



---

## **Instruction**

# **Recognition and Monitoring of Foreign Government Conformity Assessment Systems**

### **1. Purpose**

This document establishes the standard operating procedures used by the National Organic Program (NOP) for determining whether the conformity assessment systems used by a foreign government to accredit organic certification bodies meet the applicable requirements of the Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501. et seq.) and its implementing regulations (7 C.F.R. § 205. et seq.). In addition, this document establishes the standard operating procedures used by USDA to monitor performance of conformity assessment systems to which recognition has been extended.

### **2. Scope**

USDA may recognize the foreign government's conformity assessment system. Recognition determinations cover agricultural products produced or handled within the foreign government's borders and include ingredients of third countries that are substantially transformed and certified under the supervision of the foreign government's conformity assessment system.

### **3. Background**

The burden of demonstrating that a foreign government's conformity assessment system meets the applicable requirements of the OFPA and its implementing regulations rests with the requesting government.

For the purposes of this document, a conformity assessment system will be recognized as meeting the applicable requirements of the OFPA and its implementing regulations when the NOP has determined that the requesting government's conformity assessment system is identical in force and effect to the applicable requirements of the OFPA and its implementing regulations, and when the NOP has determined, through objective analysis, that the conformity assessment system is competent to carry out specific tasks.

This document uses "conformity assessment system" to mean all activities undertaken by the foreign government to ensure that the applicable technical requirements for the production, handling, and processing of organic agricultural products are fully and consistently applied.

This document does not address any other requirements (e.g., plant protection, animal health, or food safety) necessary to import food and agricultural products into the United States. These



---

procedures are for the internal use of USDA, do not create or confer any rights for or on any person or entity and do not operate to bind USDA or the public.

## **4. Policy**

### **4.1 General**

A recognition determination assesses only the foreign government's conformity assessment system. To be sold, labeled or represented in the United States as organic, raw or processed organic agricultural products certified by certifying agents accredited by the recognized foreign government must be certified in compliance with the OFPA and its implementing regulations.

Upon successful completion of a document review and, as applicable, onsite verification audit, the USDA would recognize the foreign government's conformity assessment system as being identical in force and effect to the applicable requirements of the OFPA and its implementing regulations and therefore competent to verify full compliance with the NOP technical requirements.

Alternatively, as provided by § 205.500(a), USDA will accept at any time an application for direct accreditation to perform certification activities under the NOP from any qualified foreign private or governmental certifying agent. USDA may accredit foreign certifying agents in a foreign country as well as recognize the foreign government's conformity assessment system.

### **4.2 Responsibilities of Recognized Government Accrediting Bodies**

Government agencies recognized to accredit certifying bodies for NOP certification activities are responsible for conducting specific activities related to NOP certification as described in this section. Such responsibilities are included in the Terms of Recognition agreed to by the accrediting body.

### **4.3 Notification of changes to the laws and operating procedures of the accrediting body**

Any changes to the laws or regulations related to the agency's ability to accredit to the NOP must be notified in advance to the NOP. Significant change to the approved procedures may prompt review or cancellation of the agreement if it is determined that such changes materially affect the foreign government's ability to carry out the agreed upon accreditation responsibilities.

### **4.4 Conducting document reviews and onsite evaluations**

Recognized government bodies must conduct onsite reviews of certifying bodies; one initial review prior to accreditation and additional reviews in compliance with ISO Guide 17011.

### **4.5 Review and disposition of appeals**

Recognized government agencies are responsible for receiving and handling all appeals of decisions made by accredited certifying agents in their country.

### **4.6 Complaints**

Recognized bodies are responsible for investigating and responding to complaints regarding NOP certified organic products within their sovereign borders.



---

#### **4.7 Information collection and reporting**

Recognized bodies are responsible for collecting and reporting routine information regarding NOP certified operations and products, including:

1. By January 2<sup>nd</sup> of each year, the name, contact information, and products produced by operations certified to each scope of the NOP regulations. This information will be provided in the same format prescribed for directly accredited certifying agents.
2. A current list and complete contact information of all NOP certifying bodies accredited under the agreement:
3. An annual report of the types and quantities of NOP certified organic products exported under the recognition agreement, and
4. Notices of noncompliances, proposed adverse actions, and final adverse actions issued to NOP certified operations.

### **5. Procedure**

#### **5.1 Application for Recognition**

1. Foreign governments seeking a recognition determination should contact AMS in writing.
  - a. The letter requesting a determination should be sent to:  
  
Administrator; AMS;  
1400 Independence Avenue, SW;  
Room 2643 South Agriculture Building;  
Washington, DC 20250,  
Attn: NOP Recognition Request.
2. The letter should be sent on the official letterhead of the foreign government's competent authority and should include the following information:
  - a. The competent authority's contact person(s) and contact information;
  - b. ISO 17011 evaluation matrix. NOP 2014-1.
  - c. Detailed documentation explaining the foreign government's conformity assessment program. The documentation should address:
    - i. The conformity assessment program's legal authority;
    - ii. The conformity assessment program's documented specifications or procedures;
    - iii. The conformity assessment program's compliance and enforcement process and procedures.
  - d. The documentation must be sufficient to demonstrate the foreign government's ability to:
    - i. Identify and evaluate the degree of non-compliance related to the technical requirements;
    - ii. Investigate non-compliances to determine what corrective or enforcement actions are necessary;
    - iii. Issue corrective or enforcement actions in cases of violation;
    - iv. Monitor implementation/closure of corrective or enforcement actions; and
    - v. Accurately and in a timely manner communicate with its regulated entities.



3. Documentation must be submitted in English.
4. USDA will prepare and distribute a letter acknowledging the foreign government's request for recognition determination. The letter will designate a USDA staff contact.
5. During the interim period, USDA will examine the documentation for completeness and promptly inform the applicant in a precise and complete manner of all deficiencies.

## **5.2 Evaluation of Application**

1. The application packet will be reviewed by NOP staff for completeness and the ability of the foreign government's conformity assessment system to comply with NOP regulations.
2. The foreign government will be notified if the application is incomplete or does not comply with NOP regulations.
3. If the document review determines that the foreign government's conformity assessment system is able to comply with NOP regulations then an onsite review will be conducted.

## **5.3 Onsite Reviews**

The purpose of the onsite audit(s) is to determine whether the foreign government's conformity assessment system for the country's production, handling, and processing of organic agricultural products is functioning as indicated in the document review. The onsite audit evaluates compliance with OFPA and the NOP regulations.

**5.4** Onsite reviews will be conducted according to ISO 19011: 2011 Guidelines for auditing management systems.

**5.5** The audit includes an assessment of:

1. The conformity assessment system,
2. The certification bodies, and
3. The foreign country's organic producers and handlers.

## **5.4 Final Recognition**

1. After the document review and the onsite audit are complete a final recommendation by the NOP will be advanced to AMS administrator for approval.
2. If approval is granted by the AMS administrator, the foreign government representative will be notified.
3. When finalized, USDA will record the determination with the foreign government through an exchange of letters.
4. The documentation recording the recognition will include, at a minimum, the following requirements:



- 
- a. The obligation of the foreign government to notify USDA of any legislative or administrative changes in the conformity assessment system;
  - b. The obligation of the foreign government to immediately report to USDA any non-compliance regarding the application of the NOP technical requirements to products exported to the United States;
  - c. The obligation of the foreign government to allow USDA representatives to conduct onsite audits and reviews, when properly notified in advance, of such reviews by USDA; and
5. The obligation of the foreign government to provide annually to USDA a report which contains:
- a. By January 2<sup>nd</sup> of each year, the name, contact information, and products produced by operations certified to each scope of the NOP regulations. This information will be provided in the same format prescribed for directly accredited certifying agents.
  - b. A current list and complete contact information of all NOP certifying bodies accredited under the agreement:
  - c. An annual report of the types and quantities of NOP certified organic products exported under the recognition agreement, and
  - d. Notices of noncompliances, proposed adverse actions, and final adverse actions issued to NOP certified operations.

## **5.6 Monitoring of Recognition Agreements**

1. The NOP will ensure the satisfactory performance of the recognition determination by monitoring the performance of the foreign government's conformity assessment system.
2. In addition, the NOP will perform at least one onsite surveillance audit every 2 years during which the recognition remains in force.
3. The onsite surveillance audit(s) will be conducted under the provisions of ISO 17011: 2004 Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies, and ISO 19011: 2011 Guidelines for auditing management systems.

## **5.7 Suspension and Termination of Recognition Agreements**

1. The NOP may suspend or terminate the recognition agreement if the foreign government fails to maintain its conformity assessment system in compliance with OFPA and the NOP regulations.
2. Recognition agreements may be suspended or terminated for any reason with thirty days written notice by either party.



## **6. References**

### **NOP Regulations (as amended to date)**

7 C.F.R. § 205.500 Areas of duration of accreditation.

### **Other Laws, Regulations and Standards**

ISO 17011:2004 General requirements for accreditation bodies accrediting conformity assessment bodies.

ISO 19011: 2011 Guidelines for auditing management systems.

ISO Guide 65 General requirements for bodies operating product certification systems

Approved on May 6, 2015