



503.378.0690  
PO Box 368  
Corvallis, OR 97339  
organic@tilth.org  
tilth.org



# Oregon Tilth EU Certification Manual

OTCO Certification Manual  
Version: September 1, 2023





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## Key Terminology

Key terminology includes OTCO definitions and a partial list of terminology from the NOP [Subpart A - Definitions, 205.2 Terms Defined](#) as adapted for operating the OTCO EU Program.

### OTCO Definitions

**Additional Inspections.** In addition to mandatory inspections, OTCO reserves the right to perform additional inspections that are announced or unannounced of the operators.

**Administrative Capacity.** OTCO 's ability to provide certification services for all the programs and scopes of services offered by OTCO.

**Cancellation of Certification.** When OTCO issues a suspension or revocation of services, or when the operation withdraws an application or surrenders certification, the operator's rights to sell or represent any product produced or handled as certified organic are canceled, and the operation must immediately cease use of the OTCO logo, EU seal, and all references in labeling, advertising, or otherwise to organic production. Operations that are revoked are ineligible to reapply for certification for a total of 5 years with OTCO or with another certifying agent.

**Certification office.** The legal site of the organization that is responsible for the certification activities conducted by OTCO; except for certification activities that occur at certified operations or applicants for certification, such as inspections and sampling. (7 C.F.R. §205.2) This includes any home office that is used as the certifier's primary location from which certification activities are conducted and any contracted third parties. It does not include the location of an individual person working remotely, unless it is the primary office from which the certifying agent conducts certification activities, or it is the only site where records used for organic certification activities are accessible.

**OTCO Certification office activities.** Activities; including but not limited to policy formulation and approval, process and procedure development and approval, initial assessment of competence and approval of technical personnel, contractors and subcontractors, control of monitoring or competence of personnel, contractors and subcontractors and outcomes. Contract review; including technical review of applications and determining the technical requirements for certification activity in new technical areas or areas of limited sporadic activity, decision on certification, including technical review<sup>3</sup> of evaluation tasks (such as design and documentation review<sup>4</sup>, sampling, testing, inspection and audit, client liaison and other.

**Geographical Proximity.** A common geographic area with common environmental and climate characteristics and is within sufficient proximity to the ICS headquarters to allow for adequate ICS monitoring and control. In some cases, OTCO may allow production located farther away from headquarters by monitoring the groups control over resources (economic, time, distance, personnel, etc.) and/or by establishing production units.

**Hybrid Inspection.** Evaluations performed by Inspectors using a combination using both onsite and remote components. Participants at minimum must include the inspector and an authorized representative of the operation.

**Remote Inspection.** Evaluations performed by Inspectors using advanced technology to perform a desk inspection of an operator's documents and records. These inspections are typically used during unannounced inspections; except for those inspections conducted in the EU program. Remote inspections are not allowed for service additions. Participants at minimum must include the inspector and an authorized representative of the operation.

**Self-Reporting.** When an operation suspects contamination or has concerns about the status of any incoming organic or in-conversion products, the operator verifies that the supplier certificate, labeling and all available audit trail documents are accurate and applicable to the product. If the operation suspects contamination or has concerns about the organic status of their own product, the operator immediately investigates the potential cause of any contamination. If the operator is able to substantiate (i.e. positive test or detections) or if suspicion cannot be eliminated, operations immediately notify OTCO to further investigate.

**Support Office.** The legal site of the organization that is responsible for the general support, customer service and the liaison of activities with a certification office.

**Support Office activities.** Activities including: the administration of an office, maintaining data, liaison with government agencies, the certification office and local events and meetings, and clerical and financial activities that support the certification office.

## **Subpart A -Definitions, 205.2 Terms Defined**

**Accreditation.** A determination made by the Secretary that authorizes a private, foreign, or State entity to conduct certification activities as a certifying agent under this part.

**Adverse Action.** A noncompliance decision that adversely affects certification, accreditation, or a person subject to the Act, including **a proposed suspension or revocation; a denial of certification, accreditation, or reinstatement; a cease-and-desist notice; or a civil penalty.**

**Certification Review.** The act of reviewing and evaluating a certified operation or applicant for certification and determining compliance or ability to comply with the USDA organic regulations. This does not include performing an inspection.

**Conformity Assessment System.** All activities, including oversight, accreditation, compliance review, and enforcement, undertaken by a government to ensure that the applicable technical requirements for the production and handling of organic agricultural products are fully and consistently applied.

**Organic Exporter.** The final certified exporter of the organic agricultural product, who facilitates the trade of, consigns, or arranges for the transport/shipping of the organic agricultural product from a foreign country to the United States.

**Organic Fraud.** Deceptive representation, sale, or labeling of nonorganic agricultural products or ingredients as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

**Organic Importer.** The operation responsible for accepting imported organic agricultural products within the United States and ensuring NOP Import Certificate data are entered into the U.S. Customs and Border Protection import system of record.

**Organic Integrity Database (OID).** The National Organic Program's electronic, web-based reporting tool for the submission of data, completion of certificates of organic operation, and other information, or the tool's successors.

**Producer Groups.** are multi-site operations established as a single legal entity and managed by an internal control system (ICS). **An internal control system** is an internal quality management system that establishes and governs the review, monitoring, training, and inspection of the producer group operation, and the procurement and distribution of shared production and handling inputs and resources, to maintain compliance.

**Producer Group Production Unit.** A defined subgroup of producer group members in geographic proximity within a single producer group operation that use shared practices and resources to produce similar agricultural products.

**Supply Chain Traceability Audit.** The process of identifying and tracking the movement, sale, custody, handling, and organic status of an agricultural product along a supply chain to verify the agricultural product's compliance with this part.

**Support Office.** The legal site of the organization that is responsible for the general support, customer service and the liaison of activities with a certification office.

**Support Office activities.** Activities; including the administration of an office, maintaining data, liaison with government agencies, the certification office and local events and meetings, and clerical and financial activities that support the certification office.

**Unannounced Inspections.** An inspection of all or a portion of the production or handling activities of a certified operation without advance notice to determine compliance with regulations.



## OTCO EU Certification Manual

This manual provides an overview of OTCO's compliance with ISO/IEC 17065 for the operation of the OTCO EU Certification Program.

The OTCO EU Certification Program is recognized for the purpose of equivalency under Regulation (EC) No 834/2007 and continues to be recognized under this regulation for a limited period necessary to transition to Regulation [\(EU\) 2018/848 of the EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 May 2018 on organic production and labelling of organic products.](#)

The OTCO EU Certification Program is for those operators certified organic by OTCO located in Mexico seeking trade with the European Union. Certification with this program facilitates trade with the United States, Canada, Switzerland, Sweden and the United Kingdom of Great Britain and Northern Ireland.

Certification in this program is founded upon the USDA NOP regulations and the Mexico Ley de Productores Organicos (LPO) regulations to facilitate trade between Mexico and the United States and between Mexico and Canada.

This manual is an extension of the [OTCO Certification Terms and Conditions - Oregon Tilth Certification Services and Trademark Use](#) providing responsibilities between OTCO and the operator for access to OTCO certification services.

**For more information visit [tilth.org](http://tilth.org) and [esp.tilth.org](http://esp.tilth.org)**



## OREGON TILTH, INC.

The mission is to “work to make our food and agriculture biologically sound and socially equitable.” Our efforts continue to shape food systems that benefit people and the planet together. Oregon Tilth is organized as a 501(c)(3) non-profit corporation that is governed by the Tilth Board. As part of Tilth’s leadership in advocacy, Oregon Tilth offers the Oregon Tilth Certified Organic (OTCO) certification services.



## OREGON TILTH CERTIFIED ORGANIC (OTCO)

OTCO is the certification body organized by Oregon Tilth, Inc. OTCO’s purpose is to impartially provide organic certification services to its operators and be supportive of its constituents in the organic industry.

The responsibilities of certification services are associated with the certification office in the United States and local administrations and representation are provided by the support office in Mexico.

### OTCO’s Certification Office

#### Oregon Tilth Certified Organic (OTCO)

Physical:

301 SW 4th St, Ste. 110  
Corvallis, OR 97333

Mailing:

PO Box 368  
Corvallis, OR 97333

[tilth.org](http://tilth.org)

P 503-378-0690

[organic@tilth.org](mailto:organic@tilth.org)

### OTCO’s Support Office

#### OTCO Mexico

Libramiento Oriente #8164-A Int.-1 C.P.  
60190 Uruapan, Michoacán México  
EN LA COLONIA ZUMPIMITO  
CP. 60190, URUAPAN, MICHOACÁN

[www.esp.tilth.org](http://www.esp.tilth.org)

P 01 [52] (452) 255-0953

P 503-378-0690

[Mexico@tilth.org](mailto:Mexico@tilth.org)

# OTCO Offers an Array of Organic Programs in Mexico.

## OTCO National Organic Program (NOP)

Certification Body Certificate Number: 815



Operators in the OTCO NOP program comply with the NOP [Regulations](#). The OTCO NOP program provides organic certification to operators located in the United States, Mexico, Canada (outside of COR scopes) and Iceland.

The OTCO NOP program is qualified to certify crops, wild crops, livestock and handling. This program is accredited by the [United States Department of Agriculture, Agricultural Marketing Service, National Organic Program](#). For more information visit [www.tilth.org](http://www.tilth.org)

The OTCO NOP program facilitates international trade in accordance to the multiple [trade agreements and arrangements](#) with the following countries: **Canada, European Union, Japan, Korea, Switzerland, Taiwan, and the United Kingdom of Great Britain and Northern Ireland**. These agreements and arrangements require products imported into the United States to be certified to the NOP and accompanied by a NOP Import Certificate.

**Beginning March 19, 2024, OTCO will require all products entering the United States to be accompanied by a [NOP Import Certificate](#).**

## OTCO Mexico Ley de Productores de Organicos (LPO)

Certification Body Certificate Number: OC-220622-22-CPAA-001

Export Codes: US/EU Equivalency: US-ORG-042

Mexico: MX-BIO-116



OTCO Mexico Ley de Productores de Organicos is offered to operations located in the United States and Mexico.

**In the United States**, as of January 1, 2022, OTCO provides the [OTCO Mexico Ley de Productores Organicos \(LPO\) program](#) for those operations importing organic agricultural products per tables b-f of Annex 1 to Mexico. All imports entering Mexico must be certified to Mexico's Organic Products Law and accompanied by an official OTCO Mexico Transaction Certificate. For more information visit <https://tilth.org/certification/our-services/international/>

**In Mexico**, OTCO is qualified to provide certification for the scopes of producer, wild harvest, mushrooms, processing and marketing in Mexico. The OTCO MX LPO Program does not offer certification of livestock. This program is recognized by SADER/SENASICA and accredited by the [Committee on Accreditation for Evaluation of Quality \(CAEQ\)](#). Products exported to the United States must be certified to Mexico's Organic Products Law and the NOP, and effective March 19, 2024, product must be accompanied by a NOP Import Certificate. Effective May 12, 2023, products exported to Canada, must be certified to Mexico's Organic Products Law and must be accompanied by an official OTCO Mexico/Canada Transaction Certificate. For more information visit <https://tilth.org/certification/our-services/international/> and <https://esp.tilth.org/>

## Mexico & Canada Equivalency Agreement



The [Canada-Mexico Organic Equivalency Arrangement](#) came into effect on February 15, 2023. The agreement allows products certified under the Canada Organic Regime or the **Ley de Productos Organicos** to be sold and labeled as organic in both countries.

The arrangement applies to agricultural and processed products of plant origin grown or produced within either country, livestock and livestock products produced in Canada, and organic products whose final processing or packaging occurs within either country. For example, this could include products like fresh, frozen or canned fruits and vegetables, as well as meat, poultry, dairy or egg products certified as organic in Canada. Organic equivalency arrangements are part of the Government of Canada's ongoing commitment to eliminate trade barriers and increase consumer access to a variety of organic foods.

**As of May 12, 2023, all trade between Canada and Mexico must be accompanied by an OTCO Transaction Certificate.**

### OTCO EU Certification Program<sup>1</sup>



Export Codes: US/EU Equivalency: US-ORG-042  
Mexico: MX-BIO-116

Operators in the OTCO EU Certification Program comply with the regulations located at [www.tilth.org](http://www.tilth.org) and at <https://esp.tilth.org/>. This program is recognized by the [European Commission](#) and accredited by the [Committee on Accreditation for Evaluation of Quality \(CAEQ\)](#).

The OTCO EU Certification Program offers organic certification to operators located in Mexico with access to trade with the European Union (EU) and its member countries. OTCO is qualified to provide certification for the following categories:

- Category A: Unprocessed plants and plant products, including seeds and other plant reproductive material.
- Category D: Processed agricultural products, including aquaculture products, for the use as food.
- Category E: Processed agricultural products for use as Feed.

All trade with the European Union must be registered in the [EU TRACES](#) and be accompanied by a Certificate of Inspection (COI). All products destined to the EU and the United Kingdom of Great Britain and Northern Ireland must acquire a COI **prior to the shipment leaving the port**. Any products entering the EU and/or the United Kingdom of Great Britain and Northern Ireland without a COI are subject to being rejected by port authorities.

<sup>1</sup> (EU) 2018/848 Article 35.7; REGULATION (EU) 2018/848 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, (EU) 2018/848 Article 35.7; (EU) 2021/2325; (EU) 2021/1698, (EC) No 1235/2008 Article 10A:



## OTCO KRAV Verification Program for Sweden



The OTCO EU Certification Program facilitates trade between Mexico and Sweden. With this program, EU certified organic operators are not certified to KRAV but instead receive a verification to additional requirements for products entering Sweden. The verification is then forwarded to authorities as requested by the operator for claims that KRAV extra requirements have been met. This verification does not authorize operators the use of the KRAV-label or make any claims that products are KRAV-certified.

## Switzerland Recognition of OTCO EU Certification Program



The OTCO EU Certification Program facilitates trade between Mexico and Switzerland. This program is [recognized](#) by the Federal Department of Economic Affairs, Education and Research (EAER) Federal Office for Agriculture (FOAG). The FOAG recognizes the OTCO EU Certification Program for being recognized by the [European Commission](#) and accredited by the [Committee on Accreditation for Evaluation of Quality \(CAEQ\)](#).

All trade exported to Switzerland must be registered in the EU TRACES and be accompanied by a Certificate of Inspection (COI). All products destined to the EU and Switzerland must acquire a COI prior to the shipment leaving the port. Any products entering the EU and/or Switzerland without a COI is subject to being rejected by port authorities.

## Great Britain Recognition of OTCO EU Certification Program



The OTCO EU Certification Program facilitates trade between Mexico and the United Kingdom of Great Britain and Northern Ireland. This program is recognized by the [Department for Environment Food & Rural Affairs \(DEFRA\)](#). The DEFRA is recognized by the [European Commission](#) and accredited by the [Committee on Accreditation for Evaluation of Quality \(CAEQ\)](#).

All trade exported to the United Kingdom of Great Britain and Northern Ireland must be registered in the EU TRACES and be accompanied by a Certificate of Inspection (COI). All products destined to the EU and the United Kingdom of Great Britain and Northern Ireland must acquire a COI prior to the shipment leaving the port. Any products entering the EU and/or the United Kingdom of Great Britain and Northern Ireland without a COI is subject to being rejected by port authorities.



## ACCREDITATION OF OTCO EU CERTIFICATION PROGRAM

The OTCO EU Certification Program has the confidence to provide organic certification in accordance with regulations with **recognition** by the European Commission Agricultural and Rural Development and from **accreditation** by the Committee on Accreditation for Evaluation of Quality (CAEQ).



The European Commission Agricultural and Rural Development currently lists Oregon Tilth on the Organic Farming Information System (OFIS) [LIST OF RECOGNISED CONTROL BODIES AND CONTROL AUTHORITIES FOR THE PURPOSE OF EQUIVALENCE](#). OTCO is listed as an organization whose operations are within the scope of a third country recognition in accordance with Commission Regulation (EC) No. 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 and 889/2008 as regards to the arrangements for imports of organic products from third countries.

Oregon Tilth is applying for recognition of operating in full compliance with EU regulations in 2018/848 effective beginning of January 1, 2022, for full implementation by the year 2025.

OTCO is seeking to be listed on the Commission Implementing Regulation (EU) 2021/2325 of 16 December 2021 establishing, pursuant to Regulation (EU) 2018/848 of the European Parliament and of the Council, the list of third countries and the list of control authorities and control bodies that have been recognized under Article 33(2) and (3) of Council Regulation (EC) No 834/2007 for the purpose of importing organic products in the Union.



The Conseil des appellations réservées et des termes valorisants (CAEQ), a public authority in the Province of Quebec. CAEQ performs assessments and accredits OTCO for certifying organic products.

CAEQ is recognized by the Canadian Food Inspection Agency (CFIA) and the European Commission as compliant with ISO/IEC 17011. CAEQ is a full member of the Inter-America Accreditation Cooperation (IAAC), a regional group of accreditation bodies recognized by the International Accreditation Forum (IAF). CAEQ is currently seeking direct membership with IAF to obtain a Multilateral Recognition Certification Program.

## OVERVIEW OF EU REGULATIONS

OTCO operators in the OTCO EU Certification Program comply with the Regulation EU 2018/848 - rules on organic production and labeling of organic products and the successive amendments.

For more information, see: [Legislation for the organics sector](#) (European Commission).

### **Introduction of regulations**<sup>2</sup>

Since 1 January 2022, [Regulation \(EU\) 2018/848](#) of the European Parliament and of the Council of 30 May 2018 is the applicable legislative act, also known as the basic act, laying down the rules on organic production and labelling of organic products, repealing and replacing Council [Regulation \(EC\) No 834/2007](#) of 28 June 2007.

Any amendments or corrections or guidance on implementation of the Regulation (EU) 2018/848 are published in the [Consolidated Text \(current version is 2/21/2023\)](#) and the [approved materials \(current version is 2/7/2023\)](#).

Amendments are acts of general application to supplement or amend certain non-essential elements of the basic act. Corrections are identified as corrigendums, which appropriate original regulations. The European Commission maintains the [Legislation for the Organic Sector](#), which includes a complete list of the delegated and implemented regulations organized by the following topics: Production and Labelling, Controls and Trade.

### **Changes to Regulations**<sup>3</sup>

Upon EC's release of amendments to regulations or notices of delegated or implementing regulations, OTCO notifies operators accordingly with timeframes for fully complying with changes to regulations. OTCO maintains links to EU regulations and provides summaries of changes at [tilth.org](http://tilth.org) at [tilth.org/knowledgebase\\_category/eu](http://tilth.org/knowledgebase_category/eu) and <http://esp.tilth.org/certificacion/internacional>

### **The Aim of EU 2018/848**

<sup>2</sup> [ec.europa.eu/info/food-farming-fisheries/farming/organic-farming/legislation\\_en](http://ec.europa.eu/info/food-farming-fisheries/farming/organic-farming/legislation_en)

<sup>3</sup> (EU) 2018/848 Article 9.1 and ISO/IEC 17065 7.10.1

The aim of EU 2018/848 is to revise and strengthen the [European Union's](#) (EU) rules concerning organic production and the labeling of organic products in relation to: the control system, the trade regime and production rules. In this way, it seeks to: create a level playing field for operators; harmonize and simplify rules; improve consumer confidence in organic products and in the EU's organic logo.

### **Key Points**

The regulation broadens the scope of the existing legislation on the [production and labeling of organic products](#) (Regulation (EC) No [834/2007](#)) to cover products closely linked to agriculture such as cork, salt, essential oils, cotton or wool. It harmonizes the rules applicable to organic operators in the EU [Member States](#) and non-EU countries through the introduction of the compliance system. It simplifies access to the scheme for small operators and reviews certain production rules.

### **Principles<sup>4</sup>**

Organic production should: respect natural systems and cycles and maintain and improve the state of soil, water and air, plant and animal health, and the balance among them; preserve the elements of natural landscapes; use [energy](#) and natural resources responsibly; produce a wide variety of high-quality products to meet consumer demand; ensure the integrity of organic production at all stages of the production, processing and distribution processes of food and animal feed; protect the environment by contributing to a non-toxic environment and climate with a high level of biodiversity to maintain long term soil fertility. Operators should work to develop the supply of locally adapted plant genetic material, short distribution channels and local production.

Among other things, organic production must give consideration to the selection and on-farm production of genetically diverse species and varieties of natural plant reproductive material able to meet the specific regional needs of the soil and the limitation of external inputs and non-renewable resources. Priority should be given to the preventative purpose of the plants selected such as resistance to pests and diseases, and protection of the natural enemies of pests. When necessary, inputs should be derived from organic production, natural or naturally-derived, low solubility mineral fertilizers. Waste and by-products of plant and animal origin should be recycled as an input in plant production. Any use of heterogeneous materials must be approved prior to use.

Processed food or feed intended to be labeled for organic sale should be processed with care through use of biological, mechanical and physical methods and be sourced from organic agricultural ingredients and restrict the use of non-organic ingredients, micronutrients and processing aids to a minimum. Processes should be adapted considering the sanitary status, regional differences in the ecological balance, climatic and local conditions, stages of development and specific husbandry practices.

### **Excluded Methods<sup>5</sup>**

Products intended for sale as organic or in-conversion must exclude the use of genetically modified organisms (GMOs) and products produced from or by GMOs. Container production, hydroponics, aeroponic production is prohibited. Products from animal cloning, rearing artificially induced polyploid animals and use of ionizing radiation must be excluded from the whole organic food chain. Additionally, substances and processing methods that could be misleading as to the true nature of the product and food containing, or consisting of engineered nanomaterials should be excluded.

### **Preventive and Precautionary measures<sup>6</sup>**

To avoid adverse effects on the [environment](#) and on animal and plant health, producers must: identify risks of contamination to include systematic identification of critical procedural steps, take preventive measures at each stage of production, preparation and distribution to preserve biodiversity and soil quality to prevent the occurrence of pests and diseases, control the pests and diseases; take proportionate and precautionary measures to avoid contamination with products or substances not authorized for use in organic production. Operators must regularly review all preventive and precautionary measures and adjust as needed. Organic operators that engage simultaneously in in-conversion or non-organic production must take additional steps to ensure separation of time and space to protect the organic integrity at every stage of production, preparation and distribution.

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4 (EU) 2018/848 Articles 4, 5, 6, 7 & 8, [Delegated Regulation \(EU\) 2021/1189](#)

5 (EU) 2018/848 Articles 5(f)(iii), 5(i),7(c), 7(e), 8(c), 9.4, 9.5, 11 and Annex II 1.1

6 (EU) 2018/848 Articles 9.4, 9.6., 9.10, 28, and 38.1(a)



## CODE OF CONDUCT

OTCO operates its certification program in a nondiscriminatory, impartial and confidential manner.

### **Nondiscriminatory<sup>7</sup>**

OTCO makes its certification services accessible to all applicants and operators whose activities fall within the scope and administrative capacity of its operations. Operations can be of any size and have additional certifications with other certifying agents, conditional upon the size of the client or membership of any association or group, including that Oregon Tilth certification is not conditional upon the number of certificates already issued.

OTCO accepts all operations that fall within the scope of its certification program to the extent of its administrative capacity to adequately provide service, and 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.

### **Safeguarding Impartiality<sup>8</sup>**

OTCO safeguards the impartiality of certification activities. OTCO takes responsibility for its management and certification activities at all levels of the organization to ensure certification is handled in an objective and transparent manner. OTCO monitors the risk to impartiality, takes preventive actions and takes appropriate measures to minimize or eliminate any risk to the impartiality of services offered to its operator.

### **Responsibility of OTCO<sup>9</sup>**

OTCO also maintains its responsibility for granting, maintaining, suspending or revoking certification of an operation. OTCO has the right to outsource work related to certification (e.g., testing and/or inspection) to an external body or person; in which case, OTCO takes full responsibility for such contracted and subcontracted work, including confidentiality. Upon applying for organic certification with OTCO, applicants consent to the use of contractors and subcontractors during the certification process.

For subcontractors, OTCO accepts the material review decisions of other agencies: [Organic Material Review Institute \(OMRI\)](#), the Washington State Department of Agriculture (WSDA) Organic Material

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<sup>7</sup> ISO/IEC 17065 4.4 and (EU) 2018/848 Article 46.2(c)(g) as amended by (EU) 2021/1697 Article 1

<sup>8</sup> ISO/IEC 17065 4.2, USDA NOP, 7 CFR 205.501(a)(11)

<sup>9</sup> (EU) 2018/848 Article 40

Review Program, Pennsylvania Certified Organic (PCO) Material Review Program, the California Department of Food and Agriculture (CDFA); providing that the bodies meet and maintain requirements of the [USDA NOP Handbook](#).

OTCO accepts the third-party pesticide residue testing from laboratories accredited to ISO/IEC 17025. OTCO currently utilizes the laboratory services of the Pacific Agricultural Laboratory (PAL), Matrix Sciences Company for pesticide residues and GMO testing services from OMIC USA Inc.

### **Confidentiality & Public Information<sup>10</sup>**

OTCO has a duty to maintain certification information in a confidential manner. Where information is not publicly available, OTCO maintains strict confidentiality with respect to its operators and does not disclose business related information to third parties that are not involved in the regulation or certification of the operation.

OTCO provides access to publicly available information at [www.tilth.org](http://www.tilth.org) which is a directory of all operations certified in accordance with the OTCO EU Program; including the operator's profile; name of the operation, the regulatory details for the types of activities and products evaluated for certification, the validity of the certification period, and details of type of activities performed and/or products they produce, quantity of products, information on the land/premises/units, and list of subcontractors. Directory also includes the status of the operation's certification and in cases of revocation, remains on list for 5 years. Operator's may request scope certificates issued by OTCO and the results of laboratory analysis for residues of pesticides during the current and three preceding calendar years from date of request.

Upon application, operators agree to the [Certification Terms and Conditions - Oregon Tilth Certification Services and Trademark Use](#), which includes the provisions for confidentiality and public information; including OTCO's right to release information on operations as required by local, state, or federal law, to accreditation authorities.

The [Certification Terms and Conditions - Oregon Tilth Certification Services and Trademark Use](#) obligates OTCO to exchange information necessary with another certification body to determine status of compliance; including information to certify, decertify or investigate an operation for the purpose of verifying compliance with supply chain traceability and audit trail documentation and other information as required by the regulations. Other regulatory and certification bodies involved in the exchange of information are upheld to the same requirements of confidentiality.

OTCO is required to report information in various submissions to accreditations and/or, international regulatory agencies. These submissions are submitted in a confidential manner. Types of reporting include the OFIS Annual Report, any national or international government agency Pesticide Residue Reports and other information as requested by directives, memos, investigations and other requests.

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<sup>10</sup> (EU) 2018/848 Article 34(6) & (EU) 2021/1698 Article 17, (EU) 2018/848 Article 43, (EU) 2017/625 Articles 105(1) and 106(1) and (EU) 2021/1698 Article 21



## CERTIFICATION OVERVIEW

Understanding the certification steps is the first step in pursuing organic certification. The journey of certification includes making an application or renewing services followed by an inspection and concluding with a decision on certification.

The OTCO website is a wealth of information to explain the process and make connections with OTCO for certification services. This manual provides an overview of the certification process and extends requirements of the [Certification Terms and Conditions - Oregon Tilth Certification Services and Trademark Use](#) for services offered by OTCO to operators for carrying out compliance to the regulations of EU 2018/848.





### Conversion<sup>11</sup>

OTCO assesses operators that are transitioning from conventional to organic practices. For operations that have not yet implemented organic practices, the conversion period begins when the operation submits their application for certification and begins to implement organic practices. During conversion, all organic regulations apply.

Operations transitioning to organic can apply at 9 months and obtain certification only after the operator has successfully implemented organic practices for 12 months or 12 months prior to harvest. Operations may market their products as “transitional” once a transitional certificate is issued.

Operations may apply for derogation that allows for retroactive recognition of their conversion period if there is sufficient proof that no prohibited substances have been applied to the land for at least the previous three years.



## APPLICATION

OTCO provides organic certification services for operations that produce crops and/or handle organic products. A single operation may be certified under more than one service.

### Applying<sup>12</sup>

To apply for organic certification, OTCO requires an applicant to submit legal and logistical information; including the completion of an Organic System Plan. The Organic System Plan describes the operation, the products, the practices and various activities conducted by the producers and handlers of organic products. Operators can contact OTCO or request an application from the [Oregon Tilth website](#).

Upon submission of the Organic System Plan (OSP) along with payment per the [Fee Schedule](#), OTCO sends an acknowledgment of receipt to the applicant. OTCO then reviews the application for completeness and the operation’s ability to comply with the regulations. OTCO ensures that review of the application and any further requests for information to determine compliance are communicated to the applicant within a reasonable time.

### Applicant Transfer of Control<sup>13</sup>

OTCO processes operations that transfer from another certification body as new applicants. The previous certification body and OTCO must exchange relevant compliance information about the operation. Relevant information must establish that the operation and products are capable of being certified organic to the OTCO EU Program.

Applicants are required to disclose previous certification history, including any denials, suspensions, revocations, and any unresolved noncompliances. If certification history indicates a notice of noncompliance or a notice of denial of certification, a description must be provided on how the

<sup>11</sup> (EU) 2018/848 Article 10 & (EU) 2020/464 Article 1

<sup>12</sup> (EU) 2018/848 Article 34.1 & [Implementing Regulation \(EU\) 2021/1165](#), [Implementing Regulation \(EU\) 2023/121](#) & [Delegated Regulation \(EU\) 2021/1691](#)

<sup>13</sup> (EU) 2018/848 Article 63.2 2nd subparagraph & (EU) 2021/1698 Article 21 & (EU) 2021/1698, Article 10, 3(d)



corrective actions have been implemented. With any history of adverse actions, OTCO is obligated to provide information to the NOP and/or any regulatory body with oversight.

### **Application Review<sup>14</sup>**

The application review ensures the Organic System Plan (OSP) is applicable to the type of operation and is complete with supporting documents demonstrating the ability to comply with all applicable regulations, including any international verifications requested for exporting of products. If the information appears to comply with regulations, OTCO assigns the operation an inspection.

If the OSP is incomplete or fees are not paid, OTCO issues requests for information, or issues a notice of noncompliance and/or a denial of certification.

- **Applicant Notice of Noncompliance**

When OTCO has reason to believe that an applicant is not able to comply or is not compliant with the regulations, OTCO provides a written notice of noncompliance to the applicant.

The notice of noncompliance provides a description of each noncompliance, the facts upon which the notice of noncompliance is based, and the date by which the applicant must reply and rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

When correction of a noncompliance is not possible, a notice of noncompliance and a notice of denial of certification may be combined in one notice. OTCO issues a notice of Denial of Certification If any prohibited materials or practices are described in the Organic System Plan.

- **Applicant Denial of Certification**

OTCO issues a written notice of denial of certification to an applicant who fails to respond to the notice of noncompliance, and/or fails to sufficiently apply corrective actions. A notice of denial of certification states the reason(s) for denial, the applicant's right to reapply for certification with OTCO or any other EU accredited certifying agent, and the right to request mediation or appeal the denial of certification with OTCO's Adjudication Committee.

### **Applicant Withdraw of Application<sup>15</sup>**

Applicants may withdraw the application at any time. An applicant who withdraws an application is liable for the costs of services provided up to the time of the voluntary withdrawal. If the withdrawal of application happens prior to a certification decision being made, any notice of noncompliances or denial of certification are not issued to the operation.

### **Applicant's Willful False Statements or Misrepresentation**

If OTCO has reason to believe that an applicant has willfully made a false statement or otherwise purposefully misrepresented the applicant's operation or its compliance with the regulations, a denial of certification is issued without first issuing a notice of noncompliance.

### **Applicants Re-applying for Certification**

An applicant for certification who received a written notice of noncompliance, or a written denial of certification may apply for certification again at any time with OTCO or another certifying agent.

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<sup>14</sup> (EU) 2021/1698 Article 10

<sup>15</sup> (EC) No 834/2007 Article 27

An applicant who is applying after suspension may re-apply at any time with OTCO or another certifying agent, unless the suspension specifies a time period for eligibility. Suspended operations are required to undergo reinstatement.

An applicant who is applying after revocation is not eligible to reapply for 5 years after the previous certificate is canceled. The revoked operator must submit an application accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with regulations.

## 2 INSPECTION

### Understanding the inspection

OTCO performs inspections of applicants and certified operations for the purpose of determining the operation's compliance with the regulations. Inspectors submit written reports describing the operation and organic management practices for review by OTCO for organic certification.

#### **Inspector Assignment<sup>16</sup>**

OTCO assigns an inspector who is qualified with the appropriate education, training and experience matching the operation's activities. OTCO also considers the size and complexity of the operation, the type of operation to be inspected, and the proximity and availability of the inspector.

To safeguard impartiality, OTCO screens inspectors for any potential conflicts of interests that may conflict with the ability to provide operators an objective inspection. OTCO rotates the assignment of inspectors every 3 years to avoid over- familiarity.

If the operator objects to the assignment of a particular inspector to evaluate their operation, OTCO considers the request is sufficient to reassign the inspection. The operator may not choose or recommend a specific inspector.

#### **Onsite Inspection<sup>17</sup>**

All operations must be inspected every calendar year. All inspections are performed when Inspectors have 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. All inspections are 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.

For **initial inspections**, OTCO performs onsite inspections within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the regulations, *except*, That, the initial inspection may be delayed for up to 6 months when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.

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<sup>16</sup> (EU) 2018/848 Article 46.2(c)

<sup>17</sup> (EU) 2018/848 Articles 10.10 & 38 and, (EU) 2017/625 Articles 5, 10, 15, 1, (EU) 2021/1698 Articles 9, 10, 11 & 14 & EU 2018/848 Article 38.6, & (EU) 2021/2119 Articles 2 & 3

For **annual inspections**, OTCO performs on-site inspection of operators and reserves the right to conduct hybrid inspections. A hybrid inspection is when the majority of the operation is visited on-site and the remaining portions are visually inspected using advanced technology and/or by performing a document review as a Remote Inspection.

OTCO inspectors conduct the inspection to verify information in the Organic System Plan, to describe on-site observations, evaluate and confirm the completeness and accuracy of the Organic System Plan and to document any changes to the organic system plan.

After the inspection, OTCO Inspectors conduct an exit interview with an 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.

Within a reasonable time after the inspection, OTCO provides the operator with a copy of the inspection report and any test results of samplings performed during the inspection.

### **Additional Inspections<sup>18</sup>**

OTCO performs additional inspections to verify any changes, corrective actions, issues with the operation's compliance with regulations, investigate high risk crops (known to concentrate soil pesticide residues or be GM detections, recommendations from staff or inspectors, as deemed necessary. These inspections may be announced or unannounced and may include sampling events, as deemed necessary.

- **Announced Inspections**

In addition to the annual inspection, inspections may be assigned based on random selecting, high risk assessments, or for any potential risk to the organic integrity of the products and/or activities. *Announced inspections may be performed onsite, hybrid or as a remote inspection.*

- **Unannounced Inspections**

In addition to an annual inspection, all operations are subject to unannounced inspections. inspections may be assigned based on random selecting, high risk assessments, or for any potential risk to the organic integrity of the products and/or activities. *Unannounced inspections may be performed onsite, hybrid or by a remote document review without advance notice.*

Every year, 10% of OTCO's operators in the EU program receive an unannounced inspection based on risk assessments. In addition to the 10% selected for unannounced inspections, OTCO reserves the right to randomly select operations to receive an unannounced inspection.

For high-risk products, designated by the EU includes mangos produced in Mexico. OTCO is required to schedule at least two physical onsite inspections per year of operators or Producer Groups, and one of these physical onsite inspections is without prior notice.

- **Producer Group and Member -High Risk Inspections<sup>19</sup>**

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<sup>18</sup> (EU) 2021/1698 Article 9.5 & (EU) 2018/848 Article 38.4(a), Ref Ares (2022) 8813552, (EU) 2021/279 Article 7, EU (EU) 2021/1698 Article 8 & 9.8, (EU) 2017/625 Article 9, (EU) 2018/848 Article 38.2, and (EU) 2021/1698 Article 9.2 & (EU) 2021/1698 Article 9(8), 12(5) and 16(6)

<sup>19</sup> Federal Register/Vol.88, No. 12 Thursday January 19, 2023/Rules and Regulations, p.3596, (EU) 2021/1698 Article 9.7 and 12.2

Producer Groups are potentially high-risk operations due to the nature of their complex supply chain that includes an Internal Control System with oversight of membership. As such, during the mandatory inspection, the inspector visits the membership as calculated at 1.4 times the square root or 2% of the total number of members in the Producer Group, whichever is higher.

Furthermore, all producers within the Producer Group that are assessed as high risk must be inspected at inspection. Producer Groups may also have one or more production units, which are determined by geographical proximity. For each of the determined production units, OTCO inspects at least one member per each of those units. OTCO reserves the right to inspect additional members based on any potential risks to organic integrity.

- **Compliance Investigations**

OTCO may perform an additional inspection for the purpose of investigations due to complaints, suspected fraudulent activity, positive residue results, detections of GMOs, verification of Supply Chain Traceability, fulfillment of regulatory directives and/or other concerns with the integrity of the organic certification.

### 3 GRANTING CERTIFICATION<sup>20</sup>

After applicants receive an inspection, OTCO performs a certification review of the inspection report and makes a certification decision. Applicants are granted certification based on their ability to comply with regulations based on the operator's Organic System Plan and the inspection report. Operations that comply with regulations are granted an organic certificate and listed on the OTCO Directory. The OTCO certificate for Producer Groups includes a list of members.

When granted certification, the operator can sell the product as certified organic. Organic product sold as certified organic must be labeled in compliance with the regulations. For labeling products refer to the [OTCO EU labeling guidelines](#) and in Spanish at <https://esp.tilth.org/certificacion/internacional/>. For labeling information required for export to foreign countries use the [labeling and packaging guidelines](#). In addition to the organic certificate and proper labeling, operations selling products to foreign countries may be required to accompany the certified product with a [transaction certificate](#).

### 4 CONTINUATION OF CERTIFICATION<sup>21</sup>

OTCO carries out the renewal periods beginning January 1 and April 1 of each year. Operators are required to pay certification fees and submit any changes to the Organic System Plan (OSP). Examples of changes to submit could include but are not limited to: any changes in the operator's owners, farm/business name, principal responsible person, contact person, contact information including address and phone number; any deviations from, changes or modifications to or other amendments made to the previous year's OSP; and any additions or deletions to the previous year's OSP intended to be undertaken in the coming year. Other information may be deemed necessary by OTCO to determine compliance with regulations.

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<sup>20</sup> (EU) 2021/1006 Annex; (EU) 2018/848 Article 36 and (EU) 2021/1006 Annex & (EU) 2018/848 Article 35(4) & [Delegated Regulation \(EU\) 2023/207](#)

<sup>21</sup> (EU) 2012/1698 Article 8, 9, 8, EU 2018/848 Article 35.4 and 12.5 (EU) 2018/848 Article 34(7)

OTCO sends reminders to operators that are missing information and/or missing payment for renewal. If reminders are not addressed within the provided time period, OTCO sends a notice of noncompliance to the operator. Notice of noncompliances are also sent when OTCO has reason to believe, based on information specified in the organic system plan and/or the inspection report, that a certified operator is not in compliance with the regulations.



## CATALOGUE OF MEASURES (COMs)<sup>22</sup>

OTCO issues Notices to operators that fall into three categories as defined by the EU: minor, major and critical, which are determined by the adequacy and implementation of the operation's precautionary measures, the effects of the noncompliance on the organic integrity of the product, the ability of the traceability system to locate the affected product in the supply chain to prevent import or export of products and the operation's response to previous requests or notices from OTCO. **Determinations regarding the level of noncompliance issued are made according to the OTCO Catalogue of Measures.**

When OTCO has reason to believe, based on information specified in the organic system plan and/or the inspection report, that a certified operator is not in compliance with the regulations, OTCO issues notices to the certified operator.



## NONCOMPLIANCE PROCEDURE

### Notice of Noncompliance (Minor)<sup>23</sup>

If an operation is found to be in violation of the regulations, OTCO issues a notice of noncompliance which provides a description of each noncompliance, the facts upon which the notice of noncompliance is based, and the date by which the operator must respond.

Operators must respond to the notice of noncompliance with corrective actions or an action plan to correct each noncompliance along with supporting evidence to demonstrate compliance. Operators may also rebut noncompliances. All notice of noncompliances must be responded to within the provided time period..

*Minor Catalogue of Measure: OTCO issues notices of noncompliances in circumstances where the operator is found to have minor issues that are correctable and supported by systems that have proportionate and appropriate precautionary measures in place to maintain the product's organic integrity, the systems do not affect the health or safety of workers, and the traceability system can locate the affected product in the supply chain to prevent import and export of products.*

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<sup>22</sup> (EU) 2021/1698 Article 10.4, 22.3 & Annex IV; (EU) 2018/848 Articles 41.4, 42.2, 43.1, 4.3.2; (EU) 2017/625 Articles 105(1) and 106(1); ISO/IEC 17065 7.1, EU 2018/848 Article 35.4, (EU) 2021/279 Article 8

<sup>23</sup> (EU) 2021/1698 Article 10.4, 22.3, Annex IV; (EU) 2018/848 Articles 41.4, 42.2, 43.1, 4.3.2; (EU) 2017/625 Articles 105(1) and 106(1); ISO/IEC 17065 7.1



## ADVERSE ACTION PROCEDURE<sup>24</sup>

OTCO takes adverse actions when minor issues cannot be corrected and/or there is a major noncompliance with the operation's compliance with the regulations.

### **Notice of Proposed Suspension or Notice of Proposed Revocation**

If a rebuttal of a noncompliance is unsuccessful or adequate corrective measures are not completed within the prescribed time period, a notice of proposed suspension or proposed revocation is issued. An operation that is issued a proposed suspension or proposed revocation has the option to request mediation or file an appeal with the OTCO Adjudication Committee. If violations are found uncorrectable or willfully violating the regulations, OTCO may issue a notice of noncompliance combined with a notice of proposed suspension or a notice of proposed revocation.

*Major Catalogue of Measure: A major noncompliance may be any or combination of the following that may or may not be correctable: suspected and/or confirmed contamination, commingling of product, violations of organic regulations, a breach of the Certification Terms and Conditions - Oregon Tilth Certification Services and Trademark Use, timelines for resolution are not met with a satisfactory review, precautionary measures that are not proportionate and appropriate to ensure the product's organic integrity, traceability measures cannot locate the affected product in the supply chain, any significant deviation between input and output calculations in mass balance performed and/or absence of records or missing financial records.*

*Operators issued a combined notice for major noncompliances may be subject to a new conversion period, reduction of the scope of certification, suspension, or revocation of the certificate. Product(s) from the entire lot or production run affected may be excluded from sale as organic or the operation may be prohibited from selling and/or exporting product for a specific period of time.*

### **Notice of Suspension or Notice of Revocation**

A notice of suspension or notice of revocation is issued when mediation and appeal options are not successful. If suspended, an operation can request reinstatement with OTCO or apply to another certifying agent.

If revoked, an operation and all responsibly connected parties are ineligible to reapply for certification for a total of 5 years with OTCO or another certifying agent.

Once an operator's certification is suspended or revoked, the operator's certification is **canceled** by OTCO. Operators must not sell or represent any product produced or handled as certified organic and must immediately cease use of the NOP seal, OTCO logo, and all references in labeling, advertising, or otherwise to organic production.

All major notices are reported and/or sent to OTCO's oversight body in monthly reports.<sup>25</sup>

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<sup>24</sup> (EU) 2021/1698 Annex IV, Part A(b)(i)(ii)(iii)(iv) & Part B

<sup>25</sup> (EU) 2018/848 Article 43(1) & 4.3.2, (EU) 2017/625 Articles 105(1) and 106(1)

## Willful Violations (Critical)<sup>26</sup>

If violations are found uncorrectable or willfully violating the regulations, OTCO issues a notice of noncompliance combined with a notice of proposed suspension or a notice of proposed revocation.

*Critical Catalogue of Measure: Willful violations are excessive or intentional acts, such as contamination or comingling of product, intentional violation of organic regulations, intentional use of GMOs, intentional mixing organic with in-conversion or non-organic products, intentional re-labeling of downgraded products as organic, falsification of documents connected with the certification of organic products, intentional omission of information leading to incomplete records, fraudulent transaction or activities, absence of records and financial records that can trace affected product in a supply chain, the act of refusing OTCO and/or oversight body(s) access to premises subject to controls, or to its book keepings, including financial records, or refuses to allow the control authority or control body to take samples breach of the Certification Terms and Conditions - Oregon Tilth Certification Services and Trademark Use, intentional use of non-authorized substances or products, making false statements or otherwise purposefully misrepresentation of the operation and/or the timeline for resolutions were not met with a satisfactory review.*

If OTCO has reason to believe that a certified operation has willfully violated the regulations, OTCO sends the certified operation a notice revocation for the entire operation or a portion of the operation, as applicable to the noncompliance.

Revocations are cancellations of certification. Once OTCO **cancel**s certification, the operator must not sell or represent any product produced or handled as certified organic and immediately cease use of the OTCO seal, EU logo, and all references in labeling, advertising, or otherwise to organic production. Operations that are revoked are ineligible to reapply for certification for a total of 5 years with OTCO or with another certifying agent.



## MEDIATION AND FILING AN APPEAL

### Mediation

Mediation is a collaborative process between OTCO and an operator where parties settle any dispute with respect to denial of certification, proposed suspension or proposed revocation.

Mediation may be requested by the applicant for certification or certified operation. The request must be submitted in writing to OTCO within 30 days of receipt of the applicable adverse action notice.

Following receipt, OTCO acknowledges the request for mediation and accepts or rejects the request for mediation:

- If OTCO accepts the request for mediation, such mediation is conducted by a qualified mediator mutually agreed upon by the parties. The parties have a maximum of 30 calendar days to reach an agreement from the scheduled date of mediation. Successful mediation results in a settlement agreement agreed to in writing by both parties. Any settlement agreement reached must comply with the regulations. If mediation is unsuccessful, the operation has 30 calendar days from receipt of a written notice of unsuccessful mediation to submit an appeal to the NOP or applicable state organic program.

<sup>26</sup> (EU) 2021/1698 Article 10.4, Annex IV Part A(c) & Part B, & ISO/IEC 17065 7.11

- If OTCO rejects the request for mediation, the operator has 30 days to request an appeal with OTCO.

If the terms of the finalized settlement agreement are violated, OTCO issues adverse actions.

### **Filing an Appeal with OTCO**

An operation may file an appeal with OTCO to dispute a notice of denial of certification, proposed suspension or proposed revocation within 30 calendar days of the date of receipt of the notice. Appeals must be sent to [organic@tilth.org](mailto:organic@tilth.org). OTCO formally acknowledges an appeal on the date it is received. The appellant is responsible for the cost of the appeal.

All appeals shall be reviewed, heard, and decided by persons not involved with the certification decision being appealed. OTCO does not cancel certification when an appeal is pending resolution.

The appeal must be made no later than 30 days after receipt of the certification decision. The appeal 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.

When an Adjudication Committee is needed, the Certification Director appoints at least three appropriately qualified people to reside on the appeal. The members of the Adjudication Committee must have a good understanding of the organic foods industry, and must not have been involved in the certification decision-making process of the operation.

The Certification Director chairs the Adjudication Committee meetings but is not a voting member of the committee. Adjudication Committee members must provide annual declarations of interests. Members with a conflict of interest in a particular case must temporarily step aside allowing an alternate member to take their place during the deliberations on that case.

All Adjudication Committee members and alternate members must sign a Confidentiality/Non-disclosure Agreement regarding all cases brought before the committee. Appointment as an Adjudication Committee member remains effective until the person voluntarily resigns or is excused from the position by the Certification Director.

### **Reinstatement**

Operations suspended from the OTCO EU Certification program may reapply with OTCO in accordance with regulations. Operators whose certificate is revoked are not eligible to reapply for 5 years after the previous certificate is canceled. The application request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with regulations.



### **SURRENDER OF CERTIFICATION**

A surrender of certification is when an operator **cancels** certification services with OTCO. Without undue delay, when a certified operator wants to surrender their certification, OTCO acknowledges the request with the operator and cancels the requested certification services.



Depending on where the operator is in the process of certification, OTCO reviews and determines the options for course of action. Once an operation surrenders certification, OTCO cancels certification at which time, the operator must not sell or represent any product produced or handled as certified organic; unless, the operator has already achieved organic certification with another certifying agent. 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.



## CERTIFICATION CHANGES - ADDING/REDUCING/VIOLATIONS

### Adding or Reducing Certification

Without undue delay, any **additions or changes** that affect the Organic System Plan (OSP) during certification must be communicated to OTCO, including changes to the program of services, products, product formulations, acreage, or facilities to be certified. Operators are required to immediately self-report any infringements or violations of the organic regulations, including any suspected contamination or commingling of land, products, or other situations that affect the organic integrity.

OTCO conducts a review of the request or **self-reporting** to determine the extent of the changes to the current production system. At OTCO's discretion, a decision is made whether an inspection is needed to approve the requested updates. If the changes to the system are minimal, consistent with existing practices described in the Organic System Plan and are clearly compliant with regulations, OTCO issues an amended certificate to the operator. If the changes are extensive or a document review is not sufficient, OTCO requires an inspection of the new production and/or handling system before adding the update to the certificate. (i.e. adding new fields, sites and facilities).

### Derogations<sup>27</sup>

OTCO reserves the right to grant special allowances with regulations. Derogations must be requested in advance of any implementations or only allowed for specific and/or catastrophic circumstances 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:

- Retroactive recognition of a previous period as being part of the conversion period.
- Use of in-conversion or non-organic plant reproductive material.
- Use of in-conversion or non-organic ingredients of agricultural origin in processed foods.
- Practice of parallel plant production in the following cases where varieties cannot be easily differentiated.
- Container production in specific cases.
- Production of sprouted seeds provided that seeds are organic and the obtaining of chicory heads included by dipping in clear water is allowed.

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<sup>27</sup> (EU) 2020/2146 Article 3.1; (EU) 2022/474 Annex amending (EU) 2018/848 Annex II Part I 1.8.5.2; (EU) 2021/1698 Article 25; (EU) 2020/1693 Article 1(a) amending (EU) 2018/848 Article 53.1; (EU) 2018/848 Article 10.3; (EU) 2021/1698 Article 24; (EU) 2018/848 Articles 25, 9.9, and Annex II Part I 1.3 & 1.4, Regulation (EU) 2018/848, Annex 1.3 of Part I of Annex II, (EU) 2018/848 Annex II as amended by (EU) 2020/1794



## CERTIFICATION INVESTIGATIONS

### Investigations<sup>28</sup>

OTCO performs investigations due to complaints, suspected fraudulent activity, positive pesticide residue results, detections of GMOs, verification of supply chain traceability, fulfillment of regulatory directives and/or other concerns with the integrity of the organic certification.

OTCO accepts information or complaints about suspected violations 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.

Following receipt, OTCO acknowledges the complaint to the sending party. Products under investigation may be excluded from organic sale until the suspicion is eliminated; particularly any events where prohibited substances are found above unacceptable levels of residue. Following the investigation, the sending party is provided a courtesy letter confirming resolution.

### Pesticide Residue Testing<sup>29</sup>

OTCO, or other governing officials, may require soil testing and/or preharvest or postharvest testing of any agricultural product to be sold, labeled, or represented as organic under the regulation when there is reason to believe that the product has come into contact with a prohibited substance or has been produced using genetically engineered organisms. Additional cases could deem a pesticide residue test appropriate, including but not limited to the suspicion of material input usage not approved for use in organic production. Operators may also be subject to future monitoring events.

When pesticide residue testing detects prohibited substances, OTCO investigates certified operations to determine the source of the prohibited substance. If OTCO finds adequate evidence that violation has occurred, then OTCO proceeds with a noncompliance and/or adverse actions.

Every year, a minimum of 5% of OTCO's operators in the EU program are either randomly selected or selected based on results of the potential risk to organic integrity, and for other reasons deemed necessary.

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<sup>28</sup> (EU) 2021/1698 Article 22, (EU) 2018/848 Article 28.2 and 27, (EU) 2018/848 Article 29.2, Article 41.2, (EU) 2021/279 Articles 1 and 2

<sup>29</sup> (EU) 2021/1698 Article 12 & (EU) 2017/625 Article 138 & (EU) 2018/848 Article 29, (EU) 2021/1698 Article 12.4, & (EU) 2021/279 Article 7, (EU) 2018/848 Article 42.1, (EU) 2017/625 Article 35

OTCO performs all investigations by persons not involved with the certification decision or with the claim.

**Supply Chain Traceability Audit (SCT)**

OTCO conducts supply chain traceability audits of products and operations with complex supply chains. These audits are performed when regulatory directives are issued to OTCO or in cases where OTCO has assessed high-risk operations and/or products that necessitate an investigation of the supply chain. In these audits, OTCO may collaborate with other certification agencies to fully identify and trace the movement, sale, custody, handling, and organic status of a product along the supply chain. The supply chain traceability audit can be initiated when, but not limited to a market concern, export or import activity, operations or products are determined to be high-risk, suspicion of fraud, compliance of high-risk products, patterns of activity, suspected contamination with prohibited substances or other compliance-related reasons. The number, frequency, type, and extent of the audits conducted are appropriate to the number, scope and/or complexity of OTCO certified operations.

**Market Surveillance**

OTCO periodically investigates marketplace establishments to monitor the use of the OTCO name and logo in the marketplace. Product label claims are evaluated for compliance with labeling provisions established in applicable organic regulations and provisions according to the Certification Terms and Conditions - Oregon Tilth Certification Services and Trademark Use. OTCO notifies operations of any discrepancies and takes the appropriate action.



## PRODUCER GROUPS aka GROUP OF OPERATORS (GoO)<sup>30</sup>

**The regulations described in this section are only applicable to groups of operators located in Mexico with EU services.**

Each OTCO certification program has various regulations for Producer Groups.

Producer Groups are multi-site operations established as legal entities and managed by an internal control system (ICS). An internal control system involves a centrally managed association of local growers producing similar crops using similar practices and a joint marketing system for products produced by the group members.

The multi-site operation completes a single application, with detailed grower lists and code numbers as applicable. One certificate is issued covering all individual members. Individual growers cannot market certified products outside of the group. Certification **fees** are based on sales figures of the entire operation acting as one entity and reported in the application. Additionally, the cost of individual certification must represent more than 2% of the member's annual turnover or standard output of organic production. An individual member's annual turnover of organic production must be less than EUR 25 000. The members must operate within geographical proximity to one another. Membership in any given group of operators is limited to 2000 individual members.

Members of a Producer Group must be a farmer or operator who may also be engaged in processing, preparation or placing on the market food or feed. Individual members are limited to operations that have a maximum holding of five hectares, or 0,5 hectares in the case of greenhouses, or 15 hectares in the case of permanent grassland.

Producer Groups wishing to apply for certification must have an internal control system (ICS) that details, at minimum, the criteria identified in the OTCO application and OSP documents, the group's written ICS Membership Agreement, personnel requirements and inspection policies including the duties of the ICS Manager, Inspectors and producer group members.

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<sup>30</sup> (EU) 2018/848 Article 35, (EU) 2018/848 Article 36 as amended by (EU) 2021/715, (EU) 2021/771 & (EU) 2021/279 Articles 4, 5, & 7

Where a group has fewer than 10 members, every operation is subject to annual inspection by OTCO. At least 2% of the total group of members are subject to residue sampling each year.

The ICS Manager is required to notify OTCO immediately upon suspicion of any major and critical noncompliance, suspension/withdrawal of any member or production unit, and any circumstance where a product is prohibited from sale. Deficiencies in the ICS include, at minimum, producing, processing, preparing or marketing products from suspended or withdrawn members or units, or product otherwise prohibited from labeling or advertising for organic or in-conversion sale, failure to follow internal procedures for adding new members, annual inspections, failure to identify suspended or withdrawn members, serious deviations in findings between internal and external inspections, serious deficiencies in issuing and following up on corrective actions for noncompliances and having an inadequate number of competent ICS inspectors.

OTCO withdraws certification for the entire group when deficiencies in the policies or malfunctioning of the ICS are identified, particularly when there is a failure to detect or address noncompliance by individual members of the producer group that may affect the organic integrity of the product.



**WE BELIEVE FOOD AND AGRICULTURE SHOULD BE BIOLOGICALLY SOUND AND SOCIALLY EQUITABLE. THIS BELIEF HAS GUIDED OREGON TILTH FOR NEARLY FIVE DECADES.**

**[TILTH.ORG](http://TILTH.ORG)**

**OUR MISSION**

Support and promote biologically sound and socially equitable agriculture.

**OUR VISION**

Community-led food systems that enrich people and planet, together.

**OUR VALUES**

- Integrity
- Transparency
- Compassion
- Harmony
- Teamwork
- Knowledge
- Courage

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Promoting and supporting biologically sound and socially equitable food systems and agriculture.