

Oregon Tilth Certified Organic

— Procedures Manual —



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PART 1: INTRODUCTION TO OREGON TILTH AND AN OVERVIEW OF THE OREGON TILTH CERTIFIED ORGANIC (OTCO) PROGRAM

A. WELCOME TO OREGON TILTH

Oregon Tilth, Inc is a nonprofit organization that supports and promotes biologically sound and socially equitable agriculture through education, research, advocacy and product certification. Tilth began in 1973 as an agricultural organization, which has cultivated a unique urban-rural outlook.

Oregon Tilth is best known for its development of an organic certification program, which is detailed in this manual. We coordinate conferences, produce events in local communities, and makes presentations at conferences, educational workshops, and trade shows. A bi-monthly magazine, *In Good Tilth*, keeps the public informed about the activities of Oregon Tilth as well as issues of interest to the community of organic producers, handlers, processors, and consumers. Our education programming includes an Organic Conservation Program and education of consumers about the benefits of organic agriculture and gardening. Oregon Tilth enjoys a 501(c)(3) tax-exempt charitable status.

Although many certified operators are active members of Oregon Tilth, membership is not required for OTCO certification.

B. PHILOSOPHY OF OREGON TILTH

Oregon Tilth advocates a holistic approach to agricultural production systems. Oregon Tilth encourages growers to create farm systems, which improve soils and require minimal intervention for pest control. Tilth favors the use of natural slow-release fertilizers and compost, which emulate the natural processes of soil formation. Tilth stresses prevention of pest problems using crop rotations, beneficial insects, and field sanitation. However, when pest control is necessary, Tilth urges growers to use non-toxic methods, leaving the strictly limited pesticides, which are available to organic growers, to be used only when necessary to prevent crop loss.

To ensure the organic integrity of products from the farm to the table Oregon Tilth works with processors, handlers, and marketers of organic products. Organic standards for operations handling and processing organic products emphasize the importance of prevention of contamination and/or comingling with non-organic products throughout the handling process. Facility pest management methods must use the least toxic practices possible to successfully manage pests. Detailed records and audit trails provide the documentation necessary for verification of proper attention to critical control points.

C. OVERVIEW OF THE OTCO CERTIFICATION BODY

The purpose of organic certification is to ensure that the agreed-upon conventions of organic management systems are being practiced not only by growers, but also by all the people who handle and process organic food on its journey to the final consumer. To accomplish this OTCO implements a system that combines strict production standards, verifiable third-party

inspections and legally binding contracts, which protect the producers and buyers of organic products.

Organic certification verifies that operations have implemented organic production systems that comply with established standards. Organic certification is not a final product guarantee regarding absence of residual environmental contaminants.

OTCO is specifically designed as a certification service for:

- Producers of organic crops and livestock,
- Wild harvest of organic crops
- Processors of organic foods,
- Handlers of organic foods such as packers, brokers, distributors, and wholesalers and
- Restaurants and Retailers
- Fiber and Textiles
- Personal Care Products

OTCO operates in a non-discriminatory manner. OTCO makes its certification services accessible to all applicants whose activities fall within the scope of its operations. Procedures are not used to impede or inhibit access by applicants, other than as provided in this manual. Access to the certification process is not conditional upon the size of the client or membership of any association or group; including Oregon Tilth, nor is certification be conditional upon the number of certifications already issued. There are no undue financial or other conditions nor is Oregon Tilth financially dependent on single operations that are subject to its certification in any way that compromises its impartiality. Particularly for the GOTS program, Oregon Tilth accepts GOTS inspection assignments regardless of whether they are for the entire processing chain, parts thereof or single operators.

D. ADMINISTRATION OF THE PROGRAM

The main Oregon Tilth administrative office is located in Corvallis, Oregon and is open Monday through Friday, from 9 am to 5:00 pm Pacific Time. You may contact the office at the following address:

Oregon Tilth. PO Box 368, Corvallis OR 97339

Phone number: (503) 378-0690, Fax number: (541) 753-4924

E-mail: organic@tilth.org, Web site: www.tilth.org

There is a phone answering machine available when the office is closed. Staff clears messages each business day and returns calls as soon as possible. By contacting the main administrative office, you will be directed to the appropriate personnel.

OTCO Personnel

The daily work of certification is managed by the Certification Director and implemented by inspection and certification staff, with additional support provided by administrative staff. In

some cases, OTCO hires inspectors on a contractual basis and uses other contract workers to work on specific projects. OTCO also subcontracts with laboratories for the testing of residues, GMOs and other issues as needed. Whenever contract or subcontracted services are utilized during the certification process, OTCO retains final authority and responsibility for all certification decisions.

Financial Support for the Certification Program

The certification program is a self-sustaining program within Oregon Tilth that also lends financial support to Oregon Tilth's education, advocacy and research activities that further support and promote organic agriculture and food systems. The Certification Director, in consultation with the Executive Director and the Board of Directors as part of the annual budgeting process, determines the fees paid by applicants and certified operations requesting certification to ensure that all expenses of the program are paid in full by the end of each fiscal year.

E. SCOPE OF CERTIFICATION SERVICES

In response to the increasing market demand of organic products and quality certification services, Oregon Tilth offers certification to operators throughout the United States and internationally, when it is in our administrative capacity to do so. Offering global certification services serves two purposes. It assists domestic producers and processors with access to foreign markets, while also assisting foreign producers with compliance and access to US organic markets. This can improve the economic viability of producers in developing countries by accessing better market premiums.

The primary language of OTCO is English and whenever possible OTCO provides translated versions of Standards and Controlled Documents.

Types of Operations

Certification is available for *individual operations* as well as *multi-site operations with demonstrated internal control system* (a.k.a. cooperatives or grower groups). Application forms have been adapted to reflect the organic management structure of these different types of operations.

An *individual operation* is a sole proprietorship, corporation, partnership or similarly defined single company. A single certification may cover activities at multiple sites under the direct management of the applicant company.

A *multi-site operation with demonstrated internal control system* (a.k.a. cooperative or grower group) involves a centrally managed association of local growers producing similar crops using similar practices and marketing their products in common. The operation must be constituted as a legal entity in the country where they operate. A single operation may cover numerous individual member farmers. Management must establish and maintain an internal control system including access to and education regarding organic standards. Management must also annually conduct a thorough standards compliance evaluation of each member and farm.

Categories and Classes of Certification

OTCO provides certification services for operations that produce in crops, livestock or handle organic products. Within each of these broad categories OTCO has established classes of certification to address the unique attributes and activities of each type of operation. A single operation may be certified under more than one category and class of certification, depending on the scope of their activities.

CROP PRODUCTION	
Class T Transitional	Transitional agricultural products fall outside the scope of the USDA National Organic Program. Transitional standards are based upon the Organic Foods Production Act of 1990 and the applicable production and handling standards established by the USDA National Organic Program under 7 CFR Part 205, <i>except</i> transitional products lack compliance with §205.202(b).
Class O	Organically Grown. Covers farms producing agricultural and horticultural crops including container production. Covers farms producing fungi crops for the USDA National Organic Program.
Class OF	Organically Grown. Covers farms producing fungi crops for the Mexico Organic Program.
Class OW	Organic Wild-Crop Harvest. Covers the sustainable harvest of wild crops growing in a designated area that has been free of prohibited materials for at least 3 years.
Livestock Production	
Class OLP	Organically Grown Livestock and Poultry. Covers farms producing animal products such as meat, eggs and milk.
Handling Operations	
Class OH	Organic Handlers. Covers businesses preparing food, feed and processed products as well as those participating in the distribution chain for organic foods such as packers, brokers, wholesalers, distributors and private label companies and brand owners.
Class OR	Organic Retail Stores and Restaurants. Covers retail stores and restaurants which sell organic products to the consumer, either as fresh produce, packaged goods, or ready-to-eat meals.
Class OFT	Organic Fibers and Textiles. Covers the processing and handling of fiber and textile products under the Global Organic Textile Standards.
Class OPC	Organic Personal Care. Covers the processing and handling of personal care products under the NSF/ANSI 305 Standards.

Organic Certification Standards

The OTCO Program offers assessment for compliance and/or equivalence with several different organic certification standards. Some are established and enforced via government regulations, such as the USDA National Organic Program (NOP) standards (7 CFR Part 205), the European Compliance Program (EC 834/889), and the Mexico Organic Program assessed by the Mexico Organic Standards aka Ley de Productos Orgánicos (LPO). Other organic standards are established by industry working groups, such as the Global Organic Textile Standards (GOTS), the Certified Transitional Program, Bee Better Program, and the NSF/ANSI 305 Personal Care Products Containing Organic Ingredients.

Depending on the standards, different types of products (i.e., food, fiber, or cosmetic/personal care) are required and/or eligible for compliance assessment.

OTCO notifies certified operators of changes to standards, criteria, regulations, directives, memos, program handbook updates, export arrangement provisions and not limited to any notification or change that affects the certification body and its operators, including implementation dates for compliance as necessary. OTCO will notify the operator according to the relevant notification of changes. Most notifications are in response to a regulatory change that outlines specific requirements; including when operators must be notified, when operators must comply and when OTCO must ensure effective implementation. In lieu of specific requirements, it is OTCO's best practice to notify operators within 30 days of being issued a notification of change to standards and provide a reasonable timeframe for full implementation.

Oregon Tilth currently offers the scopes outlined below with the specific standard:

USDA NOP	Producer, wild crop, livestock (including fiber), handling, retail and restaurant, multi site operations
Transitional	Producers or handlers of products that are in transition.
EU Compliance Program	For producers or processors exporting product to an EU member state.
Global Organic Textile Standards (GOTS)	Fiber and textiles.
NSF/ANSI 305	Processors and handlers of personal care products, cosmetics, oral care and personal hygiene products
Mexico Organic Program (LPO)	<p>Crop production, wild harvest plant production, animal production (domestic), production class fungi, processing of products from agricultural activities including distribution and marketing of products from agricultural activities. OTCO does not provide certification of animal production from natural or nondomestic systems, insect class animal production or aquaculture at this time.</p> <p>Per LPO Regulation, organic production is linked to the soil, except in those cases in which due to the characteristics of the product or agroecological conditions is not feasible.</p>
Bee Better	Producers, processors, and handlers of agricultural products.

F. ACCREDITATION

In November 1999, OTCO was evaluated and recognized by the USDA Agricultural Marketing Service for compliance with the International Organization for Standardization (ISO) *Guide 65: General requirements for bodies operating product certification systems*. The process involved a rigorous examination of OTCO's quality systems and certification procedures, inspection of office files and procedures, assessment of personnel qualifications and observation of on-site

inspections of certified farmers and processors. Annual audits, including on-site visits of the OTCO office and certified operations, are part of maintaining ongoing accreditation and have evolved with OTCO complying with ISO/IEC 17065.

ISO/IEC 17065 accreditation allows easier entry of OTCO certified products into international markets and establishes a strong basis for reciprocity with other certification agents. It also serves as a tool to demonstrate the OTCO program's competency and expertise when offering certification services to voluntary organic standards, such as the Global Organic Textile Standards and the NSF/ANSI 305 Standard.

On April 29, 2002, OTCO was granted accreditation by the USDA National Organic Program (NOP) for organic certification of crop, livestock, wild crop and handling operations. OTCO's accreditation means that production and handling operations certified by OTCO are deemed certified in accordance with the NOP provisions.

On July 6, 2009, OTCO was granted accreditation by the Canadian Food Inspection Agency (CFIA) for organic certification of crop, livestock, wild crop and handling [processing B3.5.8] operations. Due to a lack of growth and significant resources required to maintain the program, on April 1, 2020 OTCO dropped accreditation to the Canadian Organic Regime and no longer offers certification to this standard.

In 2016, OTCO received recognition by SADER/SENASICA to offer certification to the Mexico Organic Standards (LPO). This allows operations within Mexico with domestic sales to be certified to the nationally recognized standard. The OTCO Mexico Organic Program (MOP) is also accredited by CAEQ.

OTCO is recognized by the European Commission as an approved certification body for organic certification of crop and handling operations for food or feed. OTCO's accreditation means that production and handling operations certified by OTCO are deemed certified in accordance with the EU provisions. The OTCO EU Compliance Program is also accredited by CAEQ.

G. ENFORCEMENT

The OTCO Program has a positive reputation in the marketplace because it has created and maintained a high-quality certification program that safeguards both the food production and food delivery systems. *However, no rules or laws can strengthen the program more than the commitment of the operators of the OTCO-certified businesses to follow the production standards with care and honesty.*

OTCO investigates all written reports of violation of its standards. When the organic standards are established by government regulations, they provide the legal structures necessary to carry out enforcement activities.

PART II: PROCEDURES

A. REQUESTING A CERTIFICATION PACKET

First time applicants should contact the OTCO office to request a certification packet for the type of certification needed for their enterprise(s) or visit the website, www.tilth.org to request an application packet. The application packet includes the following documents:

- *OTCO Procedures Manual* (this document)
- *OTCO Fee Schedule*
- Reference to the applicable organic standard(s) for which compliance assessment is being requested
- The appropriate application form(s) – Organic System Plan (OSP)
- The OTCO Terms and Conditions

All of the above documents are available electronically from the Oregon Tilth web site (www.tilth.org).

B. APPLYING FOR CERTIFICATION

Begin assessing the eligibility of your operation by reading the applicable organic standard(s), the procedures manual, Organic System Plan(s) (OSP), and compare your records and practices to the certification requirements.

The next step is to fill out the applicable OSP(s) completely. Provide as much detail as possible and keep a copy of the OSP for your records.

The operation receives the “Organic Certification Contract and Trademark Use Agreement” in their initial certification packet. This document summarizes the terms and conditions of organic certification with OTCO. The Operator must sign and return the “OTCO Terms and Conditions” to the OTCO office along with their application.

A complete application contains the following components: 1) the completed application/request form or OSP; 2) a signed OTCO Terms and Conditions and 3) the initial payment towards certification services being requested. Please refer to the *OTCO Fee Schedule* for information regarding certification fees.

OTCO accepts all production and handling applications that fall within the scope of its certification program to the extent of its administrative capacity to do so without regard to size or membership in any association or group, race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, marital or family status.

OTCO applicants that are dual certified or transferring certification services from another certification body are obligated to notify the other certification body (CB) of these arrangements. Applicants must understand both certification bodies may exchange the relevant information on the operations under their control. Applicants must address all formal notices and resolve any outstanding noncompliances issued by the relevant certification body prior to

OTCO making a certification decision.

- For the EU Compliance Program applicants, the previous control body shall share and deliver relevant elements of the control file of the operator concerned and the reports referred to in the second subparagraph of Article 63(2) to the subsequent control body. The new control body must ensure that non-conformities noted in the report of the previous control authority or control body have been or are being addressed by the operator. Where the operator withdraws from the control system, the control body of that operator shall, without delay, inform the competent authority. Where a control body finds irregularities or infringements affecting the organic status of products, it shall without delay inform the competent authority of the Member State which designated or approved it in accordance with Article 27 of Regulation (EC) No 834/2007. That competent authority may require, on its own initiative, also any other information on irregularities or infringements. In case of irregularities or infringements found about products under the control of other control authorities or control bodies, it shall also inform those authorities or bodies without delay.
- For GOTS applicants, OTCO confirms that the operation does not and will not hold GOTS certification with another Certification Body at the same time as certification with OTCO. Certification is only with the applying certification body, as such, an operator cannot use up existing supplies of labels which identify their previous CB on products they produce from the moment the operator receives the new certificate.

Initial Review of the Application/Organic System Plan (OSP)

Once your OSP, contract and payment have arrived at the OTCO office, we send you acknowledgement of receipt. Our staff will review it for completeness and compliance or the ability to comply with the standard(s) for which you are requesting. OTCO staff will also assess the request for certification to ensure that OTCO has the ability to certify your operation based on your location, the standard, product or production type. If OTCO has no prior experience with the certification scheme requested, we will contact you to discuss.

OTCO communicates the initial findings of the OSP review to applicants in a reasonable amount of time. This correspondence also provides a cost estimate for certification services. The OSP must be completed in full and reviewed before an inspection can be scheduled. An additional fee is charged for any OSP, which must be returned for completion.

Material Review

Producers and handlers must provide a complete list of substances used in production and handling in their OSP. This list includes fertilizers, soil amendments, potting soil, crop production aids, and pest control materials used in crop production; livestock feed, feed supplements, feed additives, medications, and livestock production aids used in livestock production; and ingredients, processing aids, post-harvest handling substances, sanitizers, and facility pest control materials used in processing and handling. OTCO will evaluate this list to determine compliance with applicable organic regulations and then communicate acceptance of the materials. For branded formulated products used in organic production, OTCO accepts

the material review decisions of other agencies providing this service such as the Organic Material Review Institute (OMRI), the Washington State Department of Agriculture (WSDA) Organic Material Review Program and other material review programs. If the branded formulated product has not yet been evaluated by OTCO or another program, OTCO requires full ingredient disclosure of the product for evaluation.

C. THE ON-SITE INSPECTION

OTCO conducts an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and is included in an operation for which certification is requested. An on-site inspection is conducted annually thereafter for each certified operation for the purpose of determining whether the certification of the operation should continue.

- For NSF/ANSI 305 certification, OTCO may determine that an inspection is not necessary to determine compliance with the standard. If the operation requesting certification under NSF/ANSI 305 holds another valid OTCO certification under a different standard, OTCO may or may not require an additional inspection prior to the additional certification to this standard. All new operations that do not hold a current OTCO certification undergo a full inspection prior to being certified.

All scheduled inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities and activities that demonstrate compliance or capacity to comply can be observed. If necessary, the initial inspection or the annual on-site inspection of operations continuing certification may be delayed for up to 6 months from receipt of the initial application to ensure the inspection is conducted at such a time.

However, when the interval between two regular inspections has exceeded twelve months, subsequent inspections will restore the parity between the number of calendar years and the number of regular inspections.

Inspectors must be granted complete access to the production and/or handling operation, including non-certified production areas, structures, and all documentation and records (including financial) associated with organic and non-organic production. OTCO uses the following procedure for conducting on-site inspections:

- 1) OTCO assigns an inspector whose training and experience matches the operation's activities. For operations in the EU certification scheme, inspectors are rotated every 3 years. Operations have the right to refuse within reason the assignment of an inspector.
- 2) The inspector reviews the operation's certification file.
- 3) The inspector contacts the operation to make an appointment for the inspection and to review any preliminary questions concerning the operation.

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- 4) The inspector travels to the operation to conduct the inspection, beginning with an opening meeting with a representative of the operation.
 - 5) The inspector conducts the inspection, documenting:
 - a) The operation's compliance or ability to comply with the standards and applicable requirements.
 - b) The accuracy of information provided in the OSP, and the practices used or to be used by the operator.
 - c) That prohibited substances have not been and are not being applied within organic operations. Collection and testing of soil, water, waste, seeds, plant or animal tissue and processed product may be undertaken at OTCO's or the inspector's discretion.
 - 6) The inspector typically observes production records, production fields, facilities, equipment, materials, and property perimeters.
 - 7) The inspector conducts an exit interview with the authorized representative of the operation to confirm the accuracy and completeness of observations and information gathered during the inspection. The inspector also addresses the need for any additional information as well as any issues of concern.

Objecting to the Use of a Particular Inspector

If a certification applicant or certified operator objects to the assignment of a particular inspector to evaluate their operation, the applicant may submit their objections in writing to the Inspection Manager. Objections may be based on any of the following reasons:

- Previous encounters with a particular inspector were not positive
- Former relationship outside of a defined conflict of interest i.e., Consultant 3+ years ago, previous neighbor etc.
- Applicant or certified operator is not confident in the inspector's abilities in relation to their particular operation

The Inspection Manager may reassign the inspection to another inspector.

Additional Inspections

OTCO may conduct additional inspections of new applicants and/or certified operations to determine compliance with the standards.

Additional inspections may be required for new applicants to verify compliance prior to granting certification. The purpose of an additional inspection is to check for any changes in the organic production/handling system plan of the operation since the initial inspection and to verify the operation's compliance with the standards.

Additional inspections may be announced or unannounced at the discretion of OTCO. If OTCO is required to perform a specified % of additional inspections, OTCO performs those additional inspections as unannounced inspections:

- For the EU Compliance Program and the Mexico Organic Program (MOP), OTCO performs a risk analysis and conducts additional inspections of 10% of high-risk operations. These inspections are carried out as unannounced inspections in addition to the requirements for Unannounced Inspections below.

Unannounced Inspections

All certified operations are subject to unannounced inspections. No additional fees are assessed for unannounced inspections.

OTCO determines the number of unannounced inspections to be completed per certification standard at the beginning of each calendar year.

- For USDA NOP, OTCO performs unannounced inspection representing a minimum of 5% of NOP certified clients.
- For the Global Organic Textiles Standard (GOTS), OTCO performs unannounced inspection representing a minimum of 5% of the GOTS certified clients.
- For the EU Compliance Program, OTCO performs unannounced inspection representing a minimum of 10% of the total number of inspections to be performed plus the additional high-risk inspections that are conducted as unannounced. (The total # of unannounced inspections is equal to 10% of total operators + 10% of additional high-risk inspections).
- For Mexico Organic Program (MOP), OTCO performs unannounced inspection representing a minimum of 10% of the total number of inspections to be performed plus the additional high-risk inspections that are conducted as unannounced. (The total # of unannounced inspections is equal to 10% of total operators + 10% of additional high-risk inspections).
- Additional standards are evaluated for requirements of unannounced inspections and percentages required annually.

OTCO chooses the operations to receive unannounced inspections using the following criteria:

- Random choice by the Certification Director or designee
- Soil residue tests indicating a likelihood of contamination through uptake of pesticide residues
- Production of crops which are known to concentrate soil pesticide residues
- Operations with requirements for the correction of minor noncompliances identified as conditions of continuing certification
- Staff or inspector recommendation for unannounced inspection
- Complaint received by OTCO regarding operation's compliance

The Inspector's Report

Each inspection culminates in an inspection report. The report summarizes the operation's Organic System Plan practices and evaluates them for compliance with organic standards. Each report includes a list of all points of concern and potential noncompliance found by the inspector.

Documents Provided to Inspected Operations

At the conclusion of the inspection, the inspector issues the inspected operation an Exit Interview Form summarizing the Inspector's observations and signed by both the inspector and the operator. A copy of this form becomes part of the inspection report. As applicable, the inspector also provides a copy of the chain of custody sheet for any samples taken during the course of the inspection. A copy of the inspection report and any test results are sent to the inspected operation within a reasonable amount of time.

Use of Contractors and Subcontractors

OTCO maintains its responsibility for granting, maintaining, suspending or revoking certification of an operation. OTCO may decide to outsource work related to certification (e.g. testing and/or inspection) to an external body or person; in which case, OTCO promptly notifies its Accreditation Body and Global Standard GmbH (for GOTS operations) about the subcontracted body and the kind of subcontracted work. OTCO takes full responsibility for such contracted and subcontracted work, including confidentiality. By applying for certification with OTCO, applicants consent to the use of contractors and subcontractors during the certification process.

D. THE DECISION-MAKING PROCESS

Upon receipt of all necessary documentation, a qualified and designated OTCO Certification Officer creates a summary of the operation based on a review of the Organic System Plan (OSP), inspection report, test results and any additional applicable information. This review process determines if the Organic System Plan and all procedures and activities of the organic operation are in compliance with the standards and that the operator is able to conduct operations in accordance with the plan. The summary concludes with a decision concerning granting or continuing certification of the operation. The certification decisions are made within reasonable amount of time. For the GOTS program, the decision is rendered within at least 2 months of the inspection.

The certification decision may identify points of noncompliance including a timeframe within which the applicant must describe corrective actions. The decision may require the applicant to notify OTCO, in writing, of plans for corrective/preventive actions and the timeframe(s) within which these actions are made prior to granting certification. If the proposed corrective action is sufficient to qualify for certification, then the certification process continues.

Noncompliances with the Standards

To encourage producers in achieving full compliance with organic standards, the certification decision may grant or continue certification when there are noncompliances that require

corrective action to bring the operation into full compliance. An operation is given the opportunity to resolve noncompliances via corrective action only if the noncompliances do not:

- Compromise health or safety of workers,
- Compromise the organic integrity of the product,
- Result in excessive contamination of product (in excess of 5% of EPA tolerance level, or the FDA action level or other foreign regulatory levels (ex. COFEPRIS in MX), or
- Involve intentional violation of organic standards.

When an operation has been granted certification, the staff may include reminders in the approval letter identifying any issues, which may impact ongoing compliance with the standards.

E. WITHDRAWAL OF THE APPLICATION

An applicant may withdraw his/her application at any time. An applicant who withdraws his/her application is liable for the costs of services provided up to the time of the withdrawal. Please refer to the *OTCO Fee Schedule* for details.

AN APPLICANT THAT VOLUNTARILY WITHDREW HIS/HER APPLICATION PRIOR TO THE CERTIFICATION DECISION IS NOT ISSUED A NOTICE OF NONCOMPLIANCE OR A DENIAL OF CERTIFICATION BY OTCO.

F. ACKNOWLEDGMENT OF CERTIFICATION

The operation is sent a certificate after completion of the decision process. The certificate identifies the name of the certified operation, their address, the scope of certification, the validity period and the applicable standards to which compliance was evaluated. All currently certified operations, as well as the type of products they produce, are listed on the Oregon Tilth web site (www.tilth.org).

G. CONTINUATION OF CERTIFICATION

To maintain and continue certification, a certified operation must annually pay the certification fees and submit any changes to the Organic System Plan. Information included on the OSP submitted to OTCO must include:

- An update on any changes in the operator's owners, farm/business name, principal responsible person, contact person, and contact information including address and phone number.
- Information, supported by documentation, describing any deviations from, changes or modifications to, or other amendments made to the previous year's Organic System Plan (OSP);
- Any additions or deletions to the previous year's OSP intended to be undertaken in the coming year;
- An update on the correction of any noncompliances previously identified by OTCO as requiring correction for continued certification; and

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- Other information as deemed necessary by OTCO to determine compliance with organic standards.

Once your OSP update and payment have arrived at the OTCO office, we send you acknowledgement of receipt. Our staff will review it for completeness and compliance then assign your inspection.

H. POST CERTIFICATION APPROVALS

Without undue delay, an operator must inform OTCO of any changes that affects the Organic System Plan, during certification, including changes of products, product formulation, acreage, or facilities to be certified or infringements identified by the operator.

I. PRODUCT AND SERVICE ADJUSTMENTS

Without undue delay, when a certified operator wants to add or remove products to those listed on the current certificate, the operator must submit relevant information, with supporting documentation to the OTCO. OTCO conducts a review of the product adjustment request and supporting documentation to determine the extent of the changes to the current production system needed to produce the new product (i.e. new fields/facilities, remove fields/products, equipment, agricultural/processing inputs). If the changes to the system are minimal, consistent with existing practices described in the Organic System Plan and are clearly within organic standards, OTCO issues an amended certificate to the operator. If the changes are extensive or are not sufficiently described, OTCO requires an inspection of the new production and/or handling system before adding the product to the certificate.

Without undue delay, when a certified operator wants to add or remove a service (i.e. LPO, EU, GOTS, NOP), the operator must submit relevant information with supporting documentation to OTCO. Almost all service additions require an updated OSP, inspection and final approval before certification can be granted.

J. SURRENDER OF CERTIFICATION

Without undue delay, when a certified operator wants to surrender their certification, the operator must submit a written request to OTCO. OTCO will issue an acknowledgement of the surrender and require the operator to submit required information which must be received within 10 days to register the intent to surrender. Depending on where the operator is in the process of certification, OTCO will review and determine the options for course of action. Once an operation has surrendered certification, the operator must not sell or represent any product produced or handled as certified organic; unless you have already achieved organic certification with another certifier. Additionally, the operator cannot use any remaining labels that identify OTCO as the certifying agent. In the future, to be certified again by OTCO, the operator must apply for certification.

K. TEMPORARY VARIANCE

OTCO permits temporary variances where exceptions are warranted to counteract the effects, such as natural disaster, disease outbreaks or death, and as permitted by the certification scheme. OTCO reserves the right to evaluate each circumstance and the effects on the continuity of the products' organic condition and the events necessary to reestablish the

organic condition of the products and/or productive units as soon as possible.

L. EXEMPTIONS/EXCLUSIONS/DEROGATIONS

Exemptions/Exclusions

For the NOP Program, a production or handling operation, such as a retailer, restaurant, private label or an operation that only handles agricultural products that contain less than 70 percent organic ingredients that sells agricultural products as “organic” but whose gross agricultural income from organic sales totals \$5,000 or less annually is exempt from certification. Although exempt, the operator must still comply with the applicable organic production and handling requirements and products are not allowed to be used as ingredients identified as organic in processed products produced by another handling operation. Exempt operations may seek organic certification by submitting an Organic System Plan to OTCO.

Derogation

For the Mexico Organic Program (MOP) and the EU Compliance programs, OTCO reserves the right to grant special allowances to derogate from a standard. Derogations must be requested in advance of any implementations and are only allowed for a specific circumstance and for a limited time or a timeframe specified with certification. The following types of derogations may be granted according to specific circumstances and/or limitations:

EU Derogations:

- Retroactive recognition of a previous period as being part of the conversion period.
- Use of non-organic seed, vegetative propagating materials or seed potatoes.
- Use of non-organic ingredients of agricultural origin in processed foods.
- Practice of parallel plant production in the following cases where varieties cannot be easily differentiated.

MOP Derogations:

- Retroactive recognition of a previous period as being part of the conversion period.
- Use of non-organic seed, vegetative propagating materials or seed potatoes.
- Sporadic parallel production
- Use of synthetic additives or processing agents in food preparation or conservation
- Livestock -Artificial insemination
- Livestock -Physical alterations
- Livestock -reduction of animal carrying capacity
- Livestock -Reduction of animal carrying capacity
- Livestock -Antibiotics and synthetic medicines

PART III. PROCEDURES FOR CERTIFICATION OF MULTI-SITE OPERATIONS

A. DESCRIPTION OF MULTI-SITE OPERATIONS

A *multi-site operation with demonstrated internal control system* (a.k.a. cooperative or grower group) involves a centrally-managed association of local growers producing similar crops using similar practices and marketing their products in common. The multi-site operation completes a single application, which describes, in addition to the standard information, details of their internal control system, and includes detailed grower lists and code numbers as applicable. One certificate is issued covering all individual members. All sales of certified product must be sold through the certified legal entity; individual growers cannot market certified product outside of the group. Certification fees are based on sales figures of the entire operation acting as one entity and reported in the application. Please refer to the OTCO Fee Schedule for information on certification fees.

B. REQUIREMENTS FOR MULTI-SITE OPERATIONS

Groups wishing to apply as a multi-site operation must have an internal control system (ICS), which meets all the following criteria:

- An Internal Control System is defined as a written quality assurance system included in the OSP that sets forth the practice standards, recordkeeping, decision-making procedure and audit trail requirements applicable at each production unit, facility or site and that identifies the internal verification methods used.
- The internal reviewers carry out at least one annual direct observation and review of each individual operator, including visits to all fields and facilities.
- The Internal Control System maintains appropriate documentation, including at minimum a description of the subunits and the facilities, the production plans, materials used and rates of application, harvest records, the contractual arrangement with each individual member and internal inspection reports.
- The Internal Control System must include the decision making procedures used and application of sanctions to individual members who do not comply with the organization's OSP, the OFPA or the NOP Regulations, and/or other applicable standards and regulations.
- Internal control staff must inform OTCO of the irregularities and minor non-compliances found during internal audits. They must communicate back to the individual operator of the minor non-compliance the corrective actions imposed, with agreed time for completion.
- The Internal Control System must provide for the suspension or exclusion of members or subunits who are found to have major non-compliances, including a plan for corrective action that must be implemented before the member or subunit can be readmitted. Internal control staff must inform OTCO of all such actions, and a member who willfully or fraudulently violates the NOP, and/or other applicable standards and regulations, should not be permitted to rejoin the group until OTCO approves the measures taken to ensure that the violation is not repeated.

Minimum Criteria for Internal Control System Personnel

A project's Internal Control System staff auditors must meet the following criteria:

- Be fluent in the local language and dialect of the group members
- Possess the ability to read, write and report in the chosen Internal Control System (ICS) language
- Be free of any conflicts of interest with the members they are inspecting
- Be well-versed in the National Organic Program, as well as other applicable standards and regulations, especially in the sections of the regulation that relate to the subunits and members, sites or facilities that they review
- Be familiar with the local agricultural production systems
- Be familiar with the principles and practice of organic agriculture, as applicable
- Be familiar with the principles and practices of organic handling, as applicable
- Be able to demonstrate competence in internal control procedures and an understanding of the internal regulations

In order to mitigate the potential for noncompliances to go unreported, the Internal Control System personnel must receive contractual (in-writing) assurances that under no circumstances are they to be admonished in any way because they have detected and reported a noncompliance.

Multi-Site operations that cannot adequately demonstrate compliance with the above criteria to the satisfaction of OTCO staff must apply as individual growers.

C. INSPECTIONS OF MULTI-SITE OPERATIONS

The quantity of farm sites inspected depends predominately on the total number of sites within the grower group, as well as other risk variables such as sales volume of organic product, area certified, number of years certified, and previous compliance concerns. For new grower groups or grower groups seeking renewal of their certification, OTCO calculates the number of parcels to inspect by taking the square root of the total number of parcels requested for certification, and then multiplies by a risk factor, which is determined based on factors described below. For Multi-Site operations to be certified to the Mexican Organic Products Law (LPO), at least 10% of the total number of growers are inspected.

The grower group risk factor is used to determine the number of parcels to inspect annually. In all cases, predominantly different group members are inspected each year. This risk factor may be significantly higher depending on problems encountered during evaluation of the Internal Control System or concerns identified during the inspection. New members must be inspected and all noncompliances successfully resolved before being added to the group. OTCO conducts an annual inspection on every processor, exporter, and large farm of the group. A large farm is defined as a site with a production area of more than 10% of the total production area of the group and/or a farm bearing an external certification cost that is lower than 2% of their turnover. Except when the certification cost per member, based on their total annual income

when certified as an independent operator rather than a grower group member, would be greater than 5x the per member fee as a grower group member.

PART IV. TRANSITIONAL & CONVERSION CERTIFICATION

A. TRANSITIONAL Organic Foods Production Act of 1990

OTCO is pleased to offer transitional certification services in order to assist growers with the transition period. Transitional agricultural products fall outside the scope of the USDA National Organic Program and the EU Compliance Program. therefore, products must not be labeled, sold, or represented using the word “organic” (or prefixes including, but not limited to “bio” or “eco”) in any form; nor may they utilize the associated national organic seals.

Transitional standards are based upon the Organic Foods Production Act of 1990 and the applicable production and handling standards established by the USDA National Organic Program under 7 CFR Part 205, *except* transitional products lack compliance with §205.202(b). Following are the applicable sections of the USDA National Organic Program Final Rule that apply to Class T certification with OTCO:

- Subpart B Recordkeeping requirements and certain allowed and prohibited practices are located in Subpart B. Recordkeeping requirements are also described in Subpart E, subsection 205.400.
- Subpart C General production standards including farm management plans, soil fertility and pest management practice standards, and seed and planting stock standards are presented in subsections 205.200-206. Post harvest handling requirements are described in subsections 205.270-272. *Please note that the land requirement for Transitional certification is 1 year free of prohibited substances instead of 3 years for organic product, as established in 205.202 (b).*
- Subpart G Synthetic substances which are allowed for use in transitional crop production are listed in subsection 205.601. Nonsynthetic materials which are prohibited for use in transitional crop production are listed in subsection 205.602. Post harvest materials are defined in subsection 205.605.

If products in transition do not meet the standard 205.202(b), they cannot be labeled, sold or represented using the word "organic" in any form or manner.

B. CONVERSION Mexico Organic Program (LPO) Regulations

OTCO is pleased to offer conversion certification services in order to assist growers with the conversion period. Conversion agricultural products are recognized per Article 7-10 of the Reglamento de la ley de Productos Organicos. Operators seeking recognition of their in-conversion land/products may apply for certification. OTCO issues a conversion certificate for those products that meet the regulations; however, the operator in-conversion is not allowed to label, sell, or represent using the word “organic” (or prefixes including, but not limited to “bio” or “eco”) in any form; nor use the associated national organic seals.

PART V. PROCEDURES REGARDING CONFIDENTIAL INFORMATION

All records sent to OTCO are maintained in secure files. Only authorized accreditation authorities, including state and federal officials, and appropriate certification and

administrative staff have access to these files.

OTCO requires that personnel who have access to confidential information sign a “Confidentiality/Non-disclosure Agreement” which prohibits them from releasing confidential information (except as described below). This applies to all certification and administrative staff as well as any other OTCO program personnel, inspectors, contracted laboratories, and committee members including the Board of Directors.

Confidential information includes, but is not limited to discoveries, ideas, designs, drawings, specifications, techniques, models, data, documentation of programs, processes, know-how, customer lists, marketing plans, and financial and technical information.

Releasing Information

OTCO may release the following information to the public without written permission from certified operations:

- Certification certificates issued during the current and three preceding calendar years;
- A list of certified operators, including the name and address of operations, type(s) of operations, products produced, and the validity period of certification, during the current and three preceding calendar years; and
- The results of laboratory analyses for residues of pesticides and other prohibited materials conducted during the current and three preceding calendar years.

Lists may be published by regulatory bodies (USDA NOP, EC, SADER/SENASICA), listed on the OTCO website or by scheme owners (i.e. GOTS & NSF/ANSI 305).

If more information is needed, OTCO usually refers the inquiry to the published standards and directly to the certified operation. OTCO releases additional information only with the written permission of the certified operation.

OTCO requires clients to sign the Contract and Label Use Agreement, which gives OTCO the right to release information on individual operations as required by local, state, or federal law, to accreditation authorities and as required with another certification body to exchange necessary information to determine status of compliance.

Requests for Research Data

The certification staff may provide researchers with summaries or statistics based on OTCO files but may not release confidential information concerning individual operations without explicit permission to do so from the certified operation.

PART VI. ENFORCEMENT AND ADVERSE ACTION

The marketplace acceptance and success of third-party certification programs strongly depends on the consumers' confidence in the authenticity and integrity underlying certified product label claims. To this end, OTCO implements quality certification services that ensure compliance prior to granting certification and monitors continued compliance of certified operations.

After an applicant operation has been inspected and assessed for compliance with the organic standards, it is either approved for certification or denied due to non-compliance. If it is approved, the applicant receives a certificate. Certified operations submit annual changes to their Organic System Plan, are inspected annually, and are subject to unannounced inspections.

OTCO's enforcement procedures occur in various contexts and include the ability to take adverse action against noncompliant operations to protect consumer confidence in the organic

certification process. Enforcement procedures also include measures to ensure due process protects the rights of certification applicants and certified operators by providing an opportunity to respond to noncompliance findings prior to adverse action taken by OTCO. This combination of adverse action and due process ensures the certification process remains strict but fair.

Support for enforcing many of the organic standards to which OTCO offers certification services are provided by federal and/or regional governments via regulations passed by law-making bodies. These laws often provide penalties, including fines, for violations of the standards set forth in regulation, such as fraudulent mislabeling of organic products. To assist with successful implementation of standards supported by government regulation, OTCO maintains active relationships with both federal and regional government bodies.

Denial of Certification

When OTCO has reason to believe, based on information specified in the application form and/or the inspection report, that an applicant for certification is not able to comply or is not in compliance with the organic standards, OTCO provides a written notification of noncompliance to the applicant. When correction of a noncompliance is not possible, a notification of noncompliance and a notification of denial of certification may be combined in one notification.

In response to such notifications, applicants may 1) request mediation; 2) request appeal; or 3) re-apply for certification with any certification agent upon correction of identified noncompliances.

When applicants receive a notification of denial, they are provided a clear reference to the applicable regulation/standard with the option of requesting mediation or appealing the decision.

Noncompliance Issues for Certified Operations

When an inspection, review, or investigation of a certified operation by OTCO reveals any noncompliance with organic standards, a written notification of noncompliance is sent to the certified operation. The notification provides:

- A description of each noncompliance with a clear reference to the applicable regulation/standard
- The facts upon which the notification of noncompliance is based
- When correction of the noncompliance is possible, the date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction.

When a certified operation demonstrates that each noncompliance has been adequately addressed, OTCO sends the certified operation written notification that the noncompliance is resolved. If a partial or incomplete response is received OTCO sends the operation correspondence notifying them of pending conditions that require a response.

When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, OTCO sends the certified operation, and provides the appropriate government authority if necessary, a written notification of proposed suspension or revocation of certification. Certified operations notified of proposed suspension or revocation are provided with a clear reference to the applicable regulation/standard and the option of requesting mediation or appealing the decision.

If the certified operation fails to request mediation, or to file an appeal of the proposed suspension or revocation of certification, then OTCO sends the certified operation a written notification of suspension or revocation. The notification describes the effect of a suspension or revocation on future eligibility for certification. OTCO does not send a notification of suspension or revocation to a certified operation that has filed an appeal while final resolution is pending.

Requests for reinstatement of a suspended operation under the USDA NOP are reviewed according to NOP policy. Reinstatements under other OTCO standards may be subject to review by OTCO or other authorities. In all cases OTCO will followed prescribed policies identified by the accreditation or authorities. If reinstatement is granted, OTCO makes all necessary modification to formal certification documents public information, and authorizations for use of mark to ensure that the validity period, revised scope, and reinstated date are clear and transparent.

OTCO's Response To Allegations of Violations of Standards (Complaints)

OTCO may receive information or complaints about suspected violations of standards from consumers, inspectors, farmers, distributors, brokers, government officials, or any other interested party. Details about the suspected problem must be submitted in writing before OTCO begins a formal investigation. OTCO acknowledges receipt of the complaint and performs an investigation. Following investigation, the informant is provided a courtesy letter confirming resolution. As required under applicable organic regulations and/or standards, OTCO notifies the appropriate oversight authorities of all compliance proceedings and actions taken that result from a formal investigation.

Marketplace Logo Monitoring

OTCO periodically surveys retail arenas to monitor use of the OTCO name and logo in the marketplace and evaluate product label claims for conformance with labeling provisions established in applicable organic standards and provisions in the OTCO Organic Certification Contract and Trademark Use Agreement. Any discrepancies are reported to the Quality Control Manager for review and notification to the operator.

Residue Testing of Certified Organic Products

All certified products that are sold labeled or represented as organic or any other labeling category under the standards must be made accessible by certified organic production and handling operations for examination by OTCO, or any governing official with regulatory authority associated with the applicable organic standards.

OTCO, or other governing officials, may require pre-harvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as organic based on risk to compliance with the standard. When there is reason to suspect that an organic product has been produced using or contaminated with a prohibited substance, OTCO will require sampling and testing to be conducted as appropriate. An appropriately designated representative must conduct such tests for OTCO or governing officials at the official's or OTCO's own expense.

- For operations certified under the USDA NOP standards, OTCO is required to conduct sampling on 5% of the certified operations at a minimum. OTCO conducts the sampling and testing in accordance with NOP policy for sampling pesticide residues. While OTCO will typically conduct testing on organic products, we may conduct samples and testing on soil, plant tissue or other as necessary.
- For EU, MOP, GOTS, and NSF/ANSI 305 certified operators, OTCO collects and tests sample from a minimum of 5% of the operations annually, based on a risk analysis. OTCO may collect the 5% as part of an investigation of a complaint, an unannounced inspection, evaluation of risk during an inspection or as the need arises to maintain compliance with regulations.

Reporting and Investigating Residue Test Results

If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the FDA, EPA or other regulatory tolerances (ex. COFEPRIS in Mexico), OTCO promptly reports such data to the federal health agency or comparable international authorities whose regulatory tolerance or action level has been exceeded.

Exclusion from Organic Sale Under the USDA NOP

When residue testing detects prohibited substances at levels above 5 percent of the EPA tolerance level, the actual FDA action level or other regulatory tolerances (ex. COFEPRIS in Mexico), the agricultural product must not be sold, labeled or represented as organically produced. OTCO, the state organic program's governing state official, or the USDA may conduct an investigation of the certified operation to determine the cause of the prohibited substance's presence.

Part VII: APPEALS AND MEDIATION

A. PROCEDURES RELATING TO MEDIATION

Any dispute with respect to denial of certification or proposed suspension or revocation may be mediated at the request of the applicant for certification or certified operation. The request must be submitted in writing to OTCO or in some cases verbal notification is allowed. OTCO may accept or reject requests for mediation. If OTCO rejects the request for mediation, OTCO provides written notification advising the applicant or certified operation of the right to request an appeal. If OTCO accepts the request for mediation, such mediations are conducted by a

qualified mediator mutually agreed upon by all parties to the mediation. The parties have 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the applicant or certified operation have 30 days from termination of mediation to request an appeal. Any agreement reached during mediation must be in compliance with applicable organic standards.

B. PROCEDURES RELATING TO APPEALS

All appeals are reviewed, heard, and decided by persons not involved with the decision being appealed.

Appeals under the National Organic Program

Under the National Organic Program, appeals of certification decisions to deny, suspend or revoke must be made to the state organic program or, in the absence of a state program, directly to the USDA.

Persons who believe they are adversely affected by a noncompliance decision of the National Organic Program's Program Manager may appeal such decision to the Administrator for the Agricultural Marketing Service (AMS) of the USDA within 30 days from the receipt of the notification.

Appeals to the State Organic Program must be filed in writing. All appeals must include a copy of the adverse decision and a statement of the appellant's reasons for believing that the decision was not proper or made in accordance with applicable program regulations, policies, or procedures.

Appeals to the Adjudication Committee

Any operation participating in an OTCO certification program outside the scope of the National Organic Program such as the (EU, MOP, GOTS, NSF/ANSI 305) may request that the Adjudication Committee (AC) reconsider a decision made by OTCO staff. The appeal must be made no later than 30 days after receipt of the certification decision. The appeal must be submitted to the certification office by certified letter and must contain:

- Relevant background information on the case,
- OTCO's actions and rulings on the case,
- Reasons to change OTCO's position,
- Evidence to support the appellant's assertions and
- A suggested resolution to the problem.

OTCO will promptly respond to the appellant to acknowledge receipt of an appeal and confirm whether the appeal is directly related to OTCO's certification activities for that operation. Appellants are strongly encouraged to submit complete information when making an appeal. Submission of new information after the initial appeal may delay scheduling of the adjudication

meeting. In order to prevent spurious appeals and to help offset the cost of adjudication proceedings, the appellant must a fee of \$100 with the appeal.

Procedures Applicable to the Adjudication Process

The OTCO adjudication process is designed to provide any operation participating in an OTCO certification program outside the scope of the National Organic Program with the opportunity to have a certification decision reconsidered when the operator believes the decision was not made in accordance with the applicable standards and/or procedures. The adjudication process encourages detailed discussions of the case and endeavors to reach a decision that is both equitable and clearly defensible. The steps of the adjudication process are summarized in the diagram.

