assessments

AIA-3427-20 – Accepted. (NOP-14-18.NC1) 7 C.F.R. §205.403(c)(1) states, "The onsite inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations in this part;"

Comments: *During the witness audit of an annual handling inspection, the auditor observed that the inspector did not fully verify the operation's compliance with the regulations. Areas of compliance not fully verified included the following:*

- 1. Verification of inputs approved for use in the operation's OSP (Organic System Plan) by reviewing the inputs available onsite.*
- 2. Verification of valid organic certification for all organic suppliers. The inspector only verified organic certification by reviewing certificates for the incoming ingredients of the products used to conduct the trace-back and mass balance audit activities.*
- 3. Documentation for exports according to trade arrangements the USDA-NOP.*
- 4. Labels being used match those approved by and on file with MTDA.*

2018 Corrective Action: MTDA scheduled a training on October 22, 2018 for handling inspectors. The training focused on what inspectors must do during inspections to verify inputs, supplier organic certification, export documentation, and labels against the OSP and other application documentation. The training covered methods inspectors could use to ensure that these items are consistently verified. To prevent recurrence of this noncompliance, MTDA will conduct evaluations for handling inspectors during 2019.

2021 Verification of Corrective Action: The auditors' review found that MTDA inspectors are not verifying operations' OSPs for compliance at inspection. The review of six handler inspection reports reviewed by the auditors, as well as interviews with certification staff, indicated that MTDA inspectors are not always verifying the operation's compliance. Inspectors are not verifying that operations are meeting the requirements for imported and exported products and ingredients. For one certified handler file reviewed, product profiles listed "NOP" and "COR" as the certifier of organic suppliers. In addition, the labels attached to the product profiles were noncompliant with NOP labeling requirements and were not the MTDA-approved labels. The inspector did not report on these discrepancies, and the same inaccuracies were found in the OSP. The auditors also found that inspectors are not fully or accurately completing the MTDA mass balance and traceback forms.

2023 Corrective Action: MTDA conducted training on the topics of verifying import and export requirements, mass balance and traceback audit forms, and product profiles and labels. MTDA revised the forms to include reminders to verify requirements for imports, exports, labels, and product profiles. MTDA also update its internal checklist to verify requirements, *Initial & Final Review Form*, to contain a crosscheck of product profile and label requirements between the initial review, inspection, final review, and final approval stage of the certification process. MTDA also reviewed all

handling operator files in 2022 to verify labeling requirements and accuracy of documents.

AIA-3428-20 – Accepted. (NOP-14-18.NC2) 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670.” Specifically, § 205.201(a)(6) states, “An organic production or handling system plan must include: Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.”

Comments: *MTDA’s organic system plan templates do not require operations to provide information regarding use of organic product(s) imported under USDA international organic trade arrangements. MTDA’s application and handling organic system plan templates are currently limited to asking operations to provide information regarding export of products.*

2018 Corrective Action: MTDA submitted revisions to its organic handling application, handling OSP, and handling OSP update that include questions about whether operations import organic product and the country of origin. Beginning in 2019, renewing handlers will complete the revised handler application and OSP update. New handlers will complete the revised handler OSP.

2021 Verification of Corrective Action: All of the handlers reviewed were still using OSP templates that did not ask questions regarding imported products or ingredients. Interviews with certification staff confirmed that new OSP templates have not been sent to currently certified operations, only to new applicants. The auditors reviewed the new OSP template and identified that additional questions are needed in order to capture the country-specific verification points for imported products.

2023 Corrective Action: MTDA updated its template, *Handler organic system plan*, in 2021 and then required all handlers to update their plan using the most current version of the form in 2022. In 2021, MTDA revised the letter, *Handler Inspection Notification*, to inform clients and inspectors of import and export requirements that would be verified at the next inspection. MTDA also revised the document, *Internal Program Review Auditor Procedure*, to include an annual check that import and export requirements are being verified at inspection.

AIA-3433-20 - Accepted. (NOP-14-18.NC7) 7 C.F.R. §205.662(e) states, “If the certified operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of suspension or revocation.”

Comments:

1. *The auditor reviewed two Notices of Proposed Revocation where the operations did not respond or acknowledge receipt of the proposed notices and MTDA did not issue Notifications of Revocation.*
2. *The auditor reviewed one Notice of Proposed Suspension where the operation did not respond or acknowledge receipt of the proposed notice and MTDA did not issue a notification of Suspension.*

2018 Corrective Action: MTDA submitted a revised version of its tracking document for issuance of noncompliances. The revisions made include, adding columns to indicate the date when Notices of Proposed Suspension or Revocation are issued, when operation responses are due, and the date Notices of Suspension or Revocation are issued. MTDA submitted the most recent version of this revised NC tracking document to demonstrate that it is in use.

2021 Verification of Corrective Action: The auditors confirmed that the noncompliance tracking

document is being used. However, a review of two files indicated that MTDA is not following the proper adverse action procedure and instead allowing operations to submit corrective actions after the issuance of a proposed suspension.

2023 Corrective Action: MTDA revised the document, *Adverse Actions NONCS Suspension Tracker*, to allow for easier tracking of the adverse action process. Headings now clarify the name of the control point for staff tracking proposed adverse actions.

AIA-3434-20 - Accepted. (NOP-14-18.NC8) 7 C.F.R. §205.663 states, “Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent...If mediation is accepted by the certifying agent, such mediation shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed...Any agreement reached during or as a result of the mediation process shall be in compliance with the Act and the regulations in this part. The Secretary may review any mediated agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part.”

Comments: *The auditor reviewed one mediation request, which was accepted by MTDA and found the following issues:*

1. *A Settlement Agreement was sent to the operator following their written request for mediation, but MTDA did not indicate the mediation request was accepted.*
2. *A Settlement Agreement was offered to the operator but did not include information indicating the operator could reject the agreement or continue discussions with MTDA.*
3. *The Settlement Agreement did not include signatures of both parties (MTDA and operator).*

2018 Corrective Action: MTDA submitted a revised template for its Settlement Agreement Proposal letter. The revised template has language to indicate that MTDA has accepted the operation’s request for mediation; states that the operation can reject the proposed settlement and continue discussions with MTDA

2021 Verification of Corrective Action: The auditors were unable to verify this corrective action as there have been no requests for mediation or settlement agreements issued since the previous audit. Interviews with certification staff indicate that additional training is needed on the adverse action process. The implementation of this corrective action needs to be verified at the next audit.

AIA-3436-20 - Accepted. (NOP-14-18.NC10) 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part...” Specifically, § “205.304(a)(1)(ii) Packaged products labeled "made with organic (specified ingredients or food group(s)).

Agricultural products in packages described in § 205.301(c) may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product: “Made with organic (specified food groups)”: Provided, That, the statement does not list more than three of the following food groups: beans, fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables or processed milk products; and, Provided further, That, all ingredients of each listed food group in the product must be organically produced;...” NOP 5032 Section 3.4 states, “If a food group is identified in the “made with organic ***” statement:...It must be a truthful claim; all raw and processed forms of ingredients in that category must be certified

organic.”

Comments: *The review of approved product labels revealed that MTDA incorrectly approved “made with organic oils” on product labels which included non-organic essential oils in the composition. In addition, MTDA’s label review checklist does not include the verification of labeling requirements for labels of products in the “made with organic specified ingredients or food group(s).”*

2018 Corrective Action: MTDA submitted a revised label review checklist that includes correct verification of all labeling requirements for “made with organic” products. MTDA will use this revised checklist for reviewing “made with organic” product labels to ensure compliant approvals in the future.

2021 Verification of Corrective Action: The auditors' review of handlers producing products making the "made with organic" labeling claim found that the issue still remains. The labels in question have not been corrected. MTDA assessed these labels against the label worksheet, but did not identify the noncompliance. In addition, MTDA’s label worksheet did not reflect a firm understanding of the "made with organic" labeling requirements. MTDA corrected the worksheet was during the audit.

2023 Corrective Action: MTDA updated the document, *Label Review Procedure*, and associated label worksheet used to review product labels. MTDA also reviewed all handler files, including product labels on file, throughout 2022.

AIA-3444-20 - Accepted. (NOP-14-18.NC18) 7 C.F.R. §205.406(a)(1)(ii) states, “To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent: An updated organic production or handling system plan which includes: Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to §205.200;”

Comments: *The auditor’s witness audit and review of one operation’s annual OSP found the annual update did not disclose the following:*

1. *The use of a seed inoculant during the spring 2018 planting (not approved by certifier).*
2. *Planting of nonorganic seed varieties.*
3. *The operation changed the crop planting/rotation practices to include intercropping.*
4. *Adding calves to organic herd from nonorganic cows purchased in Jan 2018.*

2018 Corrective Action: MTDA submitted a revised Initial Review Procedure and a revised Inspection Procedure. The revised procedures add new steps that the initial reviewer and inspector must take to ensure that major components of the OSP that affect compliance are completed/updated before the inspection and that the body of the OSP is updated with any information submitted in the annual update. The revised Inspection Procedure also adds steps to ensure the inspector verifies that he or she has received and reviewed complete OSP information prior to conducting the inspection. To ensure the corrective action is implemented, MTDA will review these revised procedures with staff during its spring 2019 meeting.

2021 Verification of Corrective Action: The auditors' review of the completed OSP's and the annual updates found that both the OSP's and the annual updates did not accurately reflect what was occurring at several of the operations reviewed. The auditors identified several areas in operator OSPs and annual updates that were incomplete or inaccurate, however, these issues were addressed by MTDA during their pre-inspection review, inspection, and post-inspection review. Examples include:

1. One handler file reviewed added a new sanitizer, which is not on the national list, at inspection. However, the operation’s OSP did not include the name of the material, the equipment it is used on, and procedures in place to prevent contamination of organic product.

2. For two other operations who imported ingredients, the annual update was completed for the import section, which asked if there were changes to section B2 in the original OSP. However, section B2 does not exist on current OSP templates in use. Therefore, both the OSP and the update did not capture whether the operation was importing.
3. A certified handling operation's product profile forms were incomplete and stated inaccurate information, however, the operation was not required to update these forms.
4. Another certified handling operation's product profiles forms in the file had not been updated since 2013 and several ingredients of the listed products were listed as certified by a certifier that surrendered its accreditation in 2011.

2023 Corrective Actions: MTDA revised organic system plan (OSP) templates for all scopes to include requests for operations to supply detailed information about imports, exports, organic certificates, ingredients, product profiles, and materials. The MTDA also conducted training in 2020, 2021, and 2022 on the topic of **NOP Instruction 2615 – Organic System Plans (OSP), OSP Updates, and Notification of Changes**. MTDA also expanded the initial review section of the OSP to include specific requirements and regulatory information. MTDA also revised the template *Initial and Final Review Form* to collect additional information on materials and imports.

AIA-5976-21 - Accepted. 7 C.F.R. §205.670(d) states, “A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number.”

Comments: *The auditors' review of MTDA's pesticide residue sampling information found that MTDA did not meet the requirement to sample and test from 5% of its certified operations annually in 2019 and 2020. In these two years, 4.5% of operations were sampled and tested.*

Corrective Action: MTDA will use the total number of certified operations as of January instead of March to calculate the number of operations that need to be sampled from in order to meet the 5% requirement. MTDA sampled from 16 of its 280 certified operations in 2021 (5.7%) and sampled from 16 of its 285 certified operations in 2022 (5.6%). MTDA updated its procedure *Pesticide Residue SOP* to reflect the process change.

AIA-6083-21 - Accepted. 7 C.F.R. §205.501(a)(7) states, “A private or governmental entity accredited as a certifying agent under this subpart must: have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation;”

Comments: *MTDA's annual program review does not fully meet the requirements of NOP 2025 Instruction Internal Program Review and the regulations. The auditor's review of MTDA's 2018 and 2019 annual program review revealed the following issues:*

1. *The annual program review does not evaluate the certifying agent's certification system and procedures.*
2. *The review does not address how any proposed corrective actions will be addressed in a timely and appropriate manner.*
3. *The review does not address prior findings and implemented corrective actions of previous program reviews.*
4. *When findings are identified by program reviewers in file reviews conducted during the annual program review, MTDA does not take appropriate actions to correct the findings, which includes issuing a notification of noncompliance to a certified operation, when*

warranted.

Corrective Action: MTDA updated its procedure *Internal Organic Program Review* to state that (1) the person conducting the program review will review MTDA's quality system documentation, including its quality manual, policy manual and certification files, (2) that the Program Manager is responsible for documenting the "Response to Internal Program Review" and submitting it to the MTDA leadership, (3) that the program review will include 'examining noncompliances from previous audits' and 'verifying actions taken from previously identified corrective and preventative actions,' and (4) that the Program Manager is responsible for responding to findings with documented corrective actions. MTDA submitted copies of its 2020 and 2021 internal program reviews, which it conducted using the **NOP 2005 Accreditation Assessment Checklist**, the *MTDA Internal Program Review Procedure*, *MTDA Internal Program Review Auditor Procedure* and its *Response to Audit Noncompliances* template. Additionally, MTDA is no longer using an internal staff member and state agency auditor for its internal program reviews.

AIA-6084-21 - Accepted. 7 C.F.R. §205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

Comments: *MTDA does not fully implement the NOP's international organic trade arrangement policies and procedures, which are outlined in the NOP's International Trade Policies. The auditors found the following:*

1. *For products exported under the US-Canada Organic Equivalency Arrangement and the US-Japan Equivalency Arrangement, the verification statement that is linked to the individual products on the organic certificate states "COR" instead of "Canada" and "JAS" instead of "Japan", respectively.*
2. *MTDA staff could not demonstrate that they are reviewing and approving all ingredient suppliers and labels for products being exported to Canada.*
3. *During file reviews, the auditors found that a Taiwan export certificate was incorrectly issued for goods being exported to Japan.*

Corrective Action: MTDA implemented revised organic certificate templates, which state "Certified in accordance with the terms of the US-Canada Organic Equivalency Arrangement (USCOEA)" and "Certified in compliance with the terms of the US-Japan Organic Equivalency Arrangement." MTDA updated the form *Handler organic system plan* (OSP) which now includes a section for the initial reviewer to verify an operation's compliance with international marketing and labeling requirements. MTDA also updated the document *Export Certificate Procedure* to include instructions for issuing TM-11s based on the destination of the shipment. MTDA reassigned the responsibility for issuing export documents to another staff member.

AIA-6085-21 - Accepted. 7 C.F.R. §205.662(a) states, "When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation."

Comments: *MTDA did not issue a notification of noncompliance to its certified operations, even though the operations were found to be noncompliant. The auditors review of certification files revealed the following:*

1. *The inspection report of an organic slaughter facility included details of noncompliant practices that were not identified by the reviewers as noncompliances. An operation that was holding organic animals prior to entering the certified organic slaughter facility and feeding*

the organic livestock due to the length of holding, was not certified organic. A notification of noncompliance was not issued to the certified organic slaughter facility. After seeking certification, the same holding operation did not clearly identify the type of feed that was provided to organic animals in its records, which was noted by the inspector. A notification of noncompliance was not issued to the holding operation.

- 2. In two separate organic crop operation files, a MTDA inspector identified that the operation did not conduct a seed search as required by §205.204(a)(1) and NOP 5029. A notification of noncompliance was not issued.*

Corrective Action:

1. MTDA coordinated adjustments and clarification of the ownership flow of product between affected entities. MTDA also issued notices of noncompliance related to this issue after verifying the practices in 2020. MTDA provided evidence demonstrating that the missing information referenced in the noncompliance was received and provided copies of the producer's organic system plan (OSP) showing types of feed planned to be fed. The comments on the exit interview, *Document of Inspection*, are consistent with the OSP. The operation only feeds hay and the DOI states feed logs were submitted.
2. MTDA reviewed organic seed search verification in its producers' certification files and recorded identified issued in a *Seed Search QC Check* table. MTDA issued noncompliances to operations that were not compliant. MTDA also conducted staff training on organic seed search requirements on April 21, 2021

AIA-6086-21 - Accepted. 7 C.F.R. §205.501(a)(5) states “A private or governmental entity accredited as a certifying agent under this subpart must: Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.”

Comments: *MTDA does not consistently ensure that its inspectors have sufficient expertise in organic production or handling techniques prior to performing the duties assigned. The auditors' review of certification files and interviews with certification staff revealed the following:*

- 1. MTDA relies on inspectors to verify suppliers, materials, products, labels, product formulas, and other critical parts of the OSP. Operation files audited were often incomplete and did not fully demonstrate that operations were consistently verified for compliance.*
- 2. The mass balance exercises carried out by inspectors for five of six files reviewed were not adequate. The exercises did not verify whether the quantities of processed products produced and sold were supported by the quantities of organic ingredients received and used.*
- 3. The auditors' review of an OSP of a parallel crop operation found that the operation's organic and conventional fields were not clearly identified in the operation's OSP. Additionally, interviews with MTDA certification staff found that the staff were unable to direct the auditors to where the information could be found in the OSP.*

Corrective Action: MTDA revised templates for crop, livestock and handling organic system plan (OSP) documents and the OSP supplement, *Crop & Acreage Plan*, to direct review staff to verify quality control of suppliers, materials, products, labels, product formulas, and other critical parts of the OSP. MTDA also updated inspection templates, *Audit Crops*, *Audit Handler*, and *Audit Mammalian and Avian*, to include instructions for inspectors verifying information on-site.

AIA-6087-21 - Accepted. 7 C.F.R. §205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with

the requirements for accreditation set forth in this subpart.”

Comments: *MTDA does not demonstrate the ability to fully comply with the requirements for accreditation. The auditors review of certification files and interviews with staff found the following:*

1. *Organic System Plan (OSP) templates do not fully address the requirements of §205.201(a)(3), which require operators to “provide a description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented.”*
2. *MTDA’s Wild Crop Organic System Plan addendum does not include all the required OSP questions listed in **NOP 5022 Wild Crop Harvesting**. Specifically, in NOP 5022 section 5.2 question 5 is not included.*
3. *MTDA does not fully carry out the criteria for private label certification, as required by **NOP PM 11-7 Private Label Certification**. The auditors’ review of certification files found that MTDA approved a label that listed another certifier as the certifier of the product. However, MTDA was unable to confirm whether those products were certified by the other certifier.*
4. *The auditors’ review of the Organic Integrity Database (OID) found that information was inaccurate for an operation that MTDA had suspended. The operation was listed as certified by MTDA in the database.*

Corrective Action:

1. MTDA revised organic system plan (OSP) documents, *Wild Crop OSP* and *Crop OSP*, to include required elements of the OSP related wild crop verification points in **NOP 5022 Wild Crop Harvesting** and frequency of monitoring the OSP in §205.201(a)(3).
2. MTDA revised its document for recording review decisions, *Initial and Final Review*, to remind staff to verify status of products labeled as certified organic by another certifier.
3. MTDA also revised the document, *Adverse Actions NONC Suspension Tracker*, to include a red column header which alerts staff to enter the date Organic Integrity Database is updated.

AIA-6088-21 - Accepted. 7 C.F.R. §205.670(c) states, “A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent at the certifying agent's own expense” and “Sample collection pursuant to paragraphs (b) and (c) of this section must be performed by an inspector representing the Administrator, applicable State organic program's governing State official, or certifying agent. Sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory.”

Comments: *MTDA did not fully carry out the procedures of **NOP 2613 Instruction Responding to Results from Pesticide Residue Testing**.*

1. *For an operation whose organic crop was tested, and no prohibited pesticide residues were detected, MTDA did not send a notification that the product may be sold as organic.*
2. *For another operation whose organic crop was tested, and prohibited substance residue was detected, MTDA did not follow up with any notification to the operation because the operation had tilled their crops into the field.*

Corrective Action: MTDA revised the document, *Negative Test Results Letter*, so the template now includes a statement confirming the sampled product may be sold as organic. MTDA also updated the procedure, *Pesticide Residue Sampling*, to state positive detections of prohibited substances must be

reported to the client when MTDA initiates their investigation of the contamination event.

AIA-1551-22 – Accepted. 7 C.F.R. §205.403(a)(2)(ii) states, “The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.”

Comments: *MTDA did not conduct unannounced inspections of 5% of its total certified operations in 2019, which does not meet the requirements of NOP 2609 Instruction Unannounced Inspections. The auditor’s review of certification files found that 3.8% of operations received an unannounced inspection.*

Corrective Action: MTDA submitted calculations of 2021 and 2022 unannounced inspections to demonstrate a plan for inspecting at least 5% of their operations. MTDA revised the document, *Unannounced Inspection Procedure*, to calculate the number of unannounced inspections based on the total number of clients reported in the Organic Integrity Database as of January of that year.

AIA-1740-22 - Accepted. 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;”

Comments: *MTDA does not consistently carry out the provisions of the Act and regulations. The auditors’ review of certification files revealed the following issues related to organic certificates and product labeling:*

1. *For one file reviewed, MTDA issued an organic certificate listing all of the certified products as 100% Organic, however, not all products listed on the certificate qualified for that labeling claim.*
2. *For several MTDA approved retail labels, the “Certified Organic by***” statement was not located below the information identifying the handler or distributor of the product.*

Corrective Action: MTDA reviewed all handler files and certificates in 2021-2022. The review verified accuracy of 100% organic claims and checked the file organization for current documents, complete information, and correct instances of noncompliant labels. MTDA also revised the document, *Initial and Final Review checklist*, to include reminders for reviewing products, labels, and certificates to ensure they are accurate and current.

Noncompliances Identified during the Current Assessment and Corrective Actions

AIA-6155-23 - Accepted. 7 C.F.R. §205.501(a)(5) states “A private or governmental entity accredited as a certifying agent under this subpart must: Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.”

Comments: *MTDA does not ensure that its inspectors have sufficient expertise to successfully perform inspection duties. The auditors reviewed certification files and found the following:*

1. *MTDA inspectors do not always record verification of ruminant livestock dry matter demand (DMD) and dry matter intake (DMI) values for each class of animals from the operation’s feed fed records during inspection, as required by § 205.237(d)(1)(iii).*
2. *An MTDA inspector did not conduct a mass balance of the total amount of animals that*

were purchased for organic slaughter by a handler that was selling both organic and nonorganic livestock, as required by the January 18, 2023 NOP Livestock Directive.

3. MTDA inspectors incorrectly verify that a minimum of 120 days is grazed instead of verifying grazing for the entire grazing season at ruminant operations, as required by § 205.237(c)(1).

4. MTDA inspectors are not recording verification of the total number of grazing days with the start and end dates of the operation's previous grazing season, per class of animal, or verification of the producer's feed fed records per class of animal per § 205.236 and § 205.237.

5. During a witness audit of a livestock operation's annual inspection, the NOP auditor observed that the MTDA inspector did not account for a livestock feed in the dry matter intake calculations. Specifically, organic kelp meal was being fed to calving animals, but this feed was not included in the dry matter calculations or feed records for these animals.

Corrective Actions: MTDA updated the template, *Mammalian Livestock Production Operation Profile / OSP*, to include a checkpoint for inspectors to verify dry matter demand and dry matter intake (DMI) from feed fed records for each class of animal. The template also includes a checkpoint for inspectors to verify the grazing period per class of animal and verification of feed components in the ration when calculating DMI during on-site inspections. MTDA also updated the mass balance template, Master All Scopes Audit Template, to include a section for verifying the inventory of animals during livestock handler audits.

AIA-6156-23 - Accepted. 7 C.F.R. §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;"

Comments: MTDA does not consistently carry out the provisions of the Act and regulations. The auditors reviewed certification files and found that MTDA does not communicate the reason for unannounced inspections to its certified operations as required by **NOP 2609 Unannounced Inspections**.

Corrective Actions: MTDA will record the type of unannounced inspection conducted on the exit interview form, *Document of Inspection*, with a section of the form for the inspector to confirm they have notified the client of the reason for the unannounced inspection. MTDA will train inspectors regarding the updated process to use the updated form in May 2024.

AIA-6157-23 - Accepted. 7 C.F.R. §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;"

Comments: MTDA does not consistently carry out the provisions of the Act and regulations. The auditors reviewed certification files and found that MTDA does not always perform a sufficient review of material inputs to verify compliance with § 205.201(a)(2) and § 205.105. Additionally, MTDA does not always maintain documentation to support its determinations about a product's compliance with the regulations.

Corrective Actions: MTDA revised the procedure, *Material Review and Approval*, to require the use of the new *Material Log* spreadsheet. The log documents each material review and is available to assist inspectors in verifying the status of materials reviewed by MTDA staff for each client's organic system plan. In May and June 2024, staff will train on the topic of documenting and tracking material reviews when organic system plans are found to be inaccurate or incomplete.

AIA-6158-23 - Accepted. 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;”

Comments: *MTDA does not fully implement the NOP’s international organic trade arrangement policies and procedures, as outlined in the NOP’s International Trade Policies resources. The auditors reviewed certification files and found that MTDA does not use the correct attestation statement on TM-11 export certificates for Japan.*

Corrective Actions: MTDA developed a template version of the TM-11 to show staff the correct use of the attestation phrase, “Certified in compliance with the terms of ...” MTDA also updated its internal tracking document, *Export Control Log TM-11.NAQS*, for staff to confirm the template version of the TM-11 was referenced when generating each export certificate.

AIA-6159-23 - Accepted. 7 C.F.R. §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;”

Comments: *MTDA does not have a sufficient number of personnel to implement its USDA organic certification program. The auditors interviewed the Organic Program Manager who stated MTDA does not have enough adequately trained personnel to conduct all certification activities in a timely and thorough manner. MTDA does not have the necessary staff to review operation files, resulting in insufficient oversight of certified operations.*

Corrective Actions: MTDA will reduce the geographic area where it offers certification services as of April 25, 2024, for producers and September 15, 2024, for handlers. MTDA notified clients impacted by the reduction in services in a letter sent October 2, 2023. MTDA conducted staff training on May 16, 2023, on the topic of workflows and their *Organic Master Calendar* and discussed the expectations of timeliness of work, including adverse actions and the inspection calendar.

AIA-6160-23 - Accepted. 7 C.F.R. §205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.”

Comments: *MTDA does not demonstrate the ability to fully comply with the requirements for accreditation. MTDA’s livestock and handling organic system plan (OSP) templates do not require sufficient information to determine an operation’s compliance with the USDA organic regulations. The auditors’ review of certification files identified that MTDA’s OSPs do not require operations to provide enough detail for the following:*

- 1. A description of how the operation complies with the livestock regulations, including health treatments and inputs, per § 205.236 through § 205.239.*
- 2. A description of how the operation complies with livestock regulations for livestock handling operations in § 205.236 through § 205.239.*
- 3. A description of the entire grazing season.*
- 4. A description of shade and shelter.*
- 5. A full description of how slaughter animals are transported.*
- 6. Complete information required by the new origin of livestock regulation that was implemented on April 5, 2023.*

Corrective Actions: MTDA submitted a description of how they comply with the requirements with supporting documentation of their plan for livestock and livestock handling operations. MTDA revised organic system plan (OSP) forms to capture descriptions of the grazing season, livestock living conditions, and animal transport. MTDA received copies of completed OSP forms from dairy operations for MTDA to verify compliance of their activities in 2023-2024.

AIA-6161-23 - Accepted. 7 C.F.R. §205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.”

Comments: *MTDA does not consistently demonstrate the ability to fully comply with the requirements for accreditation. The auditors interviewed MTDA staff and reviewed certification files found that MTDA did not conduct mediation or enter into a settlement agreement with an operation after accepting the operation’s request for mediation. Instead of following the mediation process after accepting the request for mediation, MTDA accepted the operation’s corrective actions and issued a resolution of notification of noncompliance. Additionally, MTDA does not have a compliant procedure for conducting mediation and does not have a procedure for establishing settlement agreements as a result of mediation. MTDA also does not have criteria for accepting or rejecting mediation requests.*

Corrective Actions: MTDA developed a procedure for processing mediation requests, *Mediation/Mediation Requests and Settlement Agreements*. The procedure includes criteria for accepting or rejecting mediation requests and a reminder for staff to reach a settlement agreement within 30 days of conducting mediation. MTDA updated the internal form, *Adverse Actions NONC Suspension Tracker*, to include a column on the spreadsheet for staff to confirm the procedure was referenced when reviewing mediation requests.

AIA-6163-23 - Accepted. 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;”

Comments: *MTDA does not consistently carry out the provisions of the Act and regulations. The auditors’ review of certification files found that MTDA did not sufficiently verify an operation’s compliance with § 205.201(a)(2) and § 205.105 in the following manner:*

- 1. MTDA did not verify that dry matter intake (DMI) ration worksheets were calculated using the operation’s entire grazing season and that there was a ration worksheet for each class of animal, except for calves under 6 months of age.*
- 2. MTDA did not verify that operations had sufficient measures to prevent commingling/contamination on shared equipment used for organic and non-organic production.*
- 3. MTDA conducted an audit of a handler that traced the purchase of cattle to an uncertified supplier. Despite the lack of certification, MTDA noted in its audit that the supplier’s organic certificate had been verified. MTDA’s final reviewer, without records, then verified that the audit was “fully successful.”*
- 4. MTDA did not verify that a livestock operation maintained an animal inventory identifying which animals are eligible for organic slaughter.*

Corrective Actions: MTDA completed dry matter intake (DMI) calculations for all livestock operations in 2023. MTDA revised the Mammalian Livestock organic system plan (OSP) so producers now report applicable commingling prevention measures for feed equipment. MTDA plans

to conduct training in May 2024 on the topic of successful supply chain audits. MTDA also required livestock operations to submit herd lists with individual animal identification in 2023. In 2024, MTDA will require operators to specifically identify animals eligible for organic slaughter. MTDA expects the OSP to track treated animals and this information will be verified during the annual inspection.

AIA-6164-23 - Accepted. 7 C.F.R. §205.406(c) states, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.”

Comments: *MTDA did not issue its certified operation a notification of noncompliance even though a review of records and documents revealed that the operation did not comply with the USDA organic regulations. The auditors reviewed certification files and supporting documentation and found that a livestock handling operation’s organic system plan (OSP) listed four uncertified suppliers, one of which was sourcing organic slaughter eligible cattle. MTDA did not issue the operation a notification of noncompliance for using uncertified suppliers or for failure to maintain documentation of organic slaughter eligibility for processed animals.*

Corrective Actions: MTDA created templates for new forms, *Supplier Product / Ingredient List Addendum* and *Ruminant Animal Attestation & Handler Animal Slaughter Addendum*, which were sent to all associated handler operations in February 2024 and completed as part of the annual renewal process. MTDA also updated the template, *Mammalian Livestock Production Operation Profile / OSP*, to include a checkpoint for inspectors to verify supplier list requirements reported on the new addendums.

AIA-6874-23 - Accepted. 7 C.F.R. §205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.”

Comments: *MTDA does not consistently demonstrate the ability to fully comply with the requirements for accreditation. The auditors review of certification files and interviews with staff found that an inspection report for a handling operation included an update to the organic system plan (OSP) that stated, “When the client makes a purchase of live animals, that load is accompanied by a traceability packet, which includes ear tag numbers and organic certificates. This information is stored in Dropbox along with production data for each specific lot.” MTDA did not verify that the traceability packets assembled by the operation were complete and therefore did not verify the records of the cattle that were purchased by the handler documented the origin of the animals or the organic eligibility for slaughter.*

Corrective Actions: MTDA updated OSP forms, *Supplier Product / Ingredient List Addendum* and *Ruminant Animal Attestation & Handler Animal Slaughter Addendum*. MTDA sent copies of these forms to producers in February 2024 and MTDA expects completed forms to be returned with the 2024 renewal paperwork. MTDA scheduled staff training for May 2024 and will cover the policies for documenting what is to be verified at inspection and expectations for supply chain audits.

AIA-6875-23 - Accepted. 7 C.F.R. §205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.”

Comments: *MTDA does not consistently demonstrate the ability to fully comply with the requirements for accreditation. The auditors review of certification files and interviews with staff found that MTDA initial and final reviewers accepted incomplete or inaccurate organic system plans (OSP) and did not require the operations to provide the missing information. OSPs for two handling operations did not include all ingredients used in production of organic products, a list of all material inputs, and labels for all products listed on the organic certificate.*

Corrective Actions: MTDA will update the organic system plan (OSP) for handler operations by June 2024 to collect more information about materials and labels. The revised format will include specific questions for the inspector to verify. MTDA also collected completed versions of a revised form, *Handler/Broker OSP Addendum-Product/Ingredient/Supplier List*, in 2023. MTDA revised an additional form, *Supplier Ingredient Addendum*, to capture information on operation's current activities. In May and June 2024, MTDA will train staff on the topic of expectations for initial and final review of inaccurate or incomplete organic system plans.

AIA-6876-23 - Accepted. 7 C.F.R. §205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

Comments: *MTDA does not have criteria for staff qualifications as required by NOP 2027 Instruction Personnel Performance Evaluations specifically, a defined competency system that assesses technical and interpersonal competencies, including whether personnel have sufficient expertise in organic production or handling techniques, the ability to work competently and effectively with clients and colleagues, and knowledge of the USDA organic regulations applicable to perform the duties assigned.*

Corrective Actions: MTDA is developing a competency system and will begin implementing the system in 2024. The new document, *Staff training Assessment Criteria Model*, is now included with the personnel file training requirements. MTDA will document all training conducted in the revised *Organic Training Record Calculator*, as outlined in the Training Assessment Criteria.

NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

GENERAL INFORMATION

- **Certifier Name** Montana Department of Agriculture (MTDA)
- **Physical Address** 302 North Roberts Street, Helena, Montana 59601
- **Audit Type** Mid-term Audit (Desk Audit)
- **Auditor(s) & Audit Dates** Joshua Lindau & Jessica Walden, 03/01/2021 to 03/05/2021
- **Audit Identifier** NOP-7-21

CERTIFIER OVERVIEW

The Montana State Department of Agriculture (MTDA) is a state government agency originally accredited by the USDA National Organic Program (NOP) on April 29, 2002, to conduct organic certification for the crops, wild crops, livestock, and handling scopes. MTDA conducts NOP certification activities from its main office located in Helena, Montana.

As of January 2021, MTDA certifies 317 operations to the following scopes: 243 Crops, 2 Wild Crops, 24 Livestock and 74 Handling/Processing. MTDA does not currently certify any grower groups. Most of the operations that MTDA certifies are in Montana with some operations in Idaho, North Dakota, Wyoming.

MTDA's 13 NOP certification staff include five independent contracted inspectors (two of independent contracted inspectors also are final reviewers) and two contract final reviewers. MTDA also has a half FTE for administrative staff and a program manager.

NOP DETERMINATION:

NOP reviewed the audit results to determine whether MTDA's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the audit.

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Accepted**" indicates acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next audit.

Noncompliances from Prior Assessments

AIA-3429-20 - Cleared.

AIA-3430-20 - Cleared.

AIA-3431-20 - Cleared.

AIA-3432-20 - Cleared.

AIA-3435-20 - Cleared.

AIA-3437-20 - Cleared.

AIA-3438-20 - Cleared.

AIA-3439-20 - Cleared.

AIA-3440-20 - Cleared.

AIA-3441-20 - Cleared.

AIA-3442-20 - Cleared.

AIA-3443-20 - Cleared.

AIA-3434-20 - Accepted. (NOP-14-18.NC8) 7 C.F.R. §205.663 states, "Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent...If mediation is accepted by the certifying agent, such mediation shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed...Any agreement reached during or as a result of the mediation process shall be in compliance with the Act and the regulations in this part. The Secretary may review any mediated agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part."

Comments: *The auditor reviewed one mediation request, which was accepted by MTDA and found the following issues:*

- 1. A Settlement Agreement was sent to the operator following their written request for mediation, but MTDA did not indicate the mediation request was accepted.*
- 2. A Settlement Agreement was offered to the operator but did not include information indicating the operator could reject the agreement or continue discussions with MTDA.*

3. *The Settlement Agreement did not include signatures of both parties (MTDA and operator).*

2018 Corrective Action: MTDA submitted a revised template for its Settlement Agreement Proposal letter. The revised template has language to indicate that MTDA has accepted the operation's request for mediation; states that the operation can reject the proposed settlement and continue discussions with MTDA

2021 Verification of Corrective Action: The auditors were unable to verify this corrective action as there have been no requests for mediation or settlement agreements issued since the previous audit. Interviews with certification staff indicate that additional training is needed on the adverse action process. The implementation of this corrective action needs to be verified at the next audit.

AIA-3427-20 – Accepted. (NOP-14-18.NC1) 7 C.F.R. §205.403(c)(1) states, “The onsite inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations in this part;”

Comments: *During the witness audit of an annual handling inspection, the auditor observed that the inspector did not fully verify the operation's compliance with the regulations. Areas of compliance not fully verified included the following:*

1. *Verification of inputs approved for use in the operation's OSP (Organic System Plan) by reviewing the inputs available onsite.*
2. *Verification of valid organic certification for all organic suppliers. The inspector only verified organic certification by reviewing certificates for the incoming ingredients of the products used to conduct the trace-back and mass balance audit activities.*
3. *Documentation for exports according to trade arrangements the USDA-NOP.*
4. *Labels being used match those approved by and on file with MTDA.*

2018 Corrective Action: MTDA scheduled a training on October 22, 2018 for handling inspectors. The training focused on what inspectors must do during inspections to verify inputs, supplier organic certification, export documentation, and labels against the OSP and other application documentation. The training covered methods inspectors could use to ensure that these items are consistently verified. To prevent recurrence of this noncompliance, MTDA will conduct evaluations for handling inspectors during 2019.

2021 Verification of Corrective Action: The auditors' review found that MTDA inspectors are not verifying operations' OSPs for compliance at inspection. The review of six handler inspection reports reviewed by the auditors, as well as interviews with certification staff, indicated that MTDA inspectors are not always verifying the operation's compliance. Inspectors are not verifying that operations are meeting the requirements for imported and exported products and ingredients. For one certified handler file reviewed, product profiles listed "NOP" and "COR" as the certifier of organic suppliers. In addition, the labels attached to the product profiles were noncompliant with NOP labeling requirements and were not the MTDA-approved labels. The inspector did not report on these discrepancies, and the same inaccuracies were found in the OSP. The auditors also found that inspectors are not fully or accurately completing the

MTDA mass balance and traceback forms.

2023 Corrective Action: MTDA conducted training on the topics of verifying import and export requirements, mass balance and traceback audit forms, and product profiles and labels. MTDA revised the forms to include reminders to verify requirements for imports, exports, labels, and product profiles. MTDA also update its internal checklist to verify requirements, *Initial & Final Review Form*, to contain a crosscheck of product profile and label requirements between the initial review, inspection, final review, and final approval stage of the certification process. MTDA also reviewed all handling operator files in 2022 to verify labeling requirements and accuracy of documents.

AIA-3428-20 – Accepted. (NOP-14-18.NC2) 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670.” Specifically, § 205.201(a)(6) states, “An organic production or handling system plan must include: Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.”

Comments: *MTDA’s organic system plan templates do not require operations to provide information regarding use of organic product(s) imported under USDA international organic trade arrangements. MTDA’s application and handling organic system plan templates are currently limited to asking operations to provide information regarding export of products.*

2018 Corrective Action: MTDA submitted revisions to its organic handling application, handling OSP, and handling OSP update that include questions about whether operations import organic product and the country of origin. Beginning in 2019, renewing handlers will complete the revised handler application and OSP update. New handlers will complete the revised handler OSP.

2021 Verification of Corrective Action: All of the handlers reviewed were still using OSP templates that did not ask questions regarding imported products or ingredients. Interviews with certification staff confirmed that new OSP templates have not been sent to currently certified operations, only to new applicants. The auditors reviewed the new OSP template and identified that additional questions are needed in order to capture the country-specific verification points for imported products.

2023 Corrective Action: MTDA updated it template, *Handler organic system plan*, in 2021 and then required all handlers to update their plan using the most current version of the form in 2022. In 2021, MTDA revised the letter, *Handler Inspection Notification*, to inform clients and inspectors of import and export requirements that would be verified at the next inspection. MTDA also revised the document, *Internal Program Review Auditor Procedure*, to include an annual check that import and export requirements are being verified at inspection.

AIA-3433-20 - Accepted. (NOP-14-18.NC7) 7 C.F.R. §205.662(e) states, “If the certified operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of suspension or revocation.”

Comments:

1. *The auditor reviewed two Notices of Proposed Revocation where the operations did not respond or acknowledge receipt of the proposed notices and MTDA did not issue Notifications of Revocation.*
2. *The auditor reviewed one Notice of Proposed Suspension where the operation did not respond or acknowledge receipt of the proposed notice and MTDA did not issue a notification of Suspension.*

2018 Corrective Action: MTDA submitted a revised version of its tracking document for issuance of noncompliances. The revisions made include, adding columns to indicate the date when Notices of Proposed Suspension or Revocation are issued, when operation responses are due, and the date Notices of Suspension or Revocation are issued. MTDA submitted the most recent version of this revised NC tracking document to demonstrate that it is in use.

2021 Verification of Corrective Action: The auditors confirmed that the noncompliance tracking document is being used. However, a review of two files indicated that MTDA is not following the proper adverse action procedure and instead allowing operations to submit corrective actions after the issuance of a proposed suspension.

2023 Corrective Action: MTDA revised the document, *Adverse Actions NONCS Suspension Tracker*, to allow for easier tracking of the adverse action process. Headings now clarify the name of the control point for staff tracking proposed adverse actions.

AIA-3436-20 - Accepted. (NOP-14-18.NC10) 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part...” Specifically, § “205.304(a)(1)(ii) Packaged products labeled "made with organic (specified ingredients or food group(s)).

Agricultural products in packages described in § 205.301(c) may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product: “Made with organic (specified food groups)”: Provided, That, the statement does not list more than three of the following food groups: beans, fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables or processed milk products; and, Provided further, That, all ingredients of each listed food group in the product must be organically produced;...” NOP 5032 Section 3.4 states, “If a food group is identified in the “made with organic ***” statement:...It must be a truthful claim; all raw and processed forms of ingredients in that category must be certified organic.”

Comments: *The review of approved product labels revealed that MTDA incorrectly approved “made with organic oils” on product labels which included non-organic essential oils in the composition. In addition, MTDA’s label review checklist does not include the verification of labeling requirements for labels of products in the “made with organic specified ingredients or food group(s)).”*

2018 Corrective Action: MTDA submitted a revised label review checklist that includes correct verification of all labeling requirements for “made with organic” products. MTDA will use this revised checklist for reviewing “made with organic” product labels to ensure compliant

approvals in the future.

2021 Verification of Corrective Action: The auditors' review of handlers producing products making the "made with organic" labeling claim found that the issue still remains. The labels in question have not been corrected. MTDA assessed these labels against the label worksheet, but did not identify the noncompliance. In addition, MTDA's label worksheet did not reflect a firm understanding of the "made with organic" labeling requirements. MTDA corrected the worksheet was during the audit.

2023 Corrective Action: MTDA updated the document, *Label Review Procedure*, and associated label worksheet used to review product labels. MTDA also reviewed all handler files, including product labels on file, throughout 2022.

AIA-3444-20 - Accepted. (NOP-14-18.NC18) 7 C.F.R. §205.406(a)(1)(ii) states, "To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent: An updated organic production or handling system plan which includes: Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to §205.200;"

Comments: *The auditor's witness audit and review of one operation's annual OSP found the annual update did not disclose the following:*

1. *The use of a seed inoculant during the spring 2018 planting (not approved by certifier).*
2. *Planting of nonorganic seed varieties.*
3. *The operation changed the crop planting/rotation practices to include intercropping.*
4. *Adding calves to organic herd from nonorganic cows purchased in Jan 2018.*

2018 Corrective Action: MTDA submitted a revised Initial Review Procedure and a revised Inspection Procedure. The revised procedures add new steps that the initial reviewer and inspector must take to ensure that major components of the OSP that affect compliance are completed/updated before the inspection and that the body of the OSP is updated with any information submitted in the annual update. The revised Inspection Procedure also adds steps to ensure the inspector verifies that he or she has received and reviewed complete OSP information prior to conducting the inspection. To ensure the corrective action is implemented, MTDA will review these revised procedures with staff during its spring 2019 meeting.

2021 Verification of Corrective Action: The auditors' review of the completed OSP's and the annual updates found that both the OSP's and the annual updates did not accurately reflect what was occurring at several of the operations reviewed. The auditors identified several areas in operator OSPs and annual updates that were incomplete or inaccurate, however, these issues were addressed by MTDA during their pre-inspection review, inspection, and post-inspection review. Examples include:

1. One handler file reviewed added a new sanitizer, which is not on the national list, at inspection. However, the operation's OSP did not include the name of the material, the equipment it is used on, and procedures in place to prevent contamination of organic product.
2. For two other operations who imported ingredients, the annual update was completed for

the import section, which asked if there were changes to section B2 in the original OSP. However, section B2 does not exist on current OSP templates in use. Therefore, both the OSP and the update did not capture whether the operation was importing.

3. A certified handling operation's product profile forms were incomplete and stated inaccurate information, however, the operation was not required to update these forms.
4. Another certified handling operation's product profiles forms in the file had not been updated since 2013 and several ingredients of the listed products were listed as certified by a certifier that surrendered its accreditation in 2011.

2023 Corrective Actions: MTDA revised organic system plan (OSP) templates for all scopes to include requests for operations to supply detailed information about imports, exports, organic certificates, ingredients, product profiles, and materials. The MTDA also conducted training in 2020, 2021, and 2022 on the topic of **NOP Instruction 2615 – Organic System Plans (OSP), OSP Updates, and Notification of Changes**. MTDA also expanded the initial review section of the OSP to include specific requirements and regulatory information. MTDA also revised the template *Initial and Final Review Form* to collect additional information on materials and imports.

Noncompliances Identified during the Current Assessment

AIA-5976-21 - Accepted. 7 C.F.R. §205.670(d) states, “A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number.”

Comments: *The auditors' review of MTDA's pesticide residue sampling information found that MTDA did not meet the requirement to sample and test from 5% of its certified operations annually in 2019 and 2020. In these two years, 4.5% of operations were sampled and tested.*

Corrective Action: MTDA will use the total number of certified operations as of January instead of March to calculate the number of operations that need to be sampled from in order to meet the 5% requirement. MTDA sampled from 16 of its 280 certified operations in 2021 (5.7%) and sampled from 16 of its 285 certified operations in 2022 (5.6%). MTDA updated its procedure *Pesticide Residue SOP* to reflect the process change.

AIA-6083-21 - Accepted. 7 C.F.R. §205.501(a)(7) states, “A private or governmental entity accredited as a certifying agent under this subpart must: have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation;”

Comments: *MTDA's annual program review does not fully meet the requirements of NOP 2025 Instruction Internal Program Review and the regulations. The auditor's review of MTDA's 2018 and 2019 annual program review revealed the following issues:*

1. *The annual program review does not evaluate the certifying agent's certification system and procedures.*

2. *The review does not address how any proposed corrective actions will be addressed in a timely and appropriate manner.*
3. *The review does not address prior findings and implemented corrective actions of previous program reviews.*
4. *When findings are identified by program reviewers in file reviews conducted during the annual program review, MTDA does not take appropriate actions to correct the findings, which includes issuing a notification of noncompliance to a certified operation, when warranted.*

Corrective Action: MTDA updated its procedure *Internal Organic Program Review* to state that (1) the person conducting the program review will review MTDA’s quality system documentation, including its quality manual, policy manual and certification files, (2) that the Program Manager is responsible for documenting the “Response to Internal Program Review” and submitting it to the MTDA leadership, (3) that the program review will include ‘examining noncompliances from previous audits’ and ‘verifying actions taken from previously identified corrective and preventative actions,’ and (4) that the Program Manager is responsible for responding to findings with documented corrective actions. MTDA submitted copies of its 2020 and 2021 internal program reviews, which it conducted using the **NOP 2005 Accreditation Assessment Checklist**, the *MTDA Internal Program Review Procedure*, *MTDA Internal Program Review Auditor Procedure* and its *Response to Audit Noncompliances* template. Additionally, MTDA is no longer using an internal staff member and state agency auditor for its internal program reviews.

AIA-6084-21 - Accepted. 7 C.F.R. §205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.”

Comments: *MTDA does not fully implement the NOP’s international organic trade arrangement policies and procedures, which are outlined in the NOP’s International Trade Policies. The auditors found the following:*

1. *For products exported under the US-Canada Organic Equivalency Arrangement and the US-Japan Equivalency Arrangement, the verification statement that is linked to the individual products on the organic certificate states “COR” instead of “Canada” and “JAS” instead of “Japan”, respectively.*
2. *MTDA staff could not demonstrate that they are reviewing and approving all ingredient suppliers and labels for products being exported to Canada.*
3. *During file reviews, the auditors found that a Taiwan export certificate was incorrectly issued for goods being exported to Japan.*

Corrective Action: MTDA implemented revised organic certificate templates, which state “Certified in accordance with the terms of the US-Canada Organic Equivalency Arrangement (USCOEA)” and “Certified in compliance with the terms of the US-Japan Organic Equivalency Arrangement.” MTDA updated the form *Handler organic system plan* (OSP) which now includes a section for the initial reviewer to verify an operation’s compliance with international marketing and labeling requirements. MTDA also updated the document *Export Certificate Procedure* to include instructions for issuing TM-11s based on the destination of the shipment.

MTDA reassigned the responsibility for issuing export documents to another staff member.

AIA-6085-21 - Accepted. 7 C.F.R. §205.662(a) states, “When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation.”

Comments: *MTDA did not issue a notification of noncompliance to its certified operations, even though the operations were found to be noncompliant. The auditors review of certification files revealed the following:*

- 1. The inspection report of an organic slaughter facility included details of noncompliant practices that were not identified by the reviewers as noncompliances. An operation that was holding organic animals prior to entering the certified organic slaughter facility and feeding the organic livestock due to the length of holding, was not certified organic. A notification of noncompliance was not issued to the certified organic slaughter facility. After seeking certification, the same holding operation did not clearly identify the type of feed that was provided to organic animals in its records, which was noted by the inspector. A notification of noncompliance was not issued to the holding operation.*
- 2. In two separate organic crop operation files, a MTDA inspector identified that the operation did not conduct a seed search as required by §205.204(a)(1) and NOP 5029. A notification of noncompliance was not issued.*

Corrective Action:

1. MTDA coordinated adjustments and clarification of the ownership flow of product between affected entities. MTDA also issued notices of noncompliance related to this issue after verifying the practices in 2020. MTDA provided evidence demonstrating that the missing information referenced in the noncompliance was received and provided copies of the producer’s organic system plan (OSP) showing types of feed planned to be fed. The comments on the exit interview, *Document of Inspection*, are consistent with the OSP. The operation only feeds hay and the DOI states feed logs were submitted.
2. MTDA reviewed organic seed search verification in its producers’ certification files and recorded identified issued in a *Seed Search QC Check* table. MTDA issued noncompliances to operations that were not compliant. MTDA also conducted staff training on organic seed search requirements on April 21, 2021

AIA-6086-21 - Accepted. 7 C.F.R. §205.501(a)(5) states “A private or governmental entity accredited as a certifying agent under this subpart must: Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.”

Comments: *MTDA does not consistently ensure that its inspectors have sufficient expertise in organic production or handling techniques prior to performing the duties assigned. The auditors’ review of certification files and interviews with certification staff revealed the following:*

- 1. MTDA relies on inspectors to verify suppliers, materials, products, labels, product formulas, and other critical parts of the OSP. Operation files audited were often incomplete and did not fully demonstrate that operations were consistently verified for compliance.*

2. *The mass balance exercises carried out by inspectors for five of six files reviewed were not adequate. The exercises did not verify whether the quantities of processed products produced and sold were supported by the quantities of organic ingredients received and used.*
3. *The auditors' review of an OSP of a parallel crop operation found that the operation's organic and conventional fields were not clearly identified in the operation's OSP. Additionally, interviews with MTDA certification staff found that the staff were unable to direct the auditors to where the information could be found in the OSP.*

Corrective Action: MTDA revised templates for crop, livestock and handling organic system plan (OSP) documents and the OSP supplement, *Crop & Acreage Plan*, to direct review staff to verify quality control of suppliers, materials, products, labels, product formulas, and other critical parts of the OSP. MTDA also updated inspection templates, *Audit Crops*, *Audit Handler*, and *Audit Mammalian and Avian*, to include instructions for inspectors verifying information on-site.

AIA-6087-21 - Accepted. 7 C.F.R. §205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.”

Comments: *MTDA does not demonstrate the ability to fully comply with the requirements for accreditation. The auditors review of certification files and interviews with staff found the following:*

1. *Organic System Plan (OSP) templates do not fully address the requirements of §205.201(a)(3), which require operators to “provide a description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented.”*
2. *MTDA's Wild Crop Organic System Plan addendum does not include all the required OSP questions listed in **NOP 5022 Wild Crop Harvesting**. Specifically, in NOP 5022 section 5.2 question 5 is not included.*
3. *MTDA does not fully carry out the criteria for private label certification, as required by **NOP PM 11-7 Private Label Certification**. The auditors' review of certification files found that MTDA approved a label that listed another certifier as the certifier of the product. However, MTDA was unable to confirm whether those products were certified by the other certifier.*
4. *The auditors' review of the Organic Integrity Database (OID) found that information was inaccurate for an operation that MTDA had suspended. The operation was listed as certified by MTDA in the database.*

Corrective Action:

1. MTDA revised organic system plan (OSP) documents, *Wild Crop OSP* and *Crop OSP*, to include required elements of the OSP related wild crop verification points in **NOP 5022 Wild Crop Harvesting** and frequency of monitoring the OSP in §205.201(a)(3).
2. MTDA revised its document for recording review decisions, *Initial and Final Review*, to remind staff to verify status of products labeled as certified organic by another certifier.
3. MTDA also revised the document, *Adverse Actions NONC Suspension Tracker*, to include a red column header which alerts staff to enter the date Organic Integrity Database is updated.

AIA-6088-21 - Accepted. 7 C.F.R. §205.670(c) states, “A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent at the certifying agent's own expense” and “Sample collection pursuant to paragraphs (b) and (c) of this section must be performed by an inspector representing the Administrator, applicable State organic program's governing State official, or certifying agent. Sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory.”

Comments: *MTDA did not fully carry out the procedures of NOP 2613 Instruction Responding to Results from Pesticide Residue Testing.*

1. *For an operation whose organic crop was tested, and no prohibited pesticide residues were detected, MTDA did not send a notification that the product may be sold as organic.*
2. *For another operation whose organic crop was tested, and prohibited substance residue was detected, MTDA did not follow up with any notification to the operation because the operation had tilled their crops into the field.*

Corrective Action: MTDA revised the document, *Negative Test Results Letter*, so the template now includes a statement confirming the sampled product may be sold as organic. MTDA also updated the procedure, *Pesticide Residue Sampling*, to state positive detections of prohibited substances must be reported to the client when MTDA initiates their investigation of the contamination event.

AIA-1551-22 – Accepted. 7 C.F.R. §205.403(a)(2)(ii) states, “The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.”

Comments: *MTDA did not conduct unannounced inspections of 5% of its total certified operations in 2019, which does not meet the requirements of NOP 2609 Instruction Unannounced Inspections. The auditor’s review of certification files found that 3.8% of operations received an unannounced inspection.*

Corrective Action: MTDA submitted calculations of 2021 and 2022 unannounced inspections to demonstrate a plan for inspecting at least 5% of their operations. MTDA revised the document, *Unannounced Inspection Procedure*, to calculate the number of unannounced inspections based on the total number of clients reported in the Organic Integrity Database as of January of that year.

AIA-1740-22 - Accepted. 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;”

Comments: *MTDA does not consistently carry out the provisions of the Act and regulations. The auditors’ review of certification files revealed the following issues related to organic certificates and product labeling:*

1. *For one file reviewed, MTDA issued an organic certificate listing all of the certified products as 100% Organic, however, not all products listed on the certificate qualified for that labeling claim.*
2. *For several MTDA approved retail labels, the “Certified Organic by***” statement was not located below the information identifying the handler or distributor of the product.*

Corrective Action: MTDA reviewed all handler files and certificates in 2021-2022. The review verified accuracy of 100% organic claims and checked the file organization for current documents, complete information, and correct instances of noncompliant labels. MTDA also revised the document, *Initial and Final Review checklist*, to include reminders for reviewing products, labels, and certificates to ensure they are accurate and current.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite renewal assessment of the Montana Department of Agriculture (MTDA) organic program was conducted on July 16-20, 2018. The National Organic Program (NOP) reviewed the auditor's report to assess MTDA compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	Montana Department of Agriculture
Physical Address	302 North Roberts Street, Helena, Montana 59620
Mailing Address	302 North Roberts Street, Helena, Montana 59620
Contact & Title	Georgana Webster, Program Manager
E-mail Address	gwebster@mt.gov
Phone Number	406-444-9421
Reviewer(s) & Auditor(s)	Bridget McElroy, NOP Reviewer; Penny Zuck and Jason Lopez, On-site Auditor(s).
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP Corrective Actions Review: November 16, 2018 NOP assessment review: August 10, 2018 Onsite audit: July 16-20, 2018
Audit Identifier	NOP 14-18
Action Required	No
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of MTDA's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	MTDA's certification services in carrying out the audit criteria during the period: June 2014 through July 2018.

MTDA is a state organic certification program that been accredited by the USDA's National Organic Program (NOP) since April 29, 2002 for crops, wild crops, livestock, and handling organic certification.

MTDA currently has 291 operations certified to the USDA NOP standard; 205 for crops, 1 for wild crops, 26 for livestock, and 59 for handling (57 processors, 2 traders/brokers, and 2 retailers). MTDA provides organic certification to operators in Montana, Wyoming, North Dakota, and Idaho. MTDA does not currently certify grower groups.

All of MTDA's certification activities are carried out of the main office in Helena, Montana. MTDA has a satellite office in Missoula, Montana with one staff person who conducts the following activities: client outreach, providing certification materials, conducting field inspector evaluations, application review, inspection report review, inspections, certification decisions, noncompliance and adverse action decisions, review of materials, ingredients, and inputs.

The MTDA certification program staff consists of the Organic Program Manager, the Organic Program Administrative Assistant, 3 Plant Science Specialists, an Agricultural Specialist, a Bureau Chief, an Organic Agriculture Specialist, 6 contract inspectors, and 1 contract reviewer.

During the onsite audit, two witness audits were conducted: one Handling operation in Ulm, MT and one Crop and Livestock operation in Valier, MT.

NOP DETERMINATION

The NOP reviewed MTDA's corrective actions submitted as result of noncompliances issued from findings identified during the onsite audit. Any noncompliance labeled as "**Accepted**" indicates acceptance of the corrective actions and verification of the implementation of those corrective actions will be conducted during the next onsite audit.

Noncompliances Identified during the Current Assessment

NOP-14-18.NC1 – Accepted. 7 C.F.R. §205.403(c)(1) states, "The onsite inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations in this part;"

Comments: *During the witness audit of an annual handling inspection, the auditor observed that the inspector did not fully verify the operation's compliance with the regulations. Areas of compliance not fully verified included the following:*

- 1. Verification of inputs approved for use in the operation's OSP by reviewing the inputs available onsite.*
- 2. Verification of valid organic certification for all organic suppliers. The inspector only verified organic certification by reviewing certificates for the incoming ingredients of the products used to conduct the trace-back and mass balance audit activities.*
- 3. Documentation for exports according to trade arrangements the USDA-NOP.*
- 4. Labels being used match those approved by and on file with MTDA.*

Corrective Action: MTDA scheduled a training on October 22, 2018 for handling inspectors. The training focused on what inspectors must do during inspections to verify inputs, supplier organic certification, export documentation, and labels against the OSP and other application documentation. The training covered methods inspectors could use to ensure that these items are consistently verified. To prevent recurrence of this noncompliance, MTDS will conduct evaluations for handling inspectors during 2019.

NOP-14-18.NC2 – Accepted. 7 C.F.R. §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and

the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670.” Specifically, § 205.201(a)(6) states, “An organic production or handling system plan must include: Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.”

Comments: *MTDA’s organic system plan templates do not require operations to provide information regarding use of organic product(s) imported under USDA international organic trade arrangements. MTDA’s application and handling organic system plan templates are currently limited to asking operations to provide information regarding export of products.*

Corrective Action: MTDA submitted revisions to its organic handling application, handling OSP, and handling OSP update that include questions about whether operations import organic product and the country of origin. Beginning in 2019, renewing handlers will complete the revised handler application and OSP update. New handlers will complete the revised handler OSP.

NOP-14-18.NC3 – Accepted. 7 C.F.R. §205.642 states, “...The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification...”

Comments: *MTDA’s current estimate provided to all operations contains the full range of cost per the fee schedule and is the same for all operations. Individual estimates are not provided based on the operation’s organic production activities.*

Corrective Action: MTDA submitted revisions to the producer and handler application forms that allow the form to auto-calculate fees for each individual operation based on its specific production activities. The revised forms will be put into use by December 30, 2018 and will replace the current forms online and in electronic format.

NOP-14-18.NC4 – Accepted. 7 C.F.R. §205.662(c)(1 – 4) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program’s governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.... The notification of proposed suspension or revocation of certification shall state: The reasons for the proposed suspension or revocation; The proposed effective date of such suspension or revocation; The impact of a suspension or revocation on future eligibility for certification; and, The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.” §205.405(c)(1)(ii) states, “When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, issue the applicant a written notice of denial of certification.”

Comments:

1. *MTDA’s Notices of Proposed Suspension do not include the impact of suspension.*
2. *The Notice of Proposed Revocation and Notice of Proposed Suspension include the following language: “We are providing a copy of this Notice of Proposed Suspension/Revocation of Certification to the Administrator of the National Organic Program, and we will provide a copy of any Notice of Resolution. As the accredited certifying agent, we are required by federal rules to provide these notifications.”*

Operations that have received a Notice of Proposed Revocation or Proposed Suspension cannot submit corrective actions and receive a Notice of Resolution as a result. These operations must either request mediation or file an appeal.

Corrective Action: MTDA submitted revised templates its Notices of Proposed Suspension and Proposed Revocation that correct the noncompliances that were identified.

NOP-14-18.NC5 – Accepted. 7 C.F.R. §205.662(f)(2) states, “A certified operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation, Except, That, the Secretary may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility.”

Comments: *MTDA’s Notice of Proposed Revocation indicates the operator must request reinstatement. Operations whose certification has been revoked can apply for organic certification after 5 years.*

Corrective Action: MTDA submitted a revised Notice of Proposed Revocation with the reference to reinstatement removed. MTDA will implement this revised notice immediately, and it will be placed as a template in MTDA’s electronic files to avoid reoccurrence of the noncompliance.

NOP-14-18.NC6 – Accepted. 7 C.F.R. §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 4002 Instruction Enforcement of the USDA Organic Regulations: Penalty Matrix Section 4.4 states, “Section 2120 of the OFPA (see 7 U.S.C. 6519(c)) provides for five years of certification ineligibility in response to “knowing” violations. Accordingly, an NOPR is appropriate when sufficient evidence exists to show that an operation deliberately violated the USDA organic regulations. As stated in the penalty matrix, willful violation involves the deliberate sale, labeling or representation of agricultural products as organic in violation of the regulations...”

Comments: *MTDA issued Notices of Proposed Revocation to two operations for not submitting annual update paperwork and fees. Not submitting paperwork and fees is correctable, and not considered a “knowing” violation. According to the Penalty Matrix, this type of noncompliance would result in a Notice of Proposed Suspension.*

Corrective Action: MTDA submitted a revised Application Processing Procedure (from the MTDA Quality Manual) that addressed nonpayment by operations. The procedure now states that if the correct fees are not paid within 30 days of the annual renewal date, a Notice of Noncompliance will be issued followed by a Notice of Proposed Suspension if there is no response.

NOP-14-18.NC7 – Accepted. 7 C.F.R. §205.662(e) states, “If the certified operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of suspension or revocation.”

Comments:

1. *The auditor reviewed two Notices of Proposed Revocation where the operations did not respond or acknowledge receipt of the proposed notices and MTDA did not issue Notifications of Revocation.*
2. *The auditor reviewed one Notice of Proposed Suspension where the operation did not respond or acknowledge receipt of the proposed notice and MTDA did not issue a notification of Suspension.*

Corrective Action: MTDA submitted a revised version of its tracking document for issuance of noncompliances. The revisions made include, adding columns to indicate the date when Notices of Proposed Suspension or Revocation are issued, when operation responses are due, and the date Notices of Suspension or Revocation are issued. MTDA submitted the most recent version of this revised NC tracking document to demonstrate that it is in use.

NOP-14-18.NC8 – Accepted. 7 C.F.R. §205.663 states, “Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent...If mediation is accepted by the certifying agent, such mediation shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed...Any agreement reached during or as a result of the mediation process shall be in compliance with the Act and the regulations in this part. The Secretary may review any mediated agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part.”

Comments: *The auditor reviewed one mediation request, which was accepted by MTDA and found the following issues:*

1. *A Settlement Agreement was sent to the operator following their written request for mediation, but MTDA did not indicate the mediation request was accepted.*
2. *A Settlement Agreement was offered to the operator but did not include information indicating the operator could reject the agreement or continue discussions with MTDA.*
3. *The Settlement Agreement did not include signatures of both parties (MTDA and operator).*

Corrective Action: MTDA submitted a revised template for its Settlement Agreement Proposal letter. The revised template has language to indicate that MTDA has accepted the operation’s request for mediation; states that the operation can reject the proposed settlement and continue discussions with MTDA; and includes signature lines for representatives from both MTDA and the operator.

NOP-14-18.NC9 – Accepted. 7 C.F.R. §205.406(a)(3) states, “To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent:...An update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification; and...”

Comments: *The MTDA Organic System Plans updates do not require the operation to provide an update on the correction of minor noncompliances previously identified by the certifier as requiring correction for continued certification.*

Corrective Action: MTDA submitted revisions to its Organic System Plan(s) Update that include a section where the operation must provide an update on the correction of noncompliances identified.

NOP-14-18.NC10 – Accepted. 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part...” Specifically, § “205.304(a)(1)(ii) Packaged products labeled "made with organic (specified ingredients or food group(s)). Agricultural products in packages described in § 205.301(c) may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product: “Made with organic (specified food groups)”: Provided, That, the statement does not list more than three of the following food groups: beans, fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables or processed milk products; and, Provided further, That, all ingredients of each listed food group in the product must be organically produced;...” NOP 5032 Section 3.4 states, “If a food group is identified in the “made with organic ***” statement:...It must be a truthful claim; all raw and processed forms of ingredients in that category must be certified organic.”

Comments: *The review of approved product labels revealed that MTDA incorrectly approved “made with organic oils” on product labels which included non-organic essential oils in the composition. In addition, MTDA’s label review checklist does not include the verification of labeling requirements for labels of products in the “made with organic specified ingredients or food group(s).”*

Corrective Action: MTDA submitted a revised label review checklist that includes correct verification of all labeling requirements for “made with organic” products. MTDA will use this revised checklist for reviewing “made with organic” product labels to ensure compliant approvals in the future.

NOP-14-18.NC11 – Accepted. 7 C.F.R. §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 2609 Instruction Unannounced Inspections, Section 4.1.4 states, “The certifying agent should disclose to the operation the reason that the operation was chosen for the unannounced inspection.”

Comments: *MTDA does not disclose to operations undergoing an unannounced inspection the reason that the operation has been chosen for the unannounced inspection. MTDA’s unannounced inspection procedure instructs the inspector to note in section M the inspection was unannounced and the unannounced inspection files reviewed by the auditor did not follow this procedure.*

Corrective Action: MTDA submitted a revised unannounced inspection procedure which states that the inspector must explain that the inspection is unannounced (a requirement by the NOP) and is based on random selection, risk, a complaint or an investigation and that it will qualify as the certified operation’s yearly inspection”. MTDA also submitted revised versions of its

Document of Inspection for handling and crops, which include a check box to identify the inspection as unannounced. Print revisions of the Document of Inspection for the livestock scope will be done in 2019.

NOP-14-18.NC12 – Accepted. 7 C.F.R. §205.406(c) states, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.”

Comments: *MTDA did not issue a notice of noncompliance after an onsite inspection verified an operation’s noncompliance with §205.271(a-b). The operation did not implement accepted pest management practices to mitigate or prevent a pest infestation prior to requesting the use of a synthetic rodenticide not on the National List, despite being instructed to do so per the regulations.*

Corrective Action: MTDA submitted a new submitted a new Pest Control Substance Review Procedure, which includes verification of the facility pest management requirements under §205.271. MTDA also submitted a November 24, 2018 Notice of Noncompliance issued to an operation for failure to comply with §205.271(a-b).

NOP-14-18.NC13 – Accepted. 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must:… Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.’ §205.271(a-c) states, “The producer or handler of an organic facility must use management practices to prevent pests, including but not limited to: … If the practices provided for in paragraphs (a) and (b) of this section are not effective to prevent or control pests, a nonsynthetic or synthetic substance consistent with the National List may be applied.”

Comments: *MTDA approved the use of a synthetic rodenticide not on the national list without requiring the operation to implement the progressive pest management practices outlined in §205.271(a-c). A condition of the rodenticide approval was the operation had to implement the preventative pest management practices stated in §205.271(a-c).*

Corrective Action: MTDA submitted a new Pest Control Substance Review Procedure that will be used to approve pest control substances in the future. The procedure aligns with the steps required under §205.271, including verification of preventative pest management practices.

NOP-14-18.NC14 – Accepted. 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must:… Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.’ §205.271(e) states, “The handler of an organic handling operation who applies a nonsynthetic or synthetic substance to prevent or control pests must update the operation's organic handling plan to reflect the use of such substances and methods of application. The updated organic plan must include a list of all measures taken to prevent contact of the organically produced products or ingredients with the substance used.”

Comments: *MTDA’s approval of a synthetic rodenticide not on the national list did not require a description of the method of use and all measures taken to prevent contact with organic*

products. Additionally, the approval did not restrict the area of use or the time frame of approved use.

Corrective Action: MTDA submitted a new Pest Control Substance Review Procedure that will be used to approve pest control substances in the future. The procedure aligns with the steps required under §205.271, including specifying the timeframe and method of use for approved products, and measures to prevent contact with organic product.

NOP-14-18.NC15 – Accepted. 7 C.F.R. §205.501(a)(8) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part.”

Comments:

1. *MTDA’s crop Organic System Plan template does not require the operation to describe how, where, or how often a material input is used. Auditor’s review of Organic System Plans found cleaner/disinfectant and a pest control listed with no information provided to evaluate compliance with applicable annotations.*
2. *MTDA’s handling Organic System Plan does not require the operations to include suppliers of organic ingredients.*

Corrective Action: MTDA submitted revisions to the Organic System plan Materials Section for crops, mammalian and avian that include a description of how and how often a material is used with notes section for evaluating compliance. MTDA’s handling Organic System Plan does require operations to include suppliers of organic ingredients; it is a separate system plan document named the Product Profile, which was submitted to NOP.

NOP-14-18.NC16 – Accepted. 7 C.F.R. §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must:...” Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 2610 Section 4.4 Sample Documentation states, “Each sample should identify the following information: ...Identification of the sampling site (may include site maps or field), Sample identification, including commodity information, variety, brand name and lot number (if applicable), or other identification.”

Comments: *MTDA sample collection receipts reviewed by the auditor did not identify the sampling site to a field or field site location. In one case the identification of the sampled commodity was not stated.*

Corrective Action: The MTDA Compliance Supervisor met with field staff during October 2018 to clarify the use of field names or field site locations on sample collection report forms under item (13) “Sample Description and Collection Site Location”. To assist field staff in including this required information, MTDA will provide them the Crop Summary Plan identifying field numbers or names for the operations they will sample. During the 2019 sampling year, completed sample collection report forms will be reviewed to ensure field staff are including information identifying the sample and field or site location.

NOP-14-18.NC17 – Accepted. 7 C.F.R. §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must:...” Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” The NOP international Trade policy Taiwan overview 1.04 Requirements for Authorization states,” To be authorized to issue export certificates, a USDA accredited certifying agent must: Keep a paper-based or electronic control log that records and tracks the disposition of each export certificate”

Comments: *MTDA does not have a log to record the disposition of all TM-11 export certificates issued.*

Corrective Action: MTDA created a control log to track the disposition of TM-11 export certificates and will use it going forward.

NOP-14-18.NC18 – Accepted. 7 C.F.R. §205.406(a)(1)(ii) states, “To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent: An updated organic production or handling system plan which includes: Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to §205.200;”

Comments: *The auditor’s witness audit and review of one operation’s annual OSP found the annual update did not disclose the following:*

1. *The use of a seed inoculant during the spring 2018 planting (not approved by certifier).*
2. *Planting of nonorganic seed varieties.*
3. *The operation changed the crop planting/rotation practices to include intercropping.*
4. *Adding calves to organic herd from nonorganic cows purchased in Jan 2018.*

Corrective Action: MTDA submitted a revised Initial Review Procedure and a revised Inspection Procedure. The revised procedures add new steps that the initial reviewer and inspector must take to ensure that major components of the OSP that affect compliance are completed/updated before the inspection and that the body of the OSP is updated with any information submitted in the annual update. The revised Inspection Procedure also adds steps to ensure the inspector verifies that he or she has received and reviewed complete OSP information prior to conducting the inspection. To ensure the corrective action is implemented, MTDA will review these revised procedures with staff during its spring 2019 meeting.

ASSESSMENT INFORMATION

Certifier Name:	Montana Department of Agriculture (MTDA)
Est. Number:	N/A
Physical Address:	302 North Roberts Street, Helena, MT 59601
Mailing Address:	same
Contact & Title:	Georgana Webster, Organic Certification Program Manager
E-mail Address:	gwebster@mt.gov
Phone Number:	406-444-9421
Auditor(s):	Robert L. Pooler, Accreditation Manager
Program:	USDA National Organic Program (NOP)
Audit Date(s):	February 4 – May 28, 2013
Audit Identifier:	NP2191ZZA
Action Required:	No
Audit Type:	Corrective action review
Audit Objective:	To verify continuing compliance to the audit criteria.
Audit Criteria:	<i>7 CFR Part 205, National Organic Program; Final Rule, dated December 21, 2000; as amended November 9, 2012.</i>
Audit Scope:	MTDA's quality manual including personnel, processes, procedures, facilities and, related records and documents.
Location(s) Audited:	Desk

GENERAL INFORMATION

The Montana Department of Agriculture (MTDA) is divided into the Agricultural Sciences, Agricultural Development, and Central Management Divisions. The Agricultural Sciences Division is directed by a Division Administrator and consists of the Laboratory Bureau, Commodity Services Bureau, Technical Services Bureau, and Advisory Boards. The MTDA Organic Certification Program is located in the Commodity Services Bureau under the oversight of the Bureau Chief and management by the Organic Certification Program Manager.

MTDA was accredited as a certifying agent by the National Organic Program (NOP) on April 29, 2002 for crops, wild crops, livestock, and handling operations. MTDA's client list, as of July 9, 2012, had 94 crop, 1 wild crop, 26 livestock, and 48 handling operations certified to the NOP. One of the handling operations is only certified as a retailer. MTDA does not provide

certification outside the USA and currently has certified operations in Montana, North Dakota, and Wyoming.

MTDA's Accreditation Renewal Assessment was completed on July 13, 2012 by NOP accreditation auditors. On December 12, 2012, the NOP issued a Notice of Noncompliance to MTDA for nine noncompliances, NP2191ZZA.NC1 – 9, identified during this renewal assessment. On January 2, 2013, MTDA submitted proposed corrective actions for noncompliances NP2191ZZA.NC1 – 9. On April 17, 2013, MTDA submitted final corrective actions for noncompliances NP2191ZZA.NC1 – 9.

FINDINGS

Documents and records reviewed determined that the Montana Department of Agriculture has adequately addressed noncompliances NP2191ZZA.NC1 – 9 identified during this renewal assessment. Verification of MTDA's corrective actions will be determined at the next on-site audit.

NP2191ZZA.NC1 – Accepted - NOP §205.501(a)(6) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification...” *No performance evaluation was conducted in 2011 for 1 of the 5 staff reviewers/inspectors. The performance evaluations for 3 of 5 staff reviewer/inspectors did not include the reviewer activities (i.e. only the inspector role was evaluated).* **Corrective Action:** MTDA completed the 2012 performance evaluations for the all program staff by December 18, 2012 and submitted a list of the performance evaluation completion dates for each employee. To prevent noncompliances, MTDA modified its quality manual procedures to incorporate annual performance evaluations into staff evaluation records. MTDA also amended its procedures for inspector evaluations, and reviewer evaluations to show which performance evaluation responsibilities will be implemented by the program manager and those responsibilities to be implemented by agency administration. MTDA submitted a copy of a master spreadsheet for use in tracking staff performance evaluations. In 2013, personnel that inspect and review will be evaluated for both activities. MTDA submitted its 2013 performance evaluation plan showing which staff will be evaluated both as a reviewer and inspector, and which staff will be evaluated as an inspector.

NP2191ZZA.NC2 – Accepted - NOP §205.402 (a)(1)(2) states, “Upon acceptance of an application for certification, a certifying agent must: (1) Review the application to ensure completeness pursuant to §205.401; (2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part.” *All 4 witness audits and 4 of 6 additional files reviewed in the office revealed the organic system plans (OSP) were incomplete. The initial reviews identified numerous “potentially non-compliant” areas; however, the required information is not being submitted prior to the on-site inspection. The inspectors are conducting the initial reviews and many items that should be addressed prior to the inspection are being completed during the inspection (no clear separation between initial review activity and inspection). Examples of incomplete OSPs identified as “potentially non-compliant” by MTDA reviewers, but not required by MTDA to address prior to the inspection, included:*

- *Statement in OSP that non-organic products are not handled when other information submitted identifies non-organic products.*
- *Process flow chart and method for maintaining organic integrity not included for cider molasses and apple juice.*
- *Updated product profile sheets not completed.*
- *Method for calculating dry matter demand not identified for ruminant livestock; and calculations do not appear to be correct.*
- *Number of non-organic livestock not identified.*
- *Updated field maps not submitted.*
- *Inputs for greenhouse production of seedlings not identified.*
- *Labels for all inputs not submitted.*
- *Organic Seed Non-Availability affidavit not completed for use of non-organic seeds.*
- *Wild Crop Addendum not completed.*

Corrective action: MTDA revised its OSP forms to ensure that the 2013 annual updates and new applications provide complete OSPs. Copies of the revised forms were provided. In addition, MTDA developed template notices to be used by initial reviewers when requesting additional information on incomplete OSPs. A sample copy of this notice sent to a certified operation was provided for NOP review. For new certification applicants, MTDA will only schedule inspections for complete and compliant OSPs. For on-going certified operations, MDTA will request additional information to complete OSPs and will proceed with scheduling annual inspections. On March 28, 2013, MTDA conducted staff training on OSP review for determining completeness and requesting additional information before scheduling inspections. A copy of the training addenda was provided. The training agenda indicated that MTDA staff would require missing OSP information to be submitted for review prior to scheduling inspections. The training agenda also covered types of non-compliances and procedures for capturing minor changes during the inspector's exit interview.

NP2191ZZA.NC3 – Accepted - NOP §205.403(c)(1)states, “*Verification of information. The on-site inspection of an operation must verify: (1) The operation’s compliance or ability to comply with the Act and the regulations in this part.*” *During the witness audit of the wild crop operation, the inspector reviewed the herb products to the point of transfer to the handling operation. The certified crop and wild crop operation is located on the same property and under the same ownership as the non-certified handling operation. The inspector stated that traceability stopped at this point of product transfer since the handling operation was not certified. It was also stated that the operation was previously certified by MTDA for various beauty and health care products but had voluntarily surrendered their handling certification. The inspector did not question the operator or investigate any further how the products were labeled or if any were labeled as organic or with any organic ingredients. Upon further review by the auditor, it was discovered that many products were labeled with organic ingredients and several were observed labeled as organic. Examples observed included product labels such as Antioxidant Lotion with Organic Green Tea & Organic Shea Butter; and 100% Organic African Shea Butter. Follow-up of the file at the MTDA office, found that the operation had surrendered their handling certification in 2009 because they stated that they would only be listing organic ingredients in the ingredients list and not making any label claims of 100% organic, organic, or made with organic. MTDA had previously informed the operation of the requirements for*

certification if they made any of these label claims in the future; however, MTDA had not instructed inspectors to observe labels during the inspections, and the inspector did not consider this to be within the scope of the inspection. **Corrective action:** MTDA noted that the inspection report included a finding on the operation's noncompliant labeling and, subsequently, the agency issued a Notice of Noncompliance to the operation for the noncompliant labeling. MTDA reviewed the operation's corrective action response, accepted the action, and issued a Notice of Noncompliance Resolution. On March 28, 2013, MTDA conducted training on verifying OSP information during inspections. At this training, instruction on reviewing labels was provided to staff reviewers and inspectors. In addition, MTDA revised inspection report templates to include NOP regulation references and instruction on recording findings. MTDA provided a copy of the training agenda.

NP2191ZZA.NC4 – Accepted - NOP §205.403(c)(2)states, “Verification of information. The on-site inspection of an operation must verify: That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;” and NOP §205.403(d) states, “...The inspector must also address...any issues of concern.” *All four witness inspections and 4 of 6 additional files reviewed in the office identified areas where the organic production or handling system plan (OSP) did not accurately reflect the practices used by the applicant; however, the inspectors did not identify issues of concern for the missing, incomplete, or inaccurate information. In most cases, the inspectors simply updated the OSP during the inspection which corresponded with statements by the previous Organic Certification Program Manager that MTDA made the decision not to identify issues of concern or noncompliances for information that could be corrected during the inspection in order to speed up the process. Examples of missing, incomplete, or inaccurate information with no issue of concern being identified included the following:*

- *For the handling witness audit, the pest management plan had been revised with a new type of mouse trap and new person responsible for oversight without updating the OSP; the operation had not documented the cleanout procedure between conventional and organic coffee roasting in their OSP; the section for identifying non-organic products was not complete; and the organic product profile for vanilla flavored coffee was missing.*
- *For the livestock witness audit, the use of the antibiotic LA 200 and procedure for removal of these cattle from organic production was not identified in the OSP; and the method for calculating dry matter demand (2.5% of body weight) was not identified in the OSP.*
- *For the crop witness audit, three inputs (insecticidal soap, potting, soil, and seaweed powder) only had the generic name and not the specific product name in the OSP; and the use of mulch, plastic sheeting for weed management, and the method and equipment for vegetable washing was not included in the OSP;*

Correction action: MTDA contacted the organic coffee roaster after the witness inspection and requested additional information on pest management, labeling and product ingredients. MTDA received and reviewed the additional information for compliance, and determined that information completed the roaster's OSP. MTDA reviewed its program OSP review process and

provided training in March 2013 to staff that OSP's must be complete and compliant before inspections can be scheduled. To facilitate applicant's OSP completion, MTDA revised its crop, and livestock OSP templates to add clarification on sections describing product flow, inputs used livestock healthcare treatments, and dry matter calculations. MTDA also revised its crop and livestock inspection report templates to include more inspection information on materials. Copies of the revised OSP templates and inspection report submitted to the NOP. Instruction on these program changes were presented at MTDA's staff training in March 2013.

NP2191ZZA.NC5 – Accepted - NOP §205.406(c) states, "If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662." *MTDA is not issuing notices of noncompliance (NONC) in accordance with §205.662 when OSPs are incomplete (8 of 10 files reviewed). Noncompliances are instead simply being identified as "potentially non-compliant" items in the inspection notification letter and then updated by the inspector. The majority of NONC issued by MTDA are for certified operations not submitting an annual update at all or not paying the required fees.* **Corrective action:** MTDA procedures instruct staff to review OSP's for completeness and compliance to the regulations. MTDA amended these procedures to notify operations when incomplete or noncompliant information is described in the OSP, except for major noncompliances where MTDA would issue a Notice of Noncompliance in place of the notice for additional information. The revised procedures instruct staff to issue a notice of noncompliance when an operation inadequately responds to requests for additional information or fails to adequately address a minor noncompliance. The March 2013 program staff training included instruction on these revised procedures.

NP2191ZZA.NC6 – Accepted - NOP §205.504(b)(1), states, "A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques... A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates." *MTDA's label approval procedure does not adequately address the method used to identify the approval or disapproval of labels. The labels in the files do not document the date of approval or the name of the individual approving the label. MTDA provided an example of the method they intend to use in the future (e.g. received date, review/approval date, and approver initials); however, this had not yet been implemented.* **Corrective action:** MTDA has established and implemented a program label review procedure which describes staff responsibilities for label approval including responsibility for recording date of approval and reviewer identification. MTDA provided a copy of the procedures and records showing implementation of the label review procedures. The March 2013 training included instruction on the label review procedures.

NP2191ZZA.NC7 – Accepted - NOP §205.402(b)(3) states, "The certifying agents shall within a reasonable time: Provide the applicant with a copy of the test results for any samples taken by the inspector." *MTDA collected samples and conducted testing on samples from five operations in 2011; however, they did not provide a copy of the test results to any of the certified operations. The laboratory test results were dated December 2011 and as of July 2012, they had*

not been sent to the certified operations. The samples were tested for the list of analytes in NOP 2011-11 and the results were all “non-detected” so MTDA simply informed the operations verbally. **Corrective action:** MTDA provided a copy of a 07/12/12 email communication where a copy of the test December 2011 results were provided to the certified operation. In this communication, MTDA acknowledged that its response was overdue. To prevent future noncompliances, MTDA revised the program residue testing procedures to include instruction for reporting all test results to operations within 30 days. MTDA also established residue reporting templates of “no residue detected” or “residue detected” response letters for use when reporting test results. Copies to the revised procedures and reporting templates were provided.

NP2191ZZA.NC8 – Accepted - NOP §205.504(b)(5)(iii) states, “A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques... A copy of the procedures to be used, including any fees to be assessed, for making the following information available to any member of the public upon request: The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years.” *MTDA’s policy/procedures do not adequately address public requests for laboratory analyses for residues of pesticides and other prohibited substances. Their Policy Manual (Section 3, B.7.d.2) states the results will be available upon request; however, there are no details on the process for public requests, the authorized individuals with MTDA that can release the information, etc. MTDA has not received any requests from the public for this type of information.* **Corrective action:** MTDA revised the quality manual on procedures for releasing public information to include testing results. The revised procedures also include assigning authorization to selected staff for releasing test results as public information. Copies of the revised procedures were included in the corrective actions.

NP2191ZZA.NC9 – Accepted - NOP §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” Issuance of Export Certificates under an Export Arrangement with Taiwan (April 16, 2009) section 1.04 states, “To be authorized to issue export certificates, a USDA accredited certifying agent must: 1. Incorporate the compliance requirements of the applicable export arrangement into its quality manual under the heading “Requirements for export of U.S. organic raw and processed agricultural products to (insert country name).” *MTDA has not incorporated the compliance requirements for issuance of export certificates for Taiwan into their Quality Manual under the required heading. The requirements are listed in their Policy Manual (Section 11) under the heading “Terms of the USDA-Taiwan Export Arrangement” instead of in the Quality Manual and not all requirements are listed. MTDA issued 7 TM-11s for Taiwan in 2011 and 2 to date in 2012. A review of the TM-11s issued for Taiwan verified they were in compliance to the requirements and contained the correct compliance statement.* **Corrective action:** MTDA provided a copy of its revised quality manual section on “requirements for export of U.S. Organic raw and processed products to Taiwan. The revised section incorporates requirements for issuing export certificates to Taiwan.