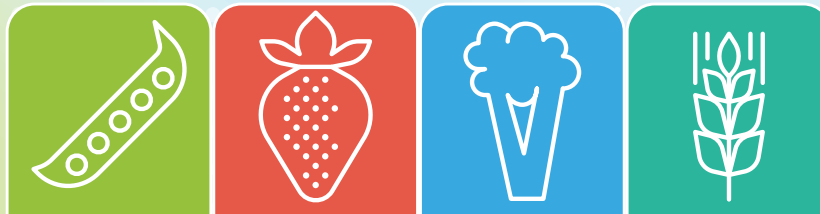


# TAIWAN EXPORT MANUAL

U.S. Industry Resource on  
How to Export U.S. Organic Products for  
Label and Sale as Organic in Taiwan



*SINCE 1985*  
**Organic**  
*trade association™*

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# OTA's Industry Export Manual for Taiwan

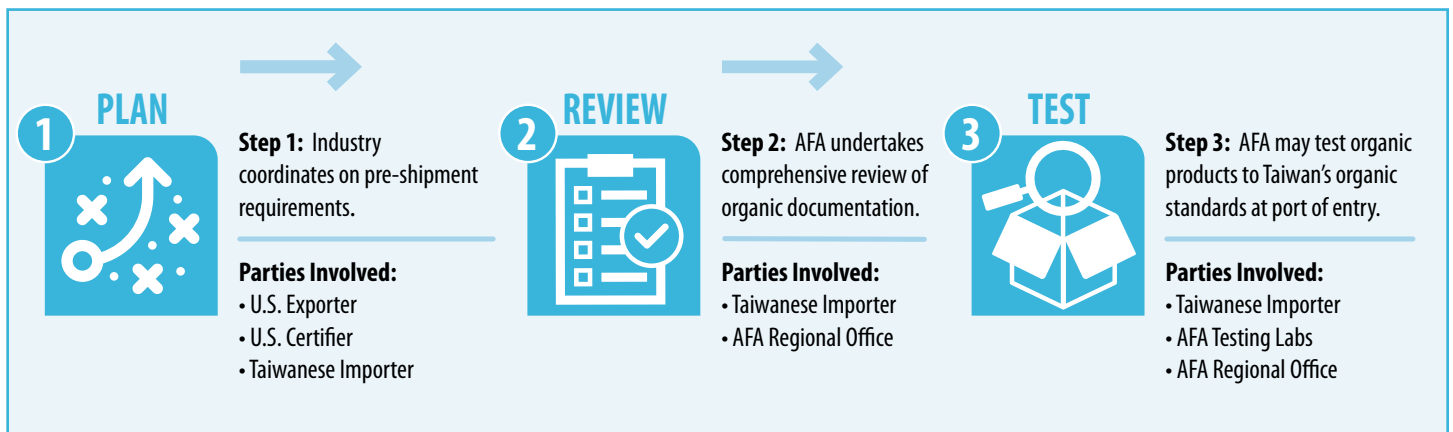
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## SECTION 1: INTRODUCTION AND OVERVIEW

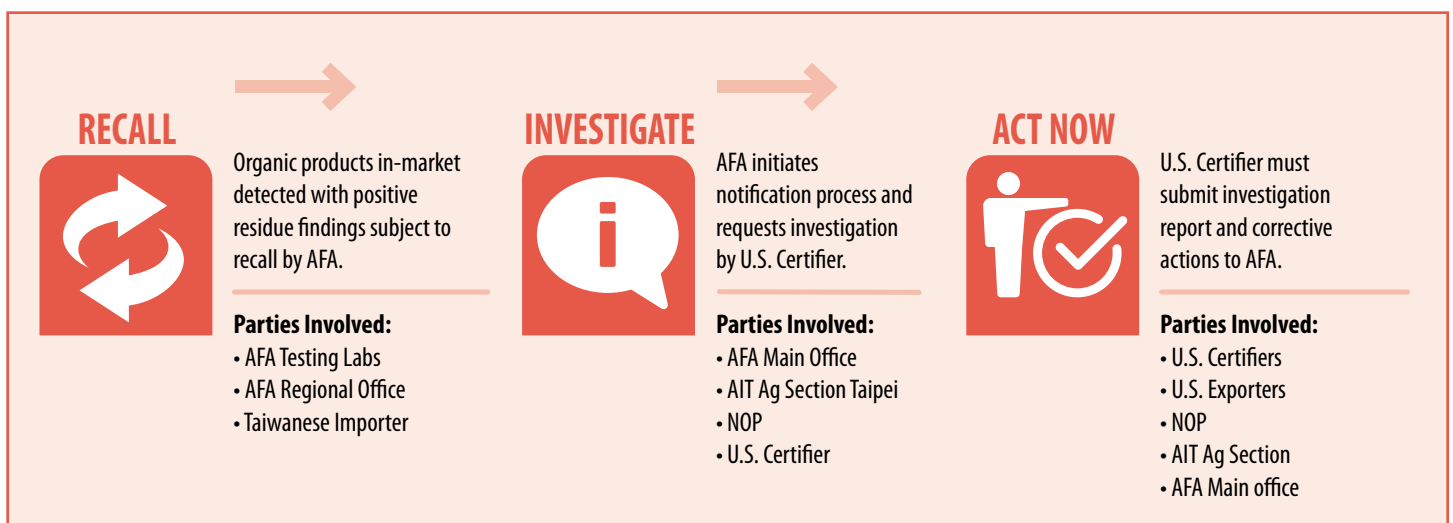
### A. Export Manual Overview and Summary

The Taiwan Export Manual, produced by the Organic Trade Association (OTA), is a technical resource for U.S. organic certifiers and U.S. exporters designed to: (a) improve U.S. industry's understanding of Taiwan's organic labeling approval process, including testing protocols; (b) clarify roles and responsibilities of key industry and organic authority stakeholders throughout the process; and (c) enhance predictability for U.S. industry to facilitate U.S. organic exports to Taiwan.

**There is a three-step process before U.S. organic exports may be labeled and sold in Taiwan as organic:**



Once approved to be sold in the Taiwan market, U.S. organic products may still be subject to testing as part of in-market surveillance conducted by Taiwan's organic authorities as a means to ensure organic integrity. As such, U.S. industry should be aware of Taiwan's testing protocols and, in particular, the importance of U.S. Certifiers responding promptly to notifications of positive residue findings to avoid 100% mandatory batch-by-batch testing at the port of entry for all U.S. organic products accompanied by a TM-11 issued by that U.S. Certifier.



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**To assist U.S. industry in preparing for shipments of U.S. organic products to Taiwan and understanding industry's role throughout the import approval process, OTA's Export Manual provides U.S. Exporters and U.S. Certifiers with the following detailed information:**

- Describes each of the three phases step-by-step required to successfully facilitate the labeling and sale of U.S. organic products in the Taiwan market;
- Provides relevant information on the role of key agencies in Taiwan and United States involved in facilitating the sale of U.S. organic products in Taiwan;
- Explains requirements for U.S. Certifiers to respond to Taiwan's organic authorities when residues are detected in U.S. organic products in the Taiwan market to prevent 100% mandatory batch-by-batch testing of the U.S. Certifiers' products at the port of entry; and
- Includes operational flow charts illustrating the entire organic import process in Taiwan; helpful checklists for both the U.S. Exporter and U.S. Certifier; as well as annexes detailing the history, regulatory environment, and other contextual information on the organic regime in Taiwan.

Any questions regarding the content of OTA's Taiwan Export Manual or about the Taiwan organic market should be directed to the Organic Trade Association, via email at [info@ota.com](mailto:info@ota.com).

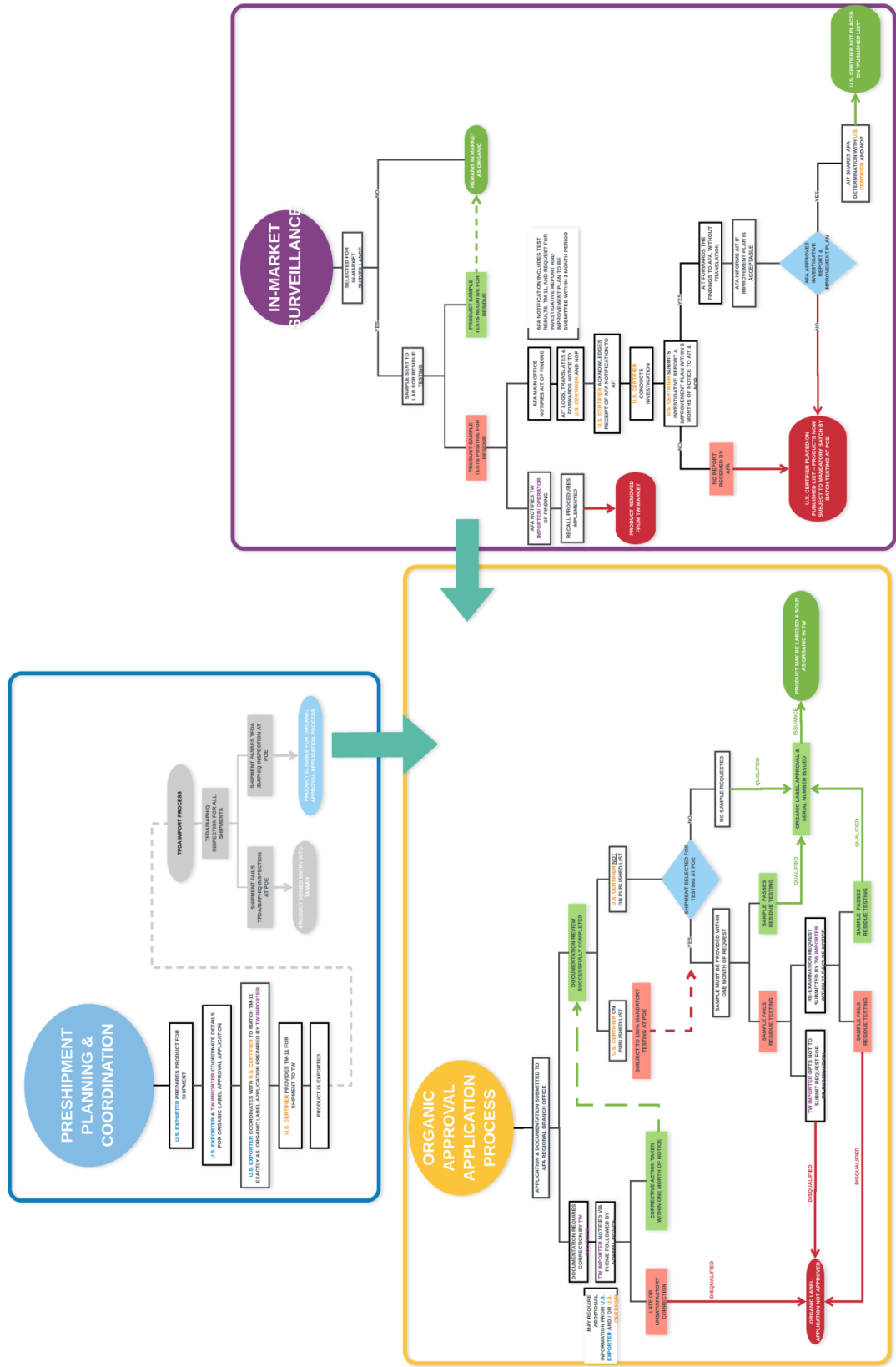
## **B. Overview of Taiwan's Organic Import Regime**

Included on the next page and in the following sections are a series of flow charts designed to illustrate Taiwan's multi-faceted approach for the approval and sale of imported organic products.

Specifically, the flow charts outline:

- Coordination and communication required by industry in the United States and Taiwan to ensure all information provided on export documentation, the TM-11 organic certificate, and Taiwan's organic approval application form is consistent and identical prior to shipping U.S. organic products to Taiwan (see [Section 2](#));
- The breakdown of Taiwan's organic application approval process via documentation review by Taiwan's organic authorities (see [Section 3](#)) and, if required, testing of samples at the port of entry (see [Section 4](#)); and
- Actions required of Taiwanese Importers and U.S. Certifiers if residues are detected in the U.S. organic product during in-market surveillance tests after it has been approved as organic for sale in Taiwan (see [Section 5](#)).

# Overview of Taiwan's Organic Import Regime





## C. Role/Responsibilities of Key Players to Support U.S. Organic Shipments to Taiwan

Below is a brief overview of each of the players involved in the sale of U.S. organic products in Taiwan including industry, U.S. Department of Agriculture, and Taiwan’s organic authorities, as well as a brief description of their respective areas of responsibility. For contact information on Taiwanese and U.S. agencies and organizations, please see [Annex 1, Key Contacts](#).

### Organic Industry

U.S. Exporter	U.S. Certifier	Taiwanese Importer
<ul style="list-style-type: none"> <li>Coordinates pre-shipment planning with U.S. Certifiers and Taiwanese Importers</li> <li>Requests TM-11 organic certificate from U.S. Certifier</li> <li>Ensures accurate, consistent, and identical information on all documentation to enable organic label approval process by Taiwanese Importer</li> <li>Works with U.S. Certifier to investigate and implement corrective actions if positive findings detected by Taiwan’s organic authorities during inmarket surveillance testing</li> </ul>	<ul style="list-style-type: none"> <li>Whether foreign or domestic –certifiers viewed by Taiwan organic authorities as gatekeepers to protect the integrity of Taiwan’s organic system</li> <li>Completes TM-11 organic certificate accurately, and with identical information as included on Taiwanese Importer’s organic approval application</li> <li>Reacts and responds promptly to notifications of any positive residue finding detected by Taiwan’s organic authorities</li> </ul>	<ul style="list-style-type: none"> <li>Acts as primary contact with Taiwanese authorities at the port of entry</li> <li>Completes organic approval application and required documents with identical information as provided by U.S. Exporter and U.S. Certifier.</li> <li>Submits documentation packet -- including TM-11 organic certificate – for review by Taiwan’s organic authorities</li> <li>Provides product samples for testing, if/as requested</li> </ul>

### AIT and U.S. Government

	<p><b>American Institute in Taiwan Agricultural Section (AIT Ag Section)</b></p>		<p><b>U.S. National Organic Program (NOP)</b></p>
<ul style="list-style-type: none"> <li>Charged with assisting U.S. exporters — including U.S. Exporters of U.S. organic products — on inquiries related to market access opportunities and barriers in Taiwan</li> <li>First point of contact and official go-between for the U.S. Government to receive notifications from Taiwan’s Agriculture &amp; Food Agency (AFA) of positive findings detected in U.S. organic products tested for residues via in-market inspections</li> <li>Communicates AFA’s notification of positive findings to the relevant U.S. Certifier and NOP</li> <li>For correspondence between AFA and U.S. Certifiers or other private sector stakeholders, AIT is a conduit for information and is not in a position to verify or support specific suggested changes or corrective actions.</li> </ul>		<ul style="list-style-type: none"> <li>U.S. organic certification body and key regulator of USDA organic products</li> <li>Lead U.S. regulatory agency responsible for establishing international import and export policies for organic products, including organic equivalency arrangements (OEA) and other organic trade arrangements with U.S. trading partners, including Taiwan</li> </ul>	



## Council of Agriculture (COA)

- Responsible for Taiwan's organic regime, as well as negotiating on organic arrangements with Taiwan's trading partners
- Has three agencies designated as the competent authorities responsible for managing Taiwan's organic regime. (Note, the highest percentage of organic component dictates responsible agency.)
  - Agriculture and Food Agency (AFA) for organic crops and processed crop products
  - Department of Animal Industry for organic livestock and processed livestock products
  - Fisheries Agency for organic aquatic and processed aquatic products



## COA's Agriculture and Food Agency (AFA)

- Handles largest portfolio of organic product applications
- Lead agency responsible for the organic application approval process for imported organic crops and processed crop products
- Consists of:
  - Four AFA Regional Offices which manage imported organic approval applications and inspections at the port of entry
  - AFA Main Office: (a) Conducts case reviews of organic products in the retail market ("in-market surveillance"); (b) Responsible for notifying AIT Ag Section to relay AFA notification of positive residue findings to U.S. Certifiers for their investigation and response; (c) Manages COA's published list of certifiers subject to 100% mandatory batch-by-batch testing

## Testing Laboratories



### Agricultural Chemicals and Toxic Substances Research Institute (TACTRI)

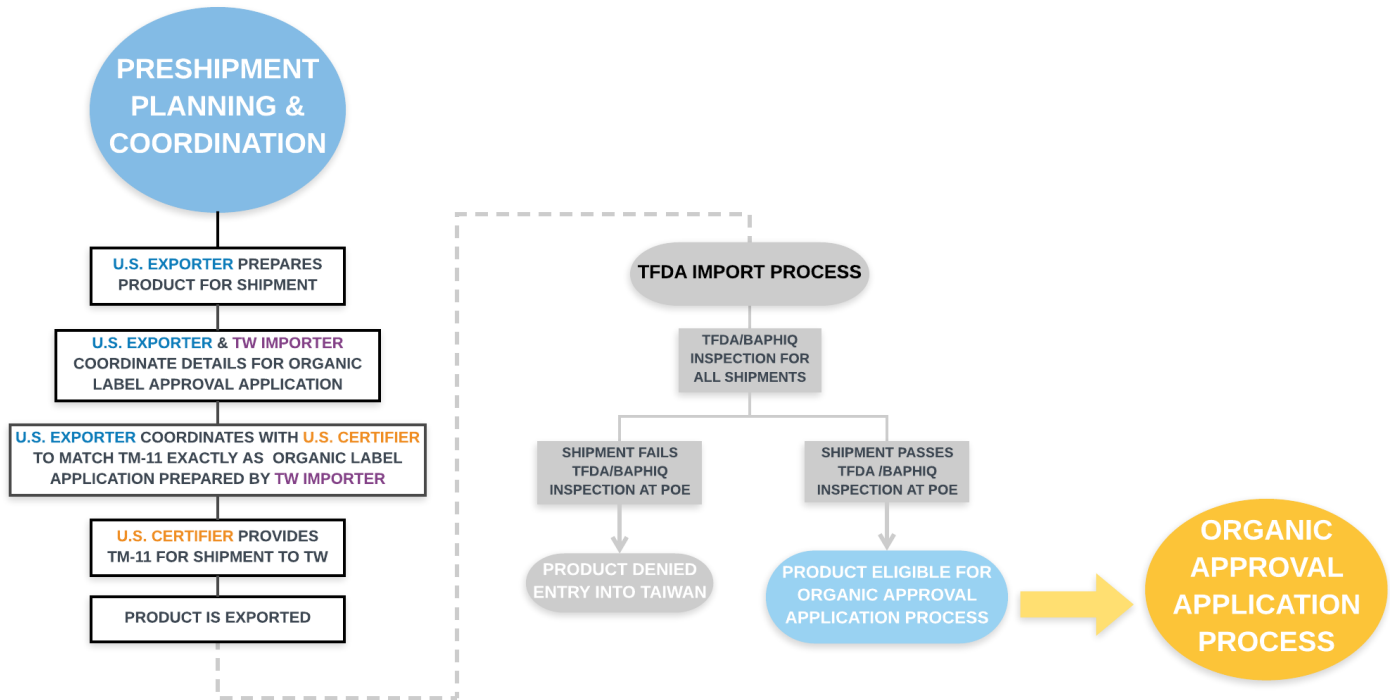
Tests organic products for pesticides



### Food Industry Research and Development Institute (FIRDI)

Tests organic products for food additives and GMOs

## SECTION 2: PRE-SHIPMENT PLANNING BY U.S. INDUSTRY



### A. Pre-Shipment Coordination and Communication Required



**To enable your Taiwanese Importer to submit a complete and accurate application for the organic approval process that precisely matches information provided by the U.S. Exporter and U.S. Certifier, close coordination and communication between the U.S. Exporter, U.S. Certifier, and Taiwanese Importer are required prior to shipping U.S. organic products to Taiwan.**

As part of Taiwan's organic approval application process, documents submitted by the importer will undergo detailed examination by one of four AFA Regional Offices. (See [Section 3](#) below for detailed information on the process.) AFA requires that information provided by the Taiwanese Importer in the application documents must be exactly identical to information in documents provided by the U.S. Exporter and U.S. Certifier. AFA has cited that up to 30% of applications for U.S. organic products have included incomplete, inaccurate, or inconsistent information on import documents -- including the TM-11 organic transaction certificate.

AFA reports that inconsistencies and errors in information submitted have periodically resulted in delays in the organic approval process as importers attempt to correct incomplete or inaccurate information submitted. In some cases, where information could not be corrected, the organic application has been denied by AFA, and therefore U.S. organic products could not be labeled or sold as organic in Taiwan.

Specific guidance is detailed below to assist industry with information coordination and sharing prior to export of the U.S. organic product. Failure to follow these guidelines may result in delays or denial of organic approval.



## 1) The TM-11 is the only U.S. organic transaction certificate accepted by Taiwan

- The TM-11 is the key document for imported organic products, and the accuracy and clarity of its information directly affect whether importers may receive official approval from AFA in the shortest time possible. Other organic transaction certificates are not acceptable.
- The TM-11 certificate specifications go beyond requirements of non-organic products, and include specific language required for U.S. exports to Taiwan.

## 2) The TM-11 must be accurately completed by the U.S. Certifier

- NOP's formal instructions on how to prepare the TM-11 certificate for exports destined for Taiwan can be found [here](#).
- Certifiers must use the correct [Certifying Agent Acronyms](#) as assigned by NOP.
- The following statements must be included in the ["REMARKS" box on the TM-11](#) for:
  - Processed products and crops: "Organic agricultural products and organic processed products, accompanied by this certificate, were produced or processed using zero prohibited substances."
  - Livestock and meat products: "Organic livestock products, accompanied by this certificate, were managed and produced without the use of systemic painkillers or analgesics, including the use of Lidocaine or Procaine."

**3) AFA has specifically called out that the following six information items must exactly match on the U.S. Exporters' TM-11 certificate and the Taiwanese Importer's organic approval application form** as shown in the table below and in the documents example immediately following on the next page:

	Information	Where to find on TM-11 Certificate	Where to find on Organic Approval Application form
1	Name and address of U.S. exporter	Exported By	U.S. Exporter 外國農產品經營業者 Name 名稱 Address 地址
2	Name and address of U.S. accredited certifier	Certifying Agent Issuing Certificate	U.S. Certifier 外國驗證機構 Name 名稱 Address 地址
3	Name of importer/buyer	Consigned To	Importer Information 進口業者資料 Chinese Name 中文名稱 English Name 英文名稱
4	Product name as labeled	Product as Labeled	Imported Products by Items 進口產品項目 Name 名稱
5	Batch/Lot numbers *	Lot Number	Batch number 批號
6	Marked weight/volume Units should be in most basic unit for retail sale and in metric only	Marked Weight of Lot	Marked weight/volume 單位重(容)量

\* Batch numbers visible on carton, organic certificate, declaration slip or invoice. (May also be filled with manufacturing or expiry date)

Figure 1: Blank TM-11 Export Certificate

REPRODUCE LOCALLY. Include form number and date on all reproductions. FORM APPROVED - OMB NO. 0581-0191

USDA U.S. DEPARTMENT OF AGRICULTURE AGRICULTURAL MARKETING SERVICE NATIONAL ORGANIC PROGRAM

EXPORT CERTIFICATE

COUNTRY OF DESTINATION: \_\_\_\_\_ DATE: \_\_\_\_\_ CERT. NO.: \_\_\_\_\_

EXPORTED BY (Name and address including ZIP Code): \_\_\_\_\_ PRODUCT EXPORTED FROM: \_\_\_\_\_

CONSIGNEE TO (Name and address including ZIP Code): \_\_\_\_\_ CERTIFYING AGENT ISSUING CERTIFICATE: \_\_\_\_\_

TOTAL MARKED NET WEIGHT: \_\_\_\_\_ TOTAL CONTAINERS: \_\_\_\_\_

PRODUCT AS LABELED	LOT NUMBER	MARKED WEIGHT OF LOT	NUMBER OF PACKAGES IN LOT	SHIPPING MARKS	PRODUCER
4	5	6			

IF AS ORDERED BY EXPORTER, REMARKS: \_\_\_\_\_

I CERTIFY that the agricultural products specified herein have been certified by a USDA accredited organic certifying agent and have been found to meet all applicable requirements of the National Organic Program.

SIGNATURE OF ACCREDITED CERTIFYING AGENT: \_\_\_\_\_ DATE: \_\_\_\_\_

NOT VALID UNLESS SIGNED BY A DESIGNATED REPRESENTATIVE OF A USDA ACCREDITED ORGANIC CERTIFYING AGENT

No financial liability shall attach to the United States Department of Agriculture or to any officer or representative of the Department with respect to this certificate.

According to the Regulatory Information Act of 1996, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0191. The time required to complete this information collection is estimated to average 20 minutes per person, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, cultural beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program (that is prohibited bases apply to all programs). Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (800) 795-3889 (voice and TDD). To file a complaint of discrimination, write to USDA, Director, Office of Civil Rights, 1495 Independence Avenue, S.W., Washington, D.C. 20250-4810, or call (800) 795-3272 (voice) or (202) 726-6962 (TDD). USDA is an equal opportunity provider and employer.

TM-11 (11-01)

Figure 2: Blank Organic Approval Application Form

附件三  
進口農糧產品及農糧加工品核發有機標示同意文件申請書

中文名稱	進口業者登錄編號(附註一)		
英文名稱	3	電話	
地址		傳真	
網址			
負責人	聯絡人		
姓名	電話	姓名	電話
			電子信箱
外國農產品名稱			
經營業者地址	1		
外國驗證名稱			
機構地址	2		
名稱	批號	總量(公)量	產品有機原料含量%
	4	5	6

申請核發有機標示同意文件字號：有機農糧輸入字第 \_\_\_\_\_ 號(附註二-四)

申請日期、文號 \_\_\_\_\_ 進口業者及負責人簽章 \_\_\_\_\_

收件日期、號碼(由農委會農糧署分署或漁業署填寫)

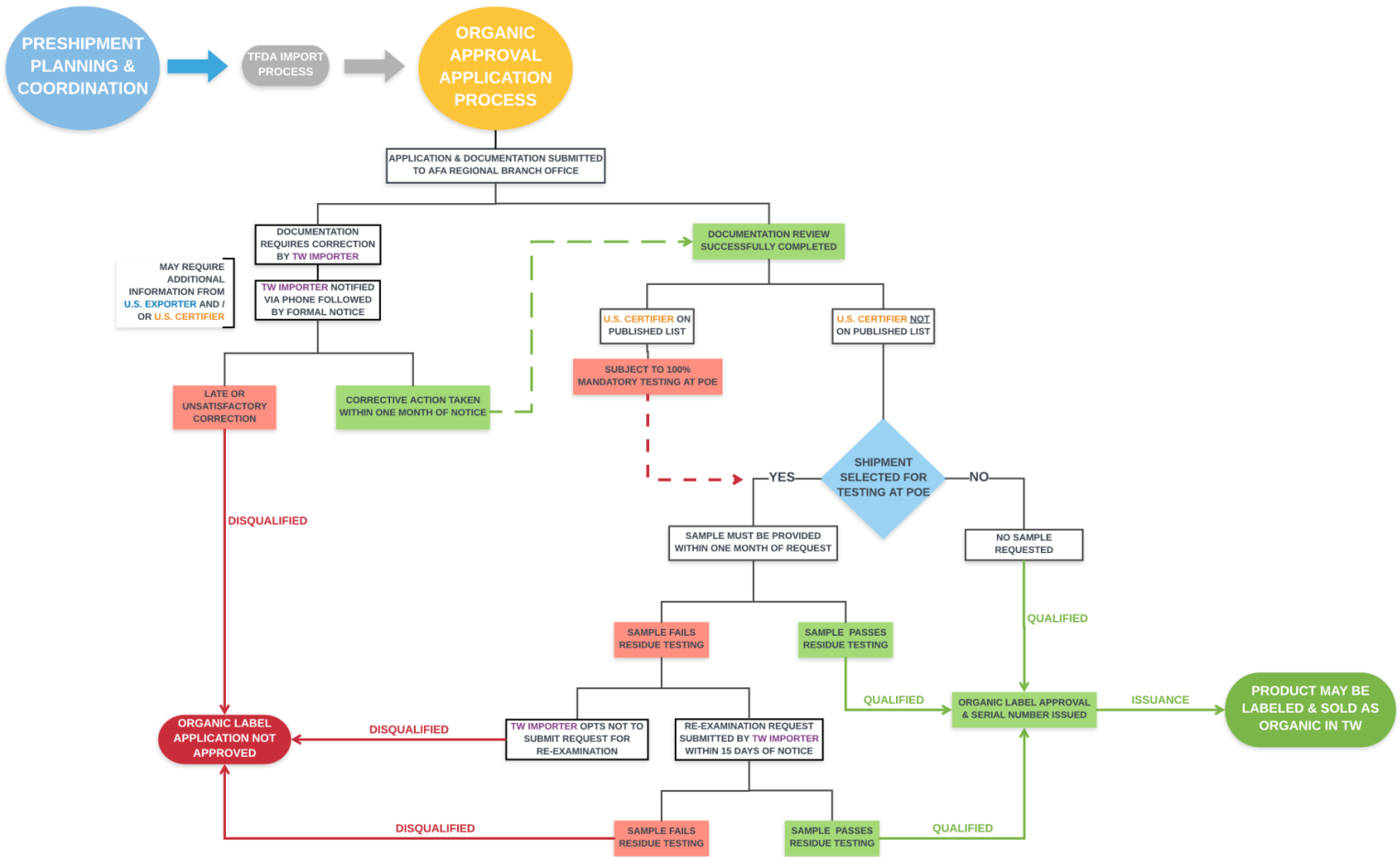
## B. Export Documents Required with U.S. Organic Shipments

In addition to the TM-11 certificate, standard custom documentation is required for all shipments at the time of entry. U.S. Exporters should share with the following documents and certificates with their Taiwanese Importer:

- Bill of lading
- Commercial invoice
- Proforma invoice
- Packing list
- Certificate of origin
- Certificate of Free Sale (may be required)

Any other required export / health certificates, such as Phytosanitary certificate (PPQ form 577) issued by APHIS if product categorized as B01 in Taiwan tariff schedule, or FSIS certificate for meat and meat processed products, etc. See [USDA FAIRS report TW17031](#).

## SECTION 3: ORGANIC APPROVAL APPLICATION PROCESS FOR IMPORTS



### A. Taiwan's Organic Approval Process for U.S. Imports

In Taiwan, imported organic products are treated differently than domestically certified organic products before they can be sold in the market. While domestically produced organic products require Taiwan's Certified Agriculture Standard (CAS) organic seal, imported organic products must receive approval for each shipment in order to use the words "organic" on the label. Therefore, for U.S. organic products to be sold as organic in Taiwan, the Taiwanese Importer must apply for organic labeling approval in Taiwan.

Taiwan's organic approval application process involves two separate steps: documentation review by AFA, and *if required*, testing of organic products for residues by designated testing labs. (See [point B](#) below for details on the documentation review process, and [Section 4](#) for information related to testing.)

- Effective 1 January 2018, Taiwanese Importers may submit the application for organic approval prior to arrival at the port to allow for faster review of the organic application.
- The application process is per product and per delivery. The Taiwanese Importer must apply for approval to the use of the word "organic" for every shipment sent separately.
- AFA's review of documents can take up to two weeks; if testing at port of entry is required, the process can take up to another two weeks.

- Products may not be sold as “organic” in Taiwan if there are errors in the documentation that are not corrected by the Taiwanese Importer, or if a product is detected with a positive residue finding during testing at the port of entry.
- Without receiving approval, any use of foreign/English words, such as “organic”, “organic farming”, “bio”, “biological” or “biologique”, will result in a fine. This extends to any unapproved use of the words in the labeling, packaging, description, introduction, or ingredients of the products.

## B. AFA’s Document Review Process and Documentation Requirements





AFA undertakes a comprehensive review of documents submitted as part of the organic label approval process to ensure that information regarding the imported product is consistent with the information provided in the various documents. The following documents must be submitted to AFA as part of the document review process. With the exception of the TM-11 certificate, all documents listed are prepared by the Taiwanese Importer.

Required Document	Description
<b>TM-11 Certificate*</b>	<ul style="list-style-type: none"> <li>• Completed by the U.S. Certifier, sent with shipment by the U.S. Exporter</li> <li>• Taiwanese Importer required to stamp with seals of importer and person responsible</li> <li>• Given that the TM-11 will be in English, importer is required to provide two transcripts in Mandarin stamped with seals of importer and person responsible with a remark indicating that the Mandarin transcript conforms to original document</li> </ul>
<a href="#">Organic Label Approval Application Form*</a>	<ul style="list-style-type: none"> <li>• Completed by the Taiwanese Importer</li> <li>• Imported products manufactured at different factories/plants must be filed with separate application forms</li> <li>• Information on application form must be identical to TM-11 &amp; import declaration</li> <li>• “Organic” (有機) must be in the product description</li> <li>• Units should be provided in most basic unit for retail sale and in metric only</li> </ul>
<b>Importers’ Business Registration**</b>	<ul style="list-style-type: none"> <li>• A printout of corresponding information from Taiwan’s Department of Commerce in the Ministry of Economic Affairs is also acceptable</li> </ul>
<a href="#">Slip of Import Declaration**</a>	<ul style="list-style-type: none"> <li>• Duty paid by Taiwanese Importer must be indicated.</li> </ul>
<a href="#">Ingredient Table**</a>	
<b>Chinese Label**</b>	
<b>Postal Money Orders for Document Review Fee</b>	<ul style="list-style-type: none"> <li>• 500 - 2,000 NTD depending on number of products (approximately 17 - 68 USD)</li> </ul>
<b>Phytosanitary Certificate Issued by BAPHIQ, COA*</b>	<ul style="list-style-type: none"> <li>• For HS Codes to which importation rule “B01” is applicable, a Phytosanitary Certificate is required.</li> </ul>
<b>Document of Authorization</b>	
<b>Request Form for the Return of Original Copy</b>	<ul style="list-style-type: none"> <li>• Required only if application is submitted by an authorized third-party</li> </ul>

\* Original required. To request original document be returned, a copy must be submitted with the original document.

\*\* A copy that is stamped with seals of importer and person responsible and with a remark indicating that the copy is identical to original document would be eligible.

**There are two possible outcomes from the documentation review process:**

	Information in all documents is consistent and accurate		Documentation review process is complete.
	Information in documents is inconsistent or incorrect		AFA will notify the Taiwanese Importer with a request to correct the documents within one month of notice. Taiwanese Importers may need to communicate and coordinate with U.S. Exporters to rectify errors.

Once the documentation review process is completed by AFA, one of two actions will occur:

- AFA will issue approval for U.S. organic products to be labeled and sold as organic, or
- AFA will select U.S. organic products for testing at the port of entry (see [Section 4](#)).

## SECTION 4: ORGANIC TESTING REQUIREMENTS AND PROCEDURES

*Note, imports into Taiwan of all agricultural products – whether or not organic – are first subject to inspection and testing protocols enforced by Taiwan’s Food and Drug Administration (TFDA) and COA’s Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ)<sup>1</sup>. The testing requirements described throughout Section 4 are specific to organic products only.*

Under Taiwan’s organic regime, imported organic products may be tested at two different points:

- At the port of entry, as part of the organic approval application process; or
- Once approved to be sold as organic in Taiwan, as part of in-market surveillance undertaken by AFA.

Under AFA testing protocols, products may be tested for pesticide residues, food additives, and GMOs.

### A. Potential Triggers for Residue Testing

AFA has cited various reasons why imported organic products may be selected for testing at the port of entry or in the Taiwan market, including, but not limited to, the following:

- Product is accompanied by TM-11 certificate issued by U.S. Certifier that is included on COA’s published list of certifiers subject to 100% mandatory batch-by-batch testing<sup>2</sup>;
- Documentation errors/inconsistencies during the organic approval application process create higher risk for selection to undergo testing;
- Close monitoring of new importers of organic products, especially in first-time applications
- Periodic in-market surveillance of organic products by local authorities at the request of AFA;
- Media scrutiny of the organic system, and/or particular organic products; or
- Perceived or real health and safety issues

<sup>1</sup> For additional details on other tests that may be required for imported agricultural products, please see [USDA FAIRS Narrative TW17027](#).

<sup>2</sup> COA’s list is formally known as the “Import Organic Agricultural Products & Agro-Processing Products Certification Body Batch Inspection List”.

---

## B. Shipments Subject to Testing at the Port of Entry (Pre-Approval Testing)

Residue testing may or may not occur at the port of entry as part of the organic approval application process.

If a U.S. Certifier is included on COA's published list of certifiers subject to batch-by-batch testing, all imported products with a TM-11 issued by that U.S. Certifier will be subject to 100% mandatory testing at the port of entry until the U.S. Certifier is removed from COA's published list. (See [Section C](#) on the next page.)

The relevant testing lab will send test results -- whether positive or negative -- to the Taiwanese Importer, as well as the appropriate AFA Regional Office.



**Note: AFA does not routinely notify AIT Ag Section of a positive residue finding at the port of entry, nor requires any corrective actions from the U.S. Certifier or U.S. Exporter. Given that the product has not yet entered the Taiwan market, only the Taiwanese Importer is notified of test results at the port of entry.**

- If a positive residue finding is detected, the Taiwanese Importer has the option to apply for a re-test within 15 days of receipt of the notice and pay the inspection fee again. The applicant may apply for re-inspection only once per shipment.
- If AFA denies approval of the product as a result of a positive residue finding, the product cannot be sold in Taiwan as organic. As a result, the importer has three available options under Taiwan law:
  - a) Forfeit the application for the use of "organic" on the label, and sell the product in Taiwan as non-organic;
  - b) Destroy the product, or
  - c) Re-export the product from Taiwan.
- The Taiwanese Importer will determine what is the most economically viable for its business and may or may not coordinate with its U.S. Exporter in deciding how to proceed if a positive finding detected.
- It is advised that in event of a positive residue finding resulting in rejection of the product as organic, the Taiwanese Importer should immediately notify the U.S. Exporter.
- U.S. Exporter should alert the U.S. Certifier that the product was unable to enter the market as organic due to positive finding at the port of entry.
- If the Taiwanese Importer chooses to sell the shipment in Taiwan as non-organic, all and any organic wording or logos from the package and marketing materials must be removed.

---

## C. Shipments Subject to Mandatory Testing at the Port of Entry (Mandatory Pre-Approval Testing)

Mandatory testing at the point of entry is required when a U.S. Certifier has been placed on COA's published list of certifiers subject to 100% batch-by-batch testing, because:

1. A U.S. organic product approved for sale as organic in Taiwan was detected with a positive finding for residues during in-market surveillance, and
2. The positive finding has not been explained to AFA by the U.S. Certifier.

As a result, all future shipments of organic products accompanied by a TM-11 issued by that particular U.S. Certifier are then subject to 100% mandatory batch-by-batch inspection at the port of entry, regardless of product type, U.S. Exporter, or Taiwanese Importer.

## D. Products Subject to Post-Entry/In-Market Surveillance Testing (Post-Approval Testing)

In addition to possible testing during the application process for the organic label, AFA reserves the right to sample organic products in-market at any time to ensure organic integrity and consumer safety. In-market surveillance and testing are conducted by local authorities at the request of AFA. If selected for sampling, the inspector will check the product label and conduct tests for residues.

If a positive finding is detected during in-market surveillance tests, AFA Main Office will contact both the Taiwanese Importer/Operator to initiate recall of the product, and AIT Ag Section in Taipei to request the U.S. Certifier of the imported U.S. organic product be notified and an investigation be undertaken. (See [Section 5](#) for more details.)

## E. Taiwan's Organic Testing Process and Procedures



**It is important to note that the U.S. NOP standard allows a 5% Maximum Residue Limit (MRL) U.S. EPA's threshold, while Taiwan's organic standards has a stricter threshold for organic products.**

Testing will be conducted by TACTRI for pesticides, and FIRDI for food additives and GMOs. Below is the process for requesting samples, information on test methodologies, and more detail on the communication process if a positive residue finding is detected.

### 1. AFA's request for samples for testing

A. *If selected for testing as **part of the pre-market approval process at the port of entry:***

- AFA requires two product samples to be submitted within one month of notification.
- Upon receipt of samples, AFA will forward to the assigned testing institution within 3 days and issue a receipt of samples received.
- Testing typically takes 2 weeks but may take up to one month once samples submitted; the lab is required to complete the test within 20 days and AFA should submit the findings to the Taiwanese Importer/applicant within 10 days.
- Inspection fees are 6,000 NTD (approximately 200 USD). Taiwanese Importers are generally responsible for the fees.
- If samples fail initial examination, AFA issues a re-examination notice. If Taiwanese Importer chooses to have products re-tested, he/she must submit new samples within 15 days.

**B. If testing occurs after product has been approved to be labeled as organic and is conducted as part of in-market surveillance:**

- Products are pulled from retail shelves or requested from processors of materials.
- Testing will take approximately 2 weeks if the case does not need supplementary documents, or other requirements to be fulfilled.
- Taiwanese Importers/Operators are typically not responsible for testing fees resulting from in-market surveillance.

**2. Test Methodologies**

*A. Tests conducted by TACTRI for pesticide residues:*

- TACTRI tests for pesticide residues in organic vegetables, grains, nuts, teas, spices and other herbal plants.
- The following table is an extraction of chemicals tested for in organic products, and the MRL of pesticide residues measured in parts per million (ppm).

**Summary of Residue MRLs for Taiwan Organic Products**

Product	Chemical	MRL		
<b>Grains</b>	Cyprodinil Diflubenzuron Ethoprophos Fenamiphos Fenthion Imazalil, Indoxacarb	Methoxyfenozide Monocrotophos Oxamyl Penoxsulam Pymetrozine Pyraclostrobin Spinetoram	Spinosad Thiamethoxam Trifloxystrobin Terbufos Pyriproxyfen	0.01 ppm
	Amisulbrom, Cypermethrin, $\alpha$ -cypermethrin		0.03 ppm	
	Chlorothalonil, Heptachlor, Imibenconazole, Mirex		0.04 ppm	
	Hexaflumuron		0.05 ppm	
	Allethrin		0.1 ppm	
	Most other chemicals		0.02 ppm	
<b>Teas</b>	Fipronil		0.002 ppm	
	Indoxacarb		0.01 ppm	
	Aldicarb and related chemicals, Promecarb		0.02 ppm	
	Bufencarb		0.03 ppm	
	Trifluralin		0.04 ppm	
	Fludioxonil		0.06 ppm	
	Allethrin, Azinphos-methyl, Imibenconazole, Isoxathion		0.1 ppm	
Most other chemicals		0.05 ppm		
<b>Vegetables</b>	Allethrin, Chlorothalonil, Imibenconazole, and Pyrimethanil		0.02 ppm	
	Most other chemicals		0.01 ppm	
<b>Vegetables &amp; Grains</b>	Fipronil		0.001 ppm	



- 
- The full list of 373 pesticide residues tested by TACTRI can be found [here](#) in Mandarin and in [Annex 3](#) in English.
  - As a helpful resource for industry, USDA has developed an analysis of Taiwan's MRLs compared to U.S. NOP standards. This can be found in [Annex 4](#).
  - The test methodology cited by TACTRI is "[Multiresidue Analysis 5, Method code MPHWP0055.03](#)" from Taiwan's Ministry of Health and Welfare. According to the methodology, TACTRI collects and tests samples using the following procedures:
    1. Samples are handled with the principle "QuEChERS" (Quick, Easy, Cheap, Effective, Rugged, and Safe).
    2. The sample is tested following Matrix-matched Calibration Curve Method and Standard Addition Method by liquid chromatograph and gas chromatograph.
    3. After researchers conduct the analyses, the results are evaluated against the MRL standard in ppm.
      - If samples are tested at or above the MRL, the result shows positive finding, which means the samples fail the test.
      - If samples are tested below the MRL, the result shows non-detected "ND," which means the samples passed the inspection.

*B. Tests completed by [FIRDI](#) (for food additives):*

- In addition to pesticide residue testing via TACTRI, an organic product may be tested by FIRDI for the presence of GMOs, and to determine if it contains any food additives not permissible in Taiwan.
- Taiwan has a list of food additives and conditions permissible for use in organic products, whether domestically produced or imported. If an organic product contains a food additive not included on the list of permitted additives, its application for the organic label will be rejected.

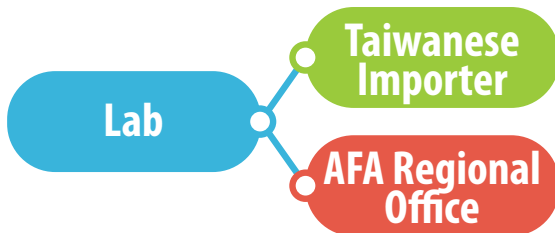
The current list of food additives permitted in organic products can be found [here](#). A list of all food additives tested by FIRDI can be found [here](#) in Mandarin. Both of these lists are presented in English in [Annex 5](#).

Note, on 3 January 2018, AFA published a [draft amendment](#) (in Mandarin) to revise and expand the scope of the list of permissible food additives in organic products. AFA has indicated that Taiwan will notify the World Trade Organization for comments from international stakeholders after they review and consider input received from Taiwan's domestic industry.

### 3. Communication of Findings

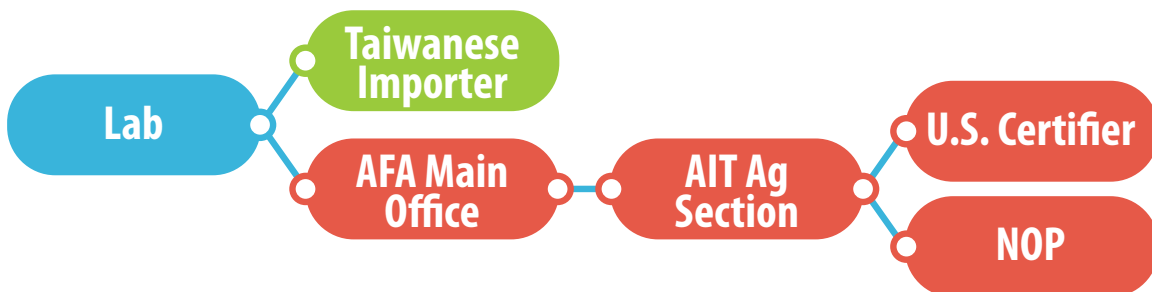
Once tests are completed, there are different protocols in communicating findings depending on whether the test was completed as part of pre-market approval process at the port of entry or post-approval via in-market surveillance.

A. Findings from tests at port of entry (pre-market approval):



- If an organic product is tested as part of the pre-market approval process at the port of entry, findings will be sent by the lab to the Taiwanese Importer as well as to the relevant AFA regional office.
- Note, neither the U.S. Exporter nor the U.S. Certifier is notified by AFA of findings (whether positive or negative) when products are tested as part of pre-market approval at the port of entry.

B. Findings from tests as part of post approval in-market surveillance:

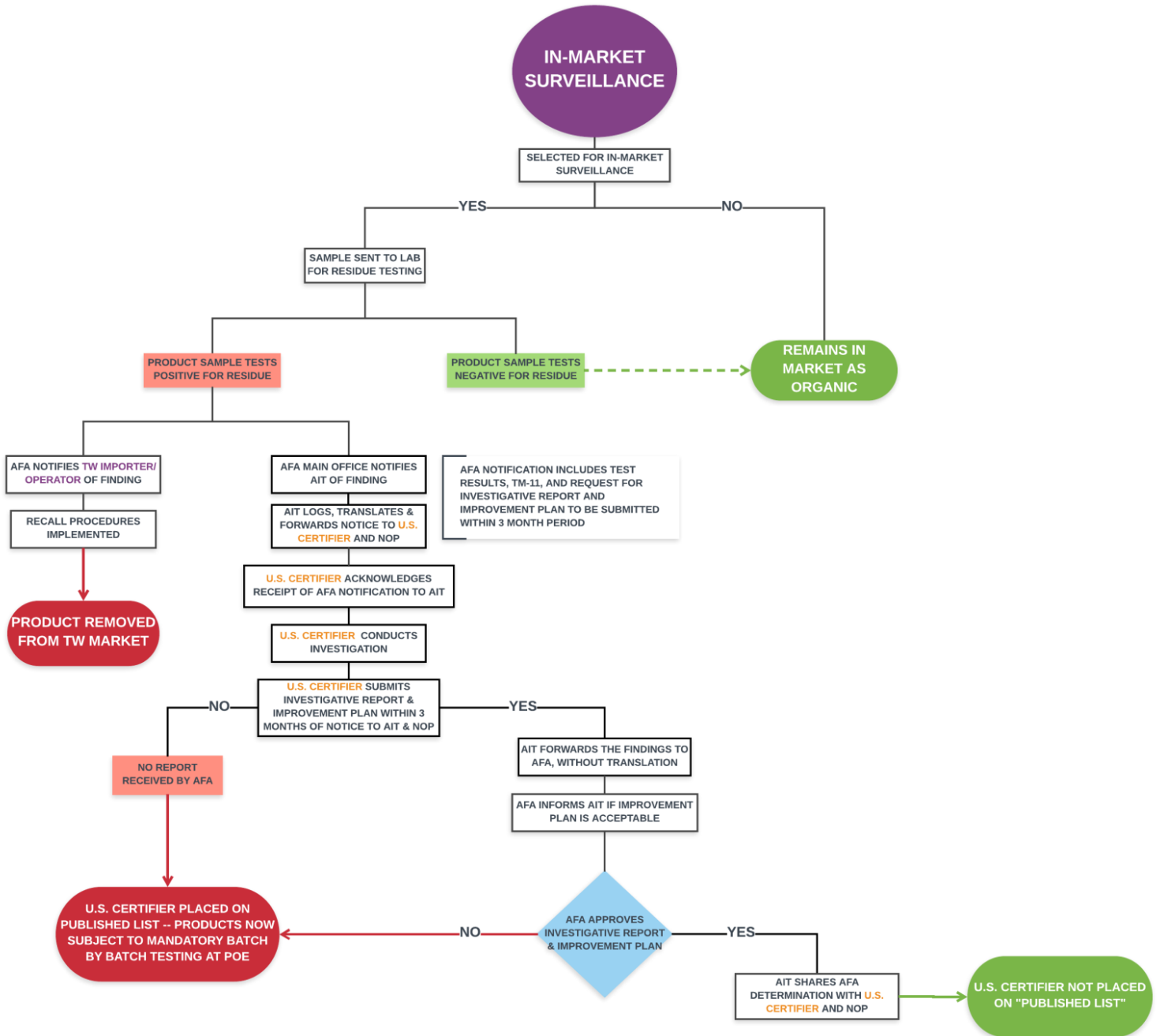


- If an organic product is tested as a result of in-market surveillance, findings will be sent by the lab to the Taiwanese Importer/Operator and the AFA Main Office.
- Positive residue findings reported to the AFA Main Office initiates the multi-party communication process by AFA to notify AIT Ag Section with the request that the positive findings be shared with the relevant U.S. Certifier and an investigation report and improvement plan be submitted to AFA by the U.S. Certifier. (See [Section 5](#) for more details, including how industry should respond to AFA.)

## SECTION 5: POST-APPROVAL SURVEILLANCE TESTING, & GUIDANCE ON HOW TO RESPOND TO POSITIVE FINDINGS IN MARKET



AFA may conduct in-market surveillance at any time on any imported organic product that has been approved for sale in Taiwan.



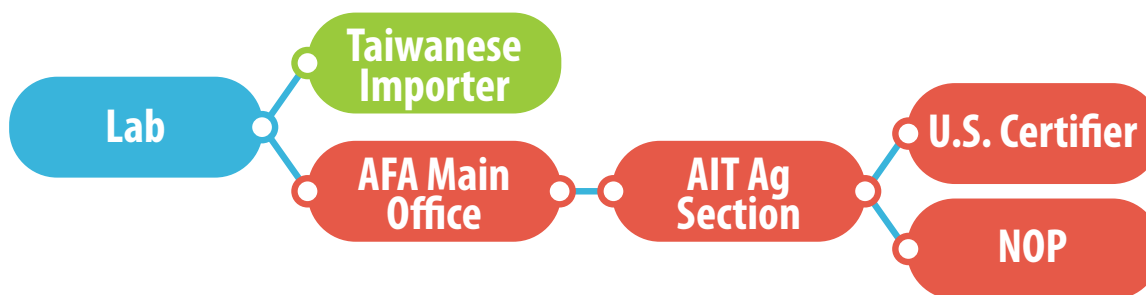
## A. Communication Protocols if Product is Detected with a Positive Finding

If a U.S. organic product approved for sale in Taiwan is detected with a positive residue finding during in-market surveillance, there is a multi-step communication process. As a first step, the lab will notify both the Taiwanese Importer/Operator and the AFA Main Office.

### Notification of Importer/Operator:

- Testing lab will notify Taiwanese Importer/Operator of positive findings with instructions on next steps. AFA may request more information from the Taiwanese Importer/Operator.
- Upon notification, the Taiwanese Importer/Operator:
  - Must withdraw the affected products within one day and recall the product within ten days after notification from AFA of recall initiation;
  - Is expected to destroy the recalled the products within 40 days and notify local authorities 5 days prior to the day of the action whether or not Taiwanese Importer/Operator appeals the finding;
  - May request one re-test, and during re-test, products will not be destroyed;
  - May be fined for recalls which can range from 60,000 NTD to 200 million NTD (approximately 2,000 USD to nearly 7 million USD); and
  - Should immediately notify U.S. Exporter of in-market surveillance test findings, and status of recall investigation.
- Results of the investigation and recall may be made public, including the business name, business address, products, and details of the residue finding. If positive finding result is appealed for retesting, the announcement may be delayed until the result of second tests is confirmed.

### Notification of U.S. Certifier via AIT Ag Section:



- In addition, the testing lab will notify AFA's Main Office and trigger the multi-step communication process to inform the U.S. Certifier.
- AFA Main Office will send a notification letter and related documents -- including test results and relevant TM-11 -- to AIT Ag Section typically within a week of receiving the test results and request an investigation report and improvement plan from the U.S. Certifier.
  - AFA's notification letter includes the following information:
  - Report number

- Date of inspection
  - Items inspected
  - Batch number
  - Methodology/type of test
  - Test results
  - Request for an investigation report and improvement plan from the U.S. Certifier.
  - In addition, AFA Main Office will copy the following Taiwanese agencies and institutions: Taiwan Accreditation Foundation, Department of Animal Industry (COA), Fisheries Agency (COA), the responsible testing lab, AFA Regional Offices, and other relevant entities within the AFA Main Office in order to inform and update records.
- AIT Ag Section will log receipt of the notification from AFA.
  - AIT Ag Section will transmit a copy of AFA's notification letter, test results, and other relevant documents to the U.S. Certifier and NOP. AIT will provide a courtesy (unofficial) translation of the notification from Mandarin to English when possible.

## B. Steps U.S. Certifiers Must Take to Respond to AFA

1. Within three months of AFA's notification, the U.S. Certifier is expected to (a) respond to AFA with an investigative report and improvement plan, or (b) request an extension from AFA.
2. Immediately upon receiving AFA's notification of positive findings from the AIT Ag Section, OTA recommends that U.S. Certifiers acknowledge receipt of the notification to AIT Ag Section ([agtaipei@fas.usda.gov](mailto:agtaipei@fas.usda.gov)).



**While Taiwan's test results may be within U.S. NOP standards, U.S. Certifiers are strongly encouraged to undertake prompt action to investigate the positive finding and report corrective actions in the same manner as if the U.S. Certifier had detected a positive residue finding via its own testing protocols.**

The difference in residue MRL thresholds is well understood between COA and NOP. AFA's request for an assessment and investigation of the positive findings, in the form of an investigative report and improvement plan, reflects the instructions found under the NOP instructions "[Responding to Results from Pesticide Residue Testing](#)" (NOP publication NOP 2613). It is important to note, the policy differences between Taiwan and U.S. MRLs are not key to this assessment by the U.S. Certifier.

3. U.S. Certifiers are advised to provide a thorough investigative report and a recommended improvement plan with corrective actions. U.S. Certifiers' reports should indicate the investigative findings and recommended actions upfront, and in clearly defined headings.

AFA will accept the U.S. Certifier's report in English. (Note, due to resource constraints, AIT Ag Section will not translate the U.S. Certifier's report or improvement plan into Mandarin. Therefore, it is important to provide clear, concise, and well laid-out reports and improvement plans to help facilitate review by AFA.)

4. Once the report and improvement plan are documented by the U.S. Certifier, responses should be sent to both AIT Ag Section ([agtaipei@fas.usda.gov](mailto:agtaipei@fas.usda.gov)) and NOP ([AIAInbox@ams.usda.gov](mailto:AIAInbox@ams.usda.gov)) in the same email. AIT Ag Section will transmit the U.S. Certifier response to AFA.

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## C. Immediate Consequences for U.S. Certifier's Products If No Response Received by AFA

It is strongly recommended that U.S. Certifiers respond to AFA within the three-month deadline with a comprehensive investigative report and corrective actions. A timely and thorough response within three months will allow U.S. Certifiers' products to continue with routine testing protocols at the port of entry.

- If AFA does not receive a response in three months, the U.S. Certifier will immediately be placed on COA's published list of certifiers subject to 100% batch-by-batch testing. From that date onwards, all U.S. organic products shipped with TM-11 certificates from that U.S. Certifier will be subject to 100% mandatory batch-by-batch testing at the port of entry.
- If a U.S. Certifier finds its company included on COA's published list, please reach out to the Organic Trade Association via email at [info@ota.com](mailto:info@ota.com), as well as initiate the process to investigate and respond to AFA as noted in *Subsection B* above.
- The current list of certifiers published by COA as of March 2018 can be found [here](#), and is updated as certifiers are added or removed.
- COA's published list can also be accessed by taking the following steps if using Chrome as the internet browser:
  - Visit [afa.gov.tw](http://afa.gov.tw)
  - Right click, Translate to English (only available for Chrome)
  - Select Organic Agriculture in the Menu. When the dropdown menu appears, select "Management of Imported Organic Agricultural Products and Processed Agricultural Products"
- Select "*Imported organic agricultural products and agro-processing products certification body batch inspection list*". Downloadable files are available via Excel in .xls or Adobe in .pdf.

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## SECTION 6: INDUSTRY CHECKLISTS FOR U.S. EXPORTERS AND U.S. CERTIFIERS

**U.S. EXPORTERS** are the lead industry player in preparing shipments for export to Taiwan, and in coordinating with Taiwanese Importers and U.S. Certifiers throughout the import process as well as during in-market surveillance testing.

**U.S. CERTIFIERS** – like Taiwan's domestic certifiers – are viewed as gatekeepers to protect the integrity of Taiwan's organic system. U.S. Certifiers are key players in pre-shipment coordination to ensure accurate TM-11s are provided to U.S. Exporters. In addition, U.S. Certifiers are the lead industry players in responding to notifications from AFA of positive findings detected in U.S. organic products during in-market (post-approval) surveillance testing. AFA expects a response from U.S. Certifiers that includes an investigative report and improvement plan with corrective findings.

**See next two pages for U.S. industry checklists, one for U.S. EXPORTERS & one for U.S. CERTIFIERS.**

# U.S. EXPORTER CHECKLIST

U.S. Exporters are responsible for the following actions:



**Coordinate and communicate with U.S. Certifier and Taiwanese Importer to ensure all documentation – including the TM-11 organic certificate -- to be submitted is identical & error-free prior to product shipment to Taiwan.** See [Section 2: Pre-Shipment Coordination](#) for full details.

- The TM-11 is the only U.S. organic certificate accepted by Taiwan.** Other organic transaction certificates are not acceptable.
- The following six information items must match on the U.S. Exporters' TM-11 certificate and the Taiwanese Importer's organic approval application form:**

	Information	Where to find on TM-11 Certificate	Where to find on Organic Approval Application form
1	Name and address of U.S. exporter	Exported By	U.S. Exporter 外國農產品經營業者 Name 名稱 Address 地址
2	Name and address of U.S. accredited certifier	Certifying Agent Issuing Certificate	U.S. Certifier 外國驗證機構 Name 名稱 Address 地址
3	Name of importer/buyer	Consigned To	Importer Information 進口業者資料 Chinese Name 中文名稱 English Name 英文名稱
4	Product name as labeled	Product as Labeled	Imported Products by Items 進口產品項目 Name 名稱
5	Batch/Lot numbers *	Lot Number	Batch number 批號
6	Marked weight/volume <i>Units should be in most basic unit for retail sale and in metric only</i>	Marked Weight of Lot	Marked weight/volume 單位重(容)量

\* Batch numbers visible on carton, organic certificate, declaration slip or invoice. (May also be filled with manufacturing or expiry date)

- U.S. Exporters must provide the following documentation for use by the Taiwanese importer:** TM-11 organic transaction certificate, bill of lading, commercial invoice, packing list, certificate of origin, certificate of free sale (if requested), and any other required export / health certificates (i.e., PPQ form 577 issued by APHIS if product categorized as B01 in Taiwan tariff schedule, or FSIS certificate for meat and meat processed products, etc. See [USDA FAIRS report TW17031](#)).



**Respond promptly to information requests from Taiwanese Importers during AFA's review of documentation, as needed.** See [Section 3: Organic Application Approval Process](#) for full details.



**Work with U.S. Certifier to investigate and implement corrective actions if positive residue findings detected in U.S. Exporter's products by Taiwan's organic authorities during in-market surveillance testing.** See [Section 5: Guidance on How to Respond to Positive Findings](#) for full details.



## U.S. CERTIFIER CHECKLIST (page 1 of 2)

U.S. Certifiers are responsible for the following actions:



**Coordinate with U.S. Exporter to ensure TM-11 organic certificate is accurate & error-free prior to product shipment to Taiwan.** See [Section 2: Pre-Shipment Coordination](#) for full details.

1. **The TM-11 is the only U.S. organic certificate accepted by Taiwan. The accuracy and clarity of the TM-11 information directly affect whether Taiwanese Importers may receive official approval from AFA in the shortest time possible. Other organic transaction certificates are not acceptable.**
  
2. **The TM-11 certificate must be accurately completed by the U.S. Certifier.**
  - NOP’s formal instructions on how to prepare the TM-11 certificate for exports destined for Taiwan can be found [here](#).
  - U.S. Certifiers must use the correct [Certifying Agent Acronyms](#) as assigned by NOP.
  - The following statements must be included in the [“REMARKS” box on the TM-11](#) for:
    - Processed products and crops: “Organic agricultural products and organic processed products, accompanied by this certificate, were produced or processed using zero prohibited substances.”
    - Livestock and meat products: “Organic livestock products, accompanied by this certificate, were managed and produced without the use of systemic painkillers or analgesics, including the use of Lidocaine or Procaine.
  
3. **The following six information items must precisely match on the U.S. Exporter’s TM-11 certificate and the Taiwanese Importer’s organic approval application form:**

	Information	Where to find on TM-11 Certificate	Where to find on Organic Approval Application form
1	Name and address of U.S. exporter	Exported By	U.S. Exporter 外國農產品經營業者 Name 名稱 Address 地址
2	Name and address of U.S. accredited certifier	Certifying Agent Issuing Certificate	U.S. Certifier 外國驗證機構 Name 名稱 Address 地址
3	Name of importer/buyer	Consigned To	Importer Information 進口業者資料 Chinese Name 中文名稱 English Name 英文名稱
4	Product name as labeled	Product as Labeled	Imported Products by Items 進口產品項目 Name 名稱
5	Batch/Lot numbers *	Lot Number	Batch number 批號
6	Marked weight/volume Units should be in most basic unit for retail sale and in metric only	Marked Weight of Lot	Marked weight/volume 單位重(容)量

\* Batch numbers visible on carton, organic certificate, declaration slip or invoice. (May also be filled with manufacturing or expiry date)

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## U.S. CERTIFIER CHECKLIST *(page 2 of 2)*



**Respond promptly to information requests from Taiwanese Importer during AFA's review of documentation, as/if needed.** See [Section 3: Organic Application Approval Process](#) for full details.



**Immediately investigate AFA's notification of positive residue findings detected during in-market (post-approval) surveillance testing.** See [Section 5: Guidance on How to Respond to Positive Findings](#) for full details.



**Provide AFA with an investigative report and improvement plan with corrective actions within 3 months to avoid 100% mandatory batch-by-batch testing of all U.S. Certifier's U.S. organic products at the port of entry.** See [Section 5: Guidance on How to Respond to Positive Findings](#) for full details.

## ANNEXES

### ANNEX 1: KEY ORGANIC CONTACTS IN TAIWAN & UNITED STATES

Agency/Organization	Contact Information
<b>Agriculture and Food Agency (AFA), Council of Agriculture (COA)</b> Main Office: No. 8, Kuang-hua Road, Chung-Hsing New Village, Nantou, 54044 Taiwan, ROC	T: (+886) (049) 233-2380
<b>AFA Northern Regional Office, COA</b> No. 111, Datong Road, Taoyuan District, Taoyuan City, 33065 Taiwan, ROC	T: (+886) (03) 332-2150
<b>Taiwan Agricultural Chemicals and Toxic Substances Research Institute (TACTRI), COA</b> No. 11, Kuang-Ming Road, Wufeng District, Taichung City, 41358 Taiwan, ROC	T: (+886) (04) 2330-2101
<b>Food Industry Research and Development Institute (FIRDI)</b> No. 331, Shih-Ping Road, East District, Hsinchu City, 30062 Taiwan, ROC	T: (+886) (03) 522-3191 E: wwwadm@firidi.org.tw
<b>American Institute in Taiwan Agricultural Section (AIT Ag Section)</b> <i>Provides technical exporter assistance</i> No. 7, Lane 314, Section 3, Xinyi Road, DaAn District, Taipei City, 10659 Taiwan, ROC	T: (+886) (02)-2162-2000 E: agtaipei@fas.usda.gov
<b>Agricultural Trade Office (ATO)</b> <i>Provides exporters marketing assistance</i> Room 704, 7th Floor, No. 136, Section 3, Renai Road, DaAn District, Taipei City, 10657 Taiwan, ROC	T: (+886) (02) 2705-6536 E: atotaipei@fas.usda.gov
<b>U.S. Foreign Agricultural Service, Processed Products Division, U.S. Department of Agriculture</b> 1400 Independence Avenue, SW Mail Stop 1001 Washington, DC 20250	Kelly Strzelecki Senior Trade Advisor T: (+1) 202-690-0522 E: Kelly.Strzelecki@fas.usda.gov
<b>National Organic Program, U.S. Department of Agriculture</b> 1400 Independence Avenue, SW Room 2642-South, Stop 0268 Washington, D.C. 20250-0268	T: (+1) 202-720-3252 E: AIAInbox@ams.usda.gov
<b>Organic Trade Association</b> 444 N. Capitol Street NW Suite 445A Washington, DC 20001	Monique Marez Director of International Trade T: (+1) 202-403-8520 E: info@ota.com

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## ANNEX 2: HISTORY & BACKGROUND ON TAIWAN'S ORGANIC REGIME

### Overview on Taiwan's Organic System

#### A. History of Taiwan's organic regime and overview of relevant organic regulations

Taiwan established its organic regime in 2007 when it enacted the Agricultural Production and Certification Act (APCA) with an aim to enhance the quality and safety of agricultural and processed products -- including organic products -- while protecting the well-being and consumer rights of its citizens. The main principles of the APCA include:

- certification of quality agricultural products its labeling system;
- management of organic agricultural products and processed products through its labeling system for both domestic products and imported products;
- management of good agricultural practice and traceability;
- investigation and inspection during production, processing, distribution, storage, and retail markets, if necessary; and
- penalties for noncompliance.

As it relates to the organic sector, the APCA's seeks to avoid inconsistencies among the quality of organic products, and regulate organic food during the production stage and *before entering the retail market*.

In Taiwan, organic certification is an important element of brand and reputation for Taiwan's organic farmers. With that mindset, Taiwan laws and regulations seek to regulate imported organic agricultural products and processed products in a similar fashion. As such, all imported products are required to comply with the laws and regulations of Taiwan's organic regime to ensure that the integrity of the system has not been compromised.

#### B. Taiwan's Regulation of Imported Organic Products

Under Taiwan's [Imported Organic Agricultural Product and Organic Agricultural Processed Product Management Regulations](#) ("Import Regulations"), Taiwan organic authorities will first recognize the export country's certification/authentication results, and then undertake a comprehensive review process in Taiwan before any imported organic product can be labeled as "organic" and enter the Taiwan market. Taiwan's Import Regulations include a list of permitted organic source countries, documents/information required for the accuracy and effectiveness of the document review process, calculation of organic contents based on domestic rules, approval process and recording requirements, and organic labeling rules.

The objective of Taiwan's [Operating Guidelines in Review for Issuance of Document to Approve Organic Labeling of Imported Organic Agricultural Food Products and Organic Agricultural Food Processed Products](#) ("Operating Guidelines") is to provide uniform specifications for government administrators to review documents provided by importers to facilitate organic labeling of imported organic agriculture and processed products. Along with instructions and directions in the processing of documents, the Operating Guidelines include nine appendices.

The Import Regulations and the Operating Guidelines together are the basis for Taiwan's "organic approval application process" that all imported organic products must undergo before they can be sold in the Taiwan market as organic. The application process requires specific documents and coordinated information shared between the U.S. Exporter, U.S. Certifier and Taiwanese Importer. See [Section 2](#) for detailed information on the need for pre-shipment coordination among and between industry.

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### **C. What is Taiwan’s “published list of certifiers subject to 100% batch-by-batch testing” and why it is important**

Taiwan’s organic system is unique in that it enforces organic regulations by monitoring products based on the products’ certifier rather than the producer, exporter, or importer. Because Taiwan relies on the certification programs of other countries for imported agricultural products and processed products, certifiers are viewed as gatekeepers to protect the integrity of the system, to ensure public safety, and to protect consumer protection on the imported aspect of Taiwan’s organic regime.

When an organic product in the Taiwan market tests positive for non-organic compounds as stipulated in the Taiwan Organic Standard and the government does not receive a response from a certifier in the form of an investigative report and improvement plan, the responsible certifier may be placed on COA’s “published list of certifiers subject to 100% batch-by-batch testing.” (COA’s list is formally known as the “Import Organic Agricultural Products & Agro-Processing Products Certification Body Batch Inspection List.”)

Once placed on the list, all future imported organic products certified by that certifier must undergo organic testing at the port of entry no matter the exporter or importer of record. Certifiers may revert back to routine testing protocols for their exporters’ products at the port of entry once they have demonstrated an investigation and improvement plan to rectify the positive residue findings.

### **History of the U.S.-Taiwan Organic Relationship**

The United States entered into an export trade relationship with Taiwan in March 2009 to ensure ongoing availability of U.S. organic products in Taiwan after Taiwan implemented its organic regime. Under the exporter trade relationship, Taiwan acknowledges four principles related to the U.S. organic regime, specifically:

- The United States is recognized by COA as one of 22 countries with an organic certification body;
- The National Organic Program (NOP) is the United States’ organic certification body;
- U.S. organic products are certified by certification bodies that are accredited by NOP; and
- The TM-11 organic transaction certificate is the designated U.S. organic certificate in lieu of multiple transaction records normally required under Taiwan’s import regulations.

The U.S. export trade relationship with Taiwan does not impart the benefits of an organic equivalency arrangement (OEA). What the export trade relationship with Taiwan does is eliminate the requirement to use a Taiwan certifier and reduce the number of steps and documents required to sell U.S. organic products in Taiwan. Beyond that, Taiwan’s organic regulations apply a number of strict requirements for all organic products, including those from the United States, specifically:

- U.S. organic products must be approved for label and sale in Taiwan on a shipment-by-shipment basis, and approval by AFA is *not guaranteed*;
- U.S. organic products *may be tested for pesticide residues at the port of entry and/or via in-market inspections to Taiwan’s MRL thresholds* which are much stricter than international norms and U.S. NOP standards (both of which generally allow for a minimal tolerance for chemical residues resulting from inadvertent environmental contamination); and
- U.S. organic products sold in Taiwan are not permitted to use the official Taiwan organic seal (known as Taiwan’s Certified Agricultural Standards (CAS) organic seal), however, *are permitted to use the words “organic” on the package, and are required to be stickered with traceability serial numbers.*

From the perspectives of COA, tests of organic products are intended for the protection of health and consumer rights for the citizens of Taiwan. Examinations may occur at the port of entry (pre-approval) and/or in the retail market (post-approval). If selected, the product is tested against MRLs under the Taiwan Organic Standard which are more stringent than the U.S. NOP standard or international norms. As such, products may test positive even if they meet the U.S. NOP standard.

### **ANNEX 3: MAXIMUM RESIDUE LIMITS FOR ORGANIC PRODUCTS**

The [Method of Test for Pesticide Residue in Foods-Multiresidue Analysis \(5\)](#) (Mandarin) contains the most up-to-date list of residues tested as part of the organic label application. This version was updated in August 2017 and entered into force on 1 January 2018. For a downloadable version in English, please click [here](#).

### **ANNEX 4: COMPARISON OF TAIWAN’S MRLS AND U.S. NOP STANDARDS**

USDA has created a comparison of maximum residue levels permitted in organic products in Taiwan with those of NOP. For the full list, click [here](#).

### **ANNEX 5: LIST OF PERMITTED FOOD ADDITIVES FOR ORGANIC PRODUCTS**

The [2018 Requirement schedule of the Names, Scopes of Use, and Limits of Food Additives](#) (in Mandarin with English-language key followed by English translation) contain the full list of food additives tested as part of the organic label application and in-market surveillance. Positive tests for any additives not specified as permissible in the Taiwan organic standard may result in a rejection of an organic application or recall of products.

According to Taiwan’s organic standard, only the following food additives may be permitted in products labeled as organic in Taiwan, via Table 2 on page 27 of the document [here](#) and included below.

Food Additive		Conditions of Use
1.	Chlorinated lime	May be used in drinking water and water used in foods; use in quantities so that residual active chlorine meets drinking water standards.
2.	Chlorine dioxide	
3.	Sodium hypochlorite solution	
4.	Hydrogen peroxide	
5.	L-Ascorbic acid (Vitamin C)	
6.	dl- α -Tocopherol (Vitamin E)	
7.	Sulfite	Limited to be used in wine and fruit drinks; SO2 residue must be under 100ppm.
8.	Sodium bicarbonate	
9.	Ammonium carbonate	Limited to be used as a swelling agent.
10.	Ammonium bicarbonate	Limited to be used as swelling agent.
11.	Potassium Carbonate	Limited to be used in cereal products.
12.	Calcium chloride	
13.	Calcium hydroxide	
14.	Calcium sulfate	From natural sources only.
15.	Calcium citrate	
16.	Calcium phosphate, monobasic	
17.	Calcium phosphates, tribasic	
18.	Calcium carbonate	
19.	Sodium carbonate	
20.	Sodium carbonate, Anhydrous	

Food Additive		Conditions of Use
21.	Magnesium carbonate	
22.	Magnesium sulfate	From natural sources only.
23.	Magnesium chloride	Only magnesium chloride extracted from seawater may be used. Limited to be used as a coagulant in legume products.
24.	Glycerin	Limited to be used only in the hydrolysis of fats.
25.	Bentonite	
26.	Diatomaceous earth	Limited to be used in filtration and absorption during the manufacture of foods.
27.	Kaolin	
28.	Talc	
29.	Perlite	Limited to be used as a filter additive.
30.	Silicon dioxide	
31.	Carnauba wax	
32.	Citric acid	May be used only when extracted from fruits or obtained from fermentation of carbohydrates or other natural raw matters.
33.	Sodium citrate	
34.	Potassium citrate	
35.	Tartaric acid	
36.	D&DL-sodium tartrate	
37.	Lactic acid	
38.	DL-malic acid (Hydroxysuccinic acid)	
39.	Potassium chloride	
40.	Alginate acid	
41.	Sodium alginate	
42.	Potassium alginate (Algin)	
43.	Calcium alginate (Algin)	
44.	Carrageenan	
45.	Xanthan gum	
46.	Sodium hydroxide	(1) Limited to be used as a pH adjuster; may be used only in processed sugar products or processed cereal products. (2) May not be used in alkaline liquors employed to remove skins from fruits or vegetables.
47.	Potassium hydroxide	(1) Limited to be used as a pH adjuster; may be used only in processed sugar products. (2) May not be used in alkaline liquors employed to remove skins from fruits or vegetables.
48.	Agar-Agar	Limited to be unbleached.
49.	Arabic gum	
50.	Guar gum	
51.	Locust bean gum or Carob bean gum	Used in processed animal products; limited to be used in dairy and meat product processing.
52.	Gelatin	
53.	Pectin	
54.	Carbon dioxide	
55.	Ethylene	
56.	Acetylene	
57.	Nitrogen	Only from non-petroleum sources; only no-oil grade.
58.	Oxygen	Limited to be used by no-oil grade.
59.	Natural colors	

Food Additive		Conditions of Use
60.	Natural yeast	
61.	Activated charcoal	
62.	Lecithin	Limited to be unbleached and not processed using organic solvent.
63.	Corn starch (native)	
64.	Natural flavors	
65.	Enzyme (1) Rennet (2) Catalase (Extract from animal's liver) (3) Animal Lipase (4) Pepsin (5) Trypsin (6) Pancreatin (7) Egg white lysozyme	(1) May be obtained solely from edible, nontoxic plants, non-pathogenic microbes, or healthy animals. (2) May not be processed using organic solvents.
66.	Casein	Limited to be used in processing of alcoholic beverages and meat products.
67.	Glucono- $\delta$ -lactone	May be obtained solely by microbial fermentation and carbohydrates oxidation.

## ANNEX 6: SOURCES & REGULATIONS

### Taiwan's Organic Regulations

A. [Agricultural Production and Certification Act \(English\)](#): The purpose of the Act is to improve the quality and safety of agricultural products and their processed products, and to protect the health of citizens and the rights of consumers. The competent authority is the Council of Agriculture at the central level, and the municipal/county/city governments at the local level. To implement the APCA, the AFA has created several bylaws, regulations, enforcement rules, and guidelines covering several areas.

#### B. Organic Label for Imported Organic Products

- [Imported Organic Agricultural Product and Organic Agricultural Processed Product Management Regulations \(English\)](#)
- [Organic Agricultural Product and Organic Agricultural Processed Product Management Regulations \(aka the Organic standard\) \(English\)](#)
  - [Appendix 1](#): Amended Provisions of the Certification Criteria for Organic Agricultural Products and Organic Agricultural Processed Products (Note – contains list of acceptable food additives and pesticides)
  - [Appendix 2](#): Amended Regulation for Table of Organic Agricultural Processed Products, Categories, and Items
- [Operating Guidelines in Review for Issuance of Document to Approve Organic Labeling of Imported Organic Agricultural Food Products and Organic Agricultural Food Processed Products \(English\)](#)
  - [Appendices](#) – Contains forms for application of organic label
  - [Forms for application of organic label \(Mandarin\)](#), updated 26 June 2017



- [Operating Guidelines in Review for Issuance of Document to Approve Organic Labeling of Imported Organic Livestock Products and Organic Processed Livestock Products](#) (27 July 2015) (Mandarin) –
  - [Annex 3 Amendments](#)
  - [Annex 4 Amendments](#)
  - [Annex 5 Amendments](#)
  - [Annex 6 Amendments](#)
  - [Annex 7 Amendments](#)
  - For approval process of organic labeling for livestock organic products and processed products, [the legal text of operating guideline](#) is similar to that of AFA. The only difference is it reports to Department of Animal Husbandry (internal unit) under COA. The final approved certificate is issued by COA.
- [Organic Guidelines in Review for Issuance of Document to Approve Organic Labeling of Imported Aquatic Products and Processed Aquatic Products](#) (Mandarin)

### C. Testing Methodologies for Organic Products

- *Maximum Residue Limits* (Limits of Quantification for Organic Crop and Processed Crop Products)
  - [Revised Method for Residue Pesticides in Foods – Multiresidue Analysis Method \(V\) \(MOHWP00.03\)](#) (31 August 2017) (Mandarin)
  - [Revised General Explanation and Amendment Checklist](#) (Mandarin)
- Food Additives (for all products) – [2018 Requirement Schedule of Names, Scopes of Use and Limits of Food Additives](#) (Mandarin)
- *Permissible Food Additives in organic products*: [Appendix 1](#) of the Imported Organic Agricultural Product and Organic Agricultural Processed Product Management Regulations
- [Taiwan Food and Drug Administration Database of Food Additives](#)

### D. Product Inspection Regulations

- [Agricultural Product Inspection, Sampling, and Testing Regulations](#) (Mandarin), updated 26 June 2007
- [Agricultural Product Inspection, Sampling, and Testing Regulations](#) (English), updated 26 June 2007.
- [Regulations Governing Incentive Award for Report of Violation Against Agricultural Product Production and Certification Management Act](#) (Mandarin), updated 20 May 2015
- [Operating Guidelines in Response to the Inspection and Sampling Test Results of Organic Agricultural Processed Products](#) (Mandarin), updated 30 July 2012
  - Appendix: [Penalty Standard on Violating Organic Agricultural Products and Organic Agricultural Processed Products Certification Management](#) (Mandarin)
- [Rules on Sampling Methods and Quantities of Agricultural Products and Processed Agricultural Products](#) (Mandarin), updated 20 September 2007

#### *E. Acceptance of Country Organic Competent Authorities*

- [Visiting Import Organic Agricultural Product Equivalence Country Verification Operation Guideline](#) (English)

#### *F. Certification Bodies*

- [Regulations Governing Management over Agricultural Product Certification Bodies](#) (Mandarin), updated 7 June 2007
- [Operating Guidelines for Accreditation of Organic Agricultural Product Certification Bodies](#) (English)

#### *G. Domestic Operators*

- [Organic Agricultural Product and Organic Agricultural Processed Product Certification Management Regulations](#) (English)
- [Regulations Governing Management over Agricultural Product Marks](#) (Mandarin), updated 3 February 2009
  - Appendix 1: GMP mark
  - Appendix 2: Organic Product mark
  - Appendix 3: Traceable agricultural products (TAP) mark

### **AIT Ag Section's Global Agriculture Information Network (GAIN) Reports**

#### *A. Organic-Specific GAIN Reports*

- [Growing Demand for Organics in Taiwan Stifled by Unique Regulatory Barriers](#) (20 September 2017)
- [New Organic Legislation developed by Taiwan authority](#) (3 December 2015)
- [Taiwan Authorities Enforce GE Testing on Organic Soybeans and Implement New Documentation for Corn and Soybean Imports](#) (29 October 2014)

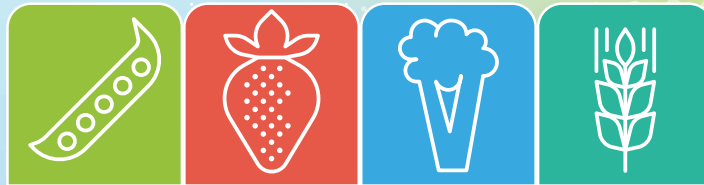
#### *B. Food and Agriculture Import Regulations and Standards (FAIRS) Narrative*

- [2017 FAIRS Narrative](#)
- [2016 FAIRS Narrative](#)
- [2015 FAIRS Narrative](#)

### **NOP's Guidance on Exporting Organic Products to Taiwan**

- [International Trade Policies: Taiwan](#)
- [Instructions for Completion of an Export Certificate](#) (TM-11)
- [Certifying Agent Acronyms for TM-11 Export Certificates](#)
- ["Responding to Results from Pesticide Residue Testing" \(NOP publication NOP 2613\)](#)

# TAIWAN EXPORT MANUAL



U.S. Industry Resource on How to Export U.S. Organic Products for Label and Sale as Organic in Taiwan

## ABOUT OTA

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members.

## ABOUT OTA EXPORT PROGRAM FUNDING

The Organic Trade Association's organic export initiatives are funded through the U.S. Department of Agriculture's (USDA) Foreign Agricultural Service (FAS) Market Access Program (MAP). Since 1999, FAS has awarded millions of dollars to OTA to help expand commercial export markets for U.S. organic products. OTA aims to showcase and educate key target markets on the quality, integrity and variety of USDA-certified organic products available for export around the world.



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