

USDA National Organic Program

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USDA Agricultural Marketing Service
National Organic Program



The National Organic Program (NOP)



- **Mission:**
Ensure the integrity of USDA organic products throughout the world
- **Vision:**
Organic Integrity from Farm to Table,
Consumers Trust the Organic Label
- **Core Role:**
Implement the Organic Foods Production Act and the USDA organic regulations

AMS-NOP Strategic Plan 2015-18



Support People
and Process

Protect Organic
Integrity

Build Technology
that Advances
Organic Integrity

Enhance Market
Access

Develop and
Communicate Clear
Standards

Support People and Process



National Organic Program

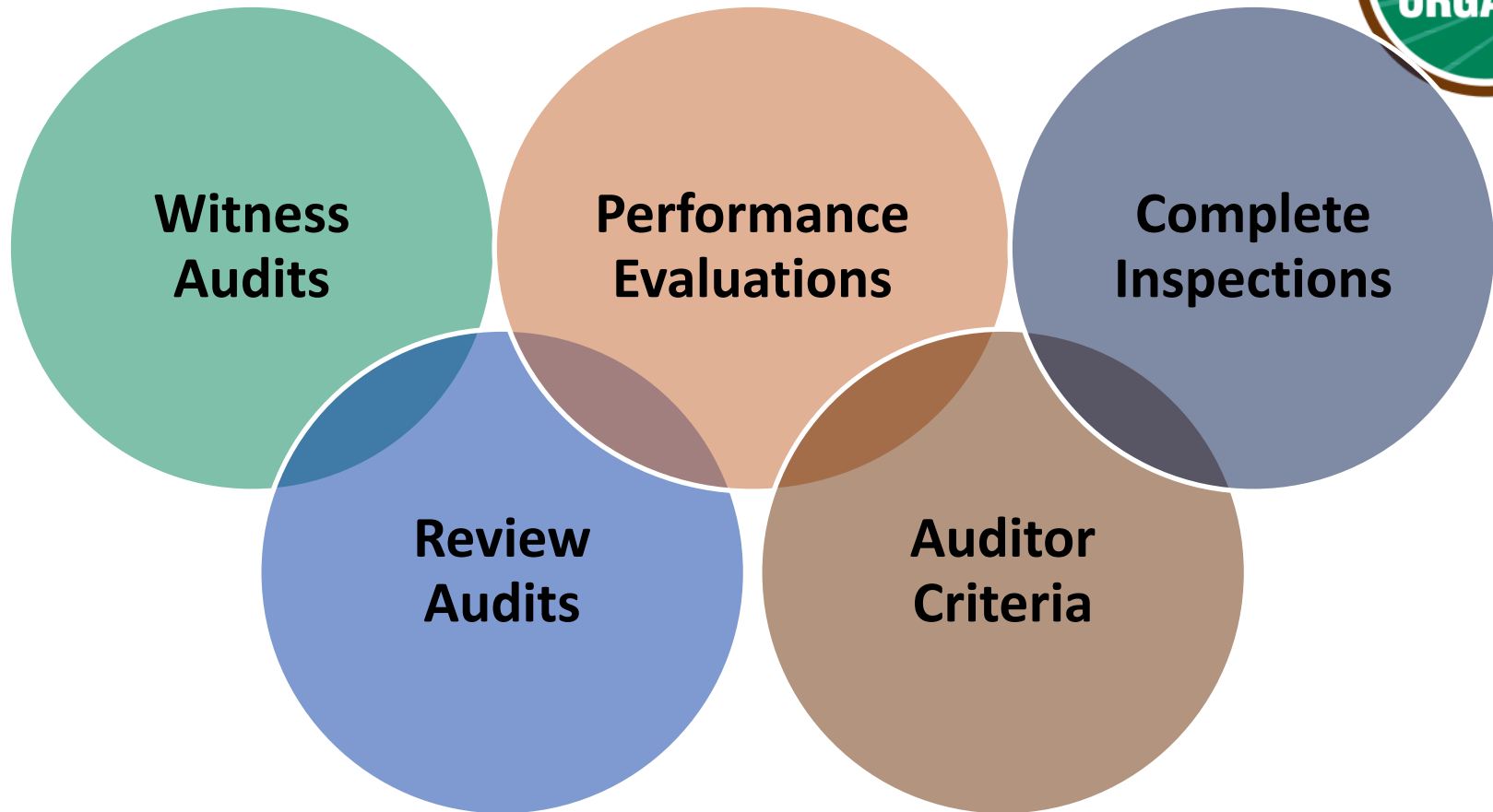


- **NOP Staffing:** 45 employees in three Divisions and the Office of the Deputy Administrator
- **NOP Budget:**
 - FY 2012: \$6.919 million
 - FY 2013: \$6.369 million
 - FY 2014 – 2016: \$9 million

Oversight Responsibility:

- 81 certifying agents worldwide
- 31,000 certified organic operations in over 120 countries
- Over \$43 billion (43,000 million) in U.S. organic sales (2015)

Processes Supporting Organic Integrity



Qualified Personnel | Quality Management
Processes | Training | Equipment/Technology

NOP Process Improvement



Internal Audits

Management
Reviews

Peer Reviews

Assessments by
Foreign
Governments

Office of
Inspector
General Audits

NOP Team Projects



Import Oversight Team | Internal Communications Team
Rulemaking Teams | FOIA Team | Integrity Database Team

Protecting Organic Integrity



10 Points of Organic Integrity



1. Clear/enforceable standards
2. Communication
3. Transparency
4. Certification
5. Effective Complaint Process
6. Penalties
7. Market surveillance
8. Unannounced inspections
9. Periodic residue testing
10. Continual improvement

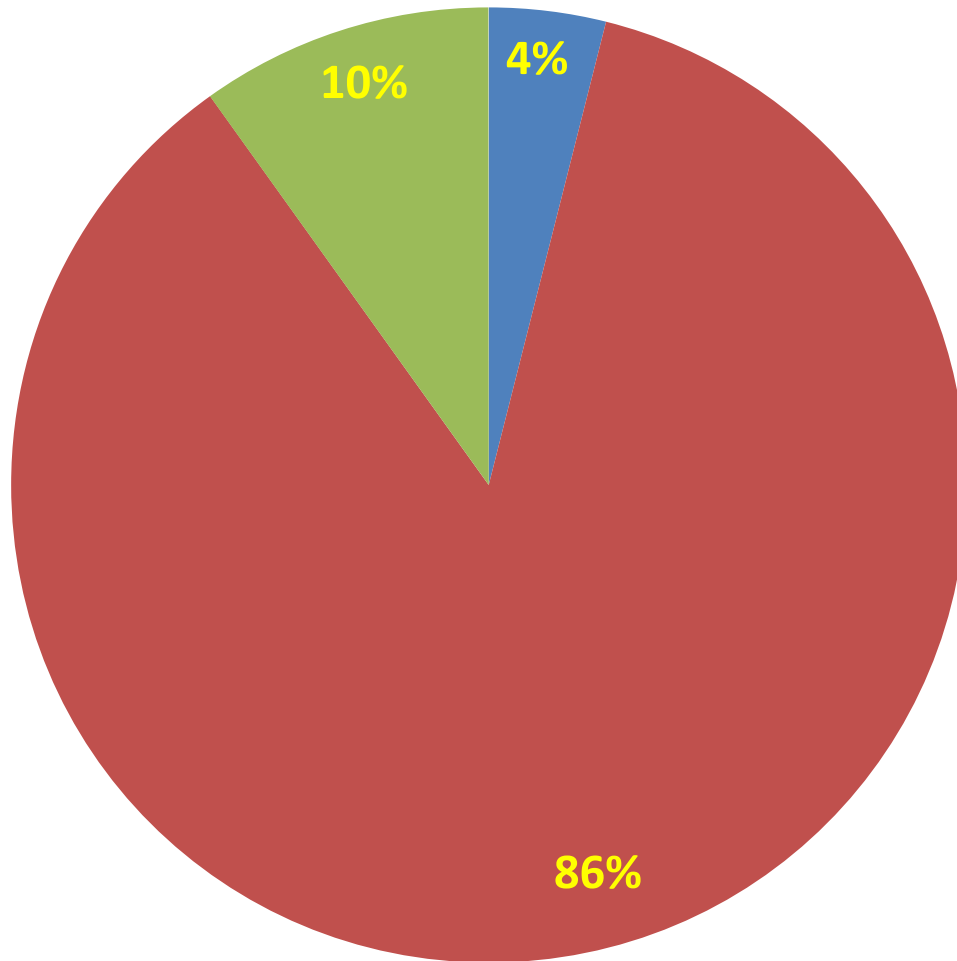
Compliance & Enforcement

FY 2015 and 2016



		FY 2015	FY 2016
Compliance & Enforcement: Overall Summary		10/1/14-9/30/15	10/1/15-9/30/16
Incoming Complaints		549	499
Completed Complaints		390	357
Summary of Initial Actions Taken			
Cease & Desist Orders		36	31
Notices of Warning		121	111
Civil Penalties Levied			
Total Number		8	9
Total Amount		\$1,872,875	\$397,750

Incoming Complaints: FY16



■ Labeling

■ Non-Certified

■ Prohibited Substances and Methods

Examples: Enforcement Actions



NOP Investigation

- Processor sold product as organic while suspended
- \$880,000 civil penalty; \$540,000 held in abeyance
- Operation remains suspended

With Partners

- NOP supported Office of Inspector General investigation
- Partnered with State Department of Agriculture
- Operation pleaded guilty to charges

Maintaining Integrity and Transparency



Enforcement Monitoring

- Investigations flagged for follow-up when complaints are closed
- Follow-up cases randomly selected from closed investigations

Enforcement Reporting

- Compliance & Enforcement/Appeals
Quarterly Reports
- Posting of Settlements, Appeal Decisions,
Administrative Law Judge Actions

Freedom of Information Act (FOIA)



- Anyone may request Federal Agency records under the Freedom of Information Act (FOIA)
- Federal agencies disclose information requested under FOIA: We maximize openness!
- Some information legally withheld (called “exemptions”): Personal privacy, open complaints, Agency harm
- Frequently requested records are posted online
- Requires resources and time:
 - Can involve 100’s/1,000’s pages, years of records
 - We have 4 full time people working on FOIA

**Build Technology
that Enhances
Organic Integrity**



The Organic *INTEGRITY* Database



Modernized certified organic operations database:

•Contains
up-to-date
accurate
information

Increases
supply chain
transparency

Enhances
integrity of
organic
control
system

The Organic *INTEGRITY* Database



•Farm Bill
Funding:
2014

Certifier
Data
Upload:
Nov 2015

Certifier
Locator:
May 2016

•Public
Website:
Sept 2015

Search,
Reports,
Faster
System:
2016

Certificate
Module:
Oct 2016

INTEGRITY: 2016 AMS and USDA Awards



Certifiers, Operations, and Data Users Are All Building INTEGRITY



•More than 20 Certifiers Regularly Provide Feedback



>100 People Attend Each Public Update Webinar



NOP Provides Certifier Outreach and Feedback



Operations Give Feedback to Certifiers on Data Quality



User Feedback Drives Improvements

What's Next for INTEGRITY?



Build Out
Certificate Module

Improve Search
and More Reports

Commodity
Reports by State:
Aggregate Acreage,
Livestock Heads

Encourage
Standard Item List
Adoption by
Certifiers

Focus on Data
Quality and
Frequency with
Certifiers

Other Technology Initiatives



Accreditation System

- Streamline and standardize NOP's processes and workflow
- Manage audit scheduling, report generation and reviews, certifier contacts

Certifier Information Submittal

- Tool will make it easier for certifiers to send information to NOP: corrective actions, annual reports, adverse actions
- NO new technology investments will be needed for certifiers

Clear Standards



Rules



- Organic Livestock and Poultry Practices
 - Final rule published
- Sunset 2016 Final Rule (published August 2016)
 - Removed egg white lysozyme, cyclohexylamine, diethylaminoethanol, octadecylamine, tetrasodium pyrophosphate from National List

The Reg Map

Informal Rulemaking

Step One

Initiating Events

Agency Initiatives

Agency initiatives for rulemaking originate from such things as:

- Agency priorities and plans
- New scientific data
- New technologies
- Accidents

Required Reviews

Statutory Mandates

Recommendations from Other Agencies/External Groups/States/Federal Advisory Committees

Lawsuits

Petitions

OMB Prompt Letters

Step Two

Determination Whether a Rule Is Needed

Administrative Procedure Act Provisions

Under the Administrative Procedure Act provisions that are included as part of the Freedom of Information Act at 5 U.S.C. 552, agencies are required to publish in the Federal Register:

- Substantive rules of general applicability
- Interpretive rules
- Statements of general policy
- Rules of procedure
- Information about forms
- Information concerning agency organization and methods of operation

Step Three

Preparation of Proposed Rule

Proposed Rule

A notice of proposed rulemaking proposes to add, change, or delete regulatory text and contains a request for public comments.

Administrative Procedure Act Provisions

Under the Administrative Procedure Act provisions at 5 U.S.C. 553, rules may be established only after proposed rulemaking procedures (steps three through six) have been followed, unless an exemption applies. The following are exempted:

- Rules concerning military or foreign affairs functions
- Rules concerning agency management or personnel
- Rules concerning public property, loans, grants, benefits, or contracts
- Interpretive rules
- General statements of policy
- Rules of agency organization, procedure, or practice
- Nonbinding rules for which the agency determines that public input is not warranted
- Rules published on an emergency basis

Note: Even if an exemption applies under the Administrative Procedure Act provisions, other statutory authority or agency policy may require that proposed rulemaking procedures be followed.

Optional Supplementary Procedures to Help Prepare a Proposed Rule

Advance Notice of Proposed Rulemaking
An advance notice of proposed rulemaking requests information needed for developing a proposed rule.

Negotiated Rulemaking
Negotiated rulemaking is a mechanism under the Negotiated Rulemaking Act (5 U.S.C. 561-570) for bringing together representatives of an agency and the regulated interests to negotiate the text of a proposed rule.

Step Four

OMB Review of Proposed Rule

OMB Review Under Executive Order 12866

OMB reviews only those rulemaking actions determined to be "significant."

Independent agencies are exempt from OMB review.

Step Five

Publication of Proposed Rule

Administrative Procedure Act Provisions

The Administrative Procedure Act provisions at 5 U.S.C. 553 require proposed rules to be published in the Federal Register.

Step Six

Public Comments

Comments

Under the Administrative Procedure Act provisions at 5 U.S.C. 553, an agency must provide the public the opportunity to submit written comments for consideration by the agency.

As required by Public Law No. 101-540, agencies must provide for submission of comments by electronic means and must make available online the comments and other materials included in the rulemaking docket under 5 U.S.C. 553 (c).

Executive Order 12866 established 60 days as the standard for the comment period.

The holding of a public hearing is discretionary unless required by statute or agency policy.

Step Seven

Preparation of Final Rule, Interim Final Rule, or Direct Final Rule

Final Rule

A final rule adds, changes, deletes, or affirms regulatory text.

Special Types of Final Rules

Interim Final Rule
An interim final rule adds, changes, or deletes regulatory text and contains a request for comments. The subsequent final rule may make changes to the text of the interim final rule.

Direct Final Rule
A direct final rule adds, changes, or deletes regulatory text at a specified future time, with a duty to withdraw the rule if the agency receives adverse comments within the period specified by the agency.

Step Eight

OMB Review of Final Rule, Interim Final Rule, or Direct Final Rule

OMB Review Under Executive Order 12866

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Step Nine

Publication of Final Rule, Interim Final Rule, or Direct Final Rule

Congressional Review Act (5 U.S.C. 801-806)

An agency must submit most final rules, interim final rules, and direct final rules, along with supporting information, to both houses of Congress and the General Accounting Office before they can take effect.

Major rules are subject to a delayed effective date (with certain exceptions). Action by Congress and the President could have an impact on the rule.

Administrative Procedure Act Provisions

Under the Administrative Procedure Act provisions that are included as part of the Freedom of Information Act at 5 U.S.C. 552, agencies are required to publish final rules, interim final rules, and direct final rules in the Federal Register.

Federal Register Act (44 U.S.C. 1501-1511)

The Federal Register Act at 44 U.S.C. 1510 implemented at 1 CFR 1.1 requires rules that have general applicability and legal effect to be published in the Code of Federal Regulations.

Specific Analyses for Steps Three and Seven

Regulatory Planning and Review (E.O. 12866)

Would the rule have a \$100 million annual impact, raise novel issues, and/or have other significant impacts? → **If yes** Prepare economic impact analysis.

Regulatory Flexibility Act (5 U.S.C. 601-612)

Is a notice of proposed rulemaking required by law? → **If yes**

Would the rule "have a significant economic impact on a substantial number of small entities?" → **and yes** Prepare regulatory flexibility analysis.

Note: Under limited circumstances, analyses also are required for certain interpretive rules involving internal revenue laws (5 U.S.C. 602, 606).

Paperwork Reduction Act (44 U.S.C. 3501-3520)

Does the rule contain a "collection of information" (reporting, disclosure, or recordkeeping)? → **If yes** Prepare information collection clearance package for OMB review and approval, and (possibly) request for public comments.

Unfunded Mandates Reform Act (2 U.S.C. Chs. 17A, 25)

Does the rulemaking process include a proposed rule? → **If yes**

Does the rule include any Federal mandate that may result in the expenditure (direct costs minus direct savings) by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year? → **and yes** Prepare unfunded mandate analysis (unless an exclusion applies).

Federalism (E.O. 13132)

Is the rule a discretionary rule that has federalism implications and imposes substantial unburdened direct compliance costs on State and local governments? → **If yes** Prepare federalism summary impact statement.

Does the rule have federalism implications and preempt State law? → **If yes** Prepare federalism summary impact statement.

Indian Tribal Governments (E.O. 13175)

Is the rule a discretionary rule that has tribal implications and imposes substantial unburdened direct compliance costs on Indian tribal governments? → **If yes** Prepare tribal summary impact statement.

Does the rule have tribal implications and preempt tribal law? → **If yes** Prepare tribal summary impact statement.

National Environmental Policy Act (42 U.S.C. 4321-4347)

Is the rule categorically excluded from review? → **If no**

Does the rule have a major Federal action significantly affecting the quality of the human environment? → **and yes** Prepare environmental assessment or

Drafting Requirements for Rulemaking Documents

Regulatory Planning and Review (E.O. 12866)

Rulemaking documents must comply with the specified regulatory philosophy and principles of regulation.

Civil Justice Reform (E.O. 12988)

Rulemaking documents must be written in clear language designed to help reduce litigation.

Presidential Memorandum on Plain Language (63 FR 31885)

Rulemaking documents must comply with plain language principles.

Agendas for Rules Under Development or Review

Unified Regulatory Agenda

The Unified Regulatory Agenda provides information concerning agency rules under development or review.

The Unified Regulatory Agenda is published in the Federal Register in the spring and fall of each year.

Regulatory Plan

The Regulatory Plan provides information concerning the most important significant regulatory actions that the agency is planning to take.

The Regulatory Plan is published in the Unified Regulatory Agenda in the fall of each year.

Regulatory Flexibility

Using The Reg Map

The Reg Map is based on general requirements. In some cases, more stringent or less stringent requirements are imposed by statutory provisions that are agency specific or subject matter specific. Also, in some cases more stringent requirements are imposed by agency policy.

In a typical case, a rulemaking action would proceed from step one through step nine with a proposed rule and a final rule.

However, if a rulemaking action is exempt from the proposed rulemaking procedures under the Administrative Procedure Act provisions (explained under step three) or under other statutory authority, an agency may:

- promulgate a final rule omitting steps three through six, or
- promulgate an Interim final rule omitting steps three through six, but providing a comment period and a final rule after step nine.

Also, if an agency determines that a rule likely would not generate adverse comments, the agency may promulgate a direct final rule.

Step One

Initiating Events

Agency Initiatives

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Step Two

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Under the Administrative Procedure Act provisions that are included as part of the Freedom of Information Act at 5 U.S.C. 552, agencies are required to publish in the Federal Register:

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Under the Administrative Procedure Act provisions at 5 U.S.C. 553, rules may be established only after proposed rulemaking procedures (steps three through six) have been followed, unless an exemption applies. The following are exempted:

- Rules concerning military or foreign affairs functions
- Rules concerning agency management or personnel
- Rules concerning public property, loans, grants, benefits, or contracts
- Interpretive rules
- General statements of policy

Step Four

OMB Review of Proposed Rule

OMB Review Under Executive Order 12866

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Step Five

Publication of Proposed Rule

Administrative Procedure Act Provisions

The Administrative Procedure Act provisions at 5 U.S.C. 553 require proposed rules to be published in the Federal Register.

Step Six

Public Comments

Comments

Under the Administrative Procedure Act provisions of 5 U.S.C. 553, an agency must provide the public the opportunity to submit written comments for consideration by the agency.

As required by Public Law No. 107-347, agencies must provide for submission of comments by electronic means and must make available online the comments and other materials included in the rulemaking docket under 5 U.S.C. 553 (c).

Executive Order 12866 established 60 days as the standard for the comment period.

The holding of a public hearing is discretionary unless required by statute or agency policy.

Step Seven

Preparation of
Final Rule,
Interim Final
Rule, or Direct
Final Rule

Final Rule

Final rule adds, changes, deletes,
or revises regulatory text.

Special Types of Final Rules

Interim Final Rule

Interim final rule adds, changes,

Step Eight

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of Final Rule,
Interim Final
Rule, or Direct
Final Rule

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Major rules are subject to a
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Action by Congress and the President
could have an impact on the rule.

Regulatory Planning and Review (E.O. 12866)

Would the rule have a \$100 million annual impact, raise novel issues, and/or have other significant impacts?



If yes

Prepare economic impact analysis.

Regulatory Flexibility Act (5 U.S.C. 601–612)

Is a notice of proposed rulemaking required by law?



If yes

Would the rule “have a significant economic impact on a substantial number of small entities”?



and yes

Prepare regulatory flexibility analysis.

Note: Under limited circumstances analyses also are required for certain interpretive rules involving internal revenue laws (5 U.S.C. 603, 604).

Paperwork Reduction Act (44 U.S.C. 3501–3520)

Does the rule contain a “collection of information” (reporting, disclosure, or recordkeeping)?



If yes

Prepare information collection clearance package for OMB review and approval, and prepare request for public comments.

Control Systems Accreditation, Certification Oversight



The U.S. Organic Sector



–Fastest-growing food industry



Double digit growth trend



Tripled in size since 2002



Estimated at >\$43 billion (U.S. sales)



>4% total U.S. food sales

Organic Control System



USDA National Organic Program

- Ensure that all organic products sold in the United States comply with USDA organic regulations

Certification and Accreditation

- Certifiers verify that organic farmers and handlers comply with organic standards
- Accreditation body (AMS) ensures that certifiers are verifying production practices, conducting production/sales audits, and ensuring complete audit trail.

Compliance and Enforcement

- Certifiers enforce the standards under their authority (Notice of Noncompliance, Notices of Suspension/Revocation)
- Competent authorities (governments) provide oversight and enforcement

International framework



- Codex Alimentarius – 1999
- European Union organic regulations, USDA organic regulations
- ISO – IEC standards for conformity assessment
 - ISO 17011
 - ISO 17065, 17021

Strengthening control systems



- Inter-American Commission on Organic Agriculture
 - Strengthening Control
 - Building internal markets
 - Technical support
- Certifier training
- Competent Authority training
- Audits, assessments, continuous improvement

Organic Integrity Around the World



Organic Workshop in Bern, Switzerland (U.S., Canada, European Union, South Korea, Japan, and Chile)





Mexico



Organic Trade with Mexico



- Trade of organic products with Mexico is significant and growing
- In 2015...
 - **U.S. exports** of selected organic products to Mexico totaled \$154 million.
 - **U.S. organic imports** from Mexico totaled \$141 million, led by coffee, avocados, and bananas.
 - Harmonized Trade Codes do not track many organic products.
 - Organic import and export values are undoubtedly much higher.
- Traded products are currently certified to the USDA organic regulations
 - NOP accredited certifiers operating in Mexico
 - NOP certified organic operations in Mexico (1635)

U.S. – Mexico negotiations



- Technical exchange of information –
 - SENASICA observe certifier audits
 - NOP observe apiculture, grower groups
- Peer review assessments
 - ISO 17011 criteria for competent authority (government)
 - ISO 17065 for control body (certifier)
- Negotiations –
 - Identify, discuss, resolve issues
 - Goal to reach mutual understanding and ensure confidence in respective control systems

Protecting Organic Integrity

Joint Organic Compliance Committee



Established by AMS Administrator Starmer and SENASICA Director Sanchez Cruz in October 2016

Primary Goals

- Strengthen compliance and enforcement
- Improve oversight and integrity of organic products

Key Activities

- Track complaints
- Monitor trends in non-compliances
- Training for certifiers
- Market surveillance residue testing
- Support certifiers working in high security risk areas
- **Implement the use of import certificates in both countries**



Import Certificates



Current requirements

- Codex Guidelines
- IFOAM
- EU – Certificate of Inspection
- NOP Import Certificate

Importance

- Verifies organic integrity of individual shipments
- Provides clear audit trail information to buyers and certifiers
- Provides organic inspectors with tools to verify compliance
- Provides AMS with ability to quickly trace organic products when residues or other issues are identified.



- **International Trade Page for Mexico**
<https://www.ams.usda.gov/services/organic-certification/international-trade-mexico>
- **Joint Organic Compliance Committee**
<https://www.ams.usda.gov/services/enforcement/organic/joint-committee>
- **NOP Handbook** (includes Import Certificate)
<https://www.ams.usda.gov/rules-regulations/organic/handbook>



Development

- First developed for U.S. – European Union Organic Equivalency Arrangement (2012)
- Required for all organic imports coming from the 23 EU member countries, Japan, South Korea, and Switzerland

Organic Imports from Mexico

- Implementation delayed until later this year
- Mexico plans to implement its requirement in May 2017

NOP Import 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

NOP IMPORT CERTIFICATE

A knowingly false entry or false alteration of any entry on this certificate may result in a fine of not more than \$11,000 or imprisonment for not more than five years or both (18 USC 1001).

1. CERTIFIED TO _____ ORGANIC STANDARDS

2. CITY AND STATE OF PRODUCT DESTINATION _____

3. DATE _____

4. IMPORT CERTIFICATE NUMBER _____

5. EXPORTED BY (NAME AND ADDRESS)

6. PRODUCT EXPORTED FROM

7. RECIPIENT IN THE U.S. (NAME AND ADDRESS)

8. CERTIFYING BODY ISSUING CERTIFICATE (NAME AND ADDRESS)

9. TOTAL NET WEIGHT _____

10. TOTAL CONTAINERS _____

11. PRODUCT AS LABELED	12. HARMONIZED TARIFF CODE AS APPLICABLE	13. SHIPPING IDENTIFICATION	14. FINAL HANDLER	15. CERTIFYING BODY OF FINAL HANDLER

16. REMARKS AND ATTESTATIONS

I CERTIFY that the agricultural products specified herein have been certified under an organic certification program that is at least equivalent to the requirements of the Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. Sec. 6501 et seq.) and are therefore deemed by USDA to have been produced and handled in accordance with the OFPA and USDA organic regulations under the National Organic Program 7 CFR part 205.

17. SIGNATURE OF CERTIFYING BODY _____

18. DATE _____

- Fillable form
- Form and instructions available online:
 - NOP Handbook
 - International trade web pages

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 Paperwork Reduction Act of 1995, 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 30 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.

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NOP 2110-1



When an NOP Import Certificate is requested, the certifier:

1. Confirms organic certification status of the handler and each organic product.
2. Completes information on the NOP Import Certificate.
3. Signs the certificate.
4. Provides the signed certificate to the certified operation.

US Certified Organic Handlers



- Certified organic handlers must have procedures in place to verify all organic products/ingredients received comply with USDA organic regulations.
- Implement processes to obtain an NOP import certificate for organic products as applicable (e.g. imports from EU, Japan, Korea, Switzerland)
- If procedures are not in place, or not being followed, then the certifier will take appropriate action to ensure compliance with NOP Import Certificate requirements.

An Organic Future



- Enhance organic control systems
- Provide support to farmers, handlers, and others interested in organic production and marketing
- Clarify and improve organic standards

Thank You

Organic Integrity from
Farm to Table,
Consumers Trust the
Organic Label

www.ams.usda.gov/nop

