

WESCCON Rancho Las Palmas

October 15, 2021

FDA ORA OEIO Resources:

[Fraudulent Coronavirus Disease 2019 \(COVID-19\) Products | FDA](#)

[Thai National Charged with Fraudulently Selling Unapproved Chloroquine Phosphate as A Treatment for Covid-19 | FDA](#)

[Why You Should Not Use Ivermectin to Treat or Prevent COVID-19 | FDA](#)

[Are There "FDA Registered" or "FDA Certified" Medical Devices? How Do I Know What Is FDA Approved? | FDA](#)

[Coronavirus \(COVID-19\) Update: FDA Reiterates Warning About Dangerous Alcohol-Based Hand Sanitizers Containing Methanol, Takes Additional Action to Address Concerning Products | FDA](#)

[Counterfeit Respirators / Misrepresentation of NIOSH-Approval | NPPTL | NIOSH | CDC](#)

[Buyer Beware: How to Avoid Scams & Misinformation during COVID-19 | Blogs | CDC](#)

[Fraudulent Coronavirus Disease 2019 \(COVID-19\) Products | Flickr](#)

For Questions-Contacts Information:

[Drug Related: FDA's Division of Drug Information at \(855\) 543-3784 or email: druginfo@fda.hhs.gov](#)

[Contacts for Medical Devices During the COVID-19 Pandemic | FDA](#)

[Reporting Unlawful Sales of Medical Products on the Internet | FDA](#)

[Importing COVID-19 Supplies | FDA: COVID19FDAIMPORTINQUIRIES@fda.hhs.gov](#)

Hand Sanitizer Resources:

[Hand Sanitizers | COVID-19 | FDA](#)

[Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency \(COVID-19\) \(fda.gov\)](#)

[How to Use the Hand Sanitizer List on FDA's Website](#)

Additional Resources:

[Vaccines and Related Biological Products Advisory Committee October 22, 2020 Meeting Presentation- COVID19 Vaccine Development- Portfolio \(fda.gov\)](#)

[COVID-19: An Update on the Federal Response - 09/23/2020 | FDA](#)

[Revoked EUAs for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators | FDA](#)

[Umbrella EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators \(FFRs\) \(Revoked effective July 6, 2021\)](#)

[FDA Reissues Emergency Use Authorization for Certain Non-NIOSH-Approved Filtering Face-Piece Respirators Manufactured in China | FDA](#)

[Infection Control: Severe acute respiratory syndrome coronavirus 2 \(SARS-CoV-2\) | CDC cdc_cough.pdf](#)

[FDA Response to the Fukushima Daiichi Nuclear Power Facility Incident](#)

FDA Unit	Contact Information	Areas of Focus
ACE Support Center	ACE_Support@fda.hhs.gov Toll Free: 877-345-1101 Local/International: 571-620-7320	Technical issues related to the FDA supplemental guide, required data elements, and general ACE submission questions, including entry submissions rejected by FDA.
FDA Imports Inquiry	FDAImportsInquiry@fda.hhs.gov 301-796-0356	General questions regarding FDA import operations and policy, including product classification (program, processing, product and HTS codes) and declaration
Local FDA Import Office	https://www.fda.gov/industry/import-program-food-and-drug-administration-fda/import-offices-and-ports-entry	First-line support for product coding and entry-specific questions, including working through the FDA entry admissibility process, once the entry is successfully transmitted to FDA and accepted
Division of Food Defense Targeting	Prior.Notice@fda.hhs.gov 866-521-2297 https://www.fda.gov/food/importing-food-products-united-states/prior-notice-imported-foods	General questions regarding Prior Notice for food shipments

USDA Agricultural Marketing Service (AMS)

Update from the National Organic Program for WESCCON PGA Session

Organic Import Certificates

Presented by

Jennifer Tucker, Ph.D.

Deputy Administrator, National Organic Program

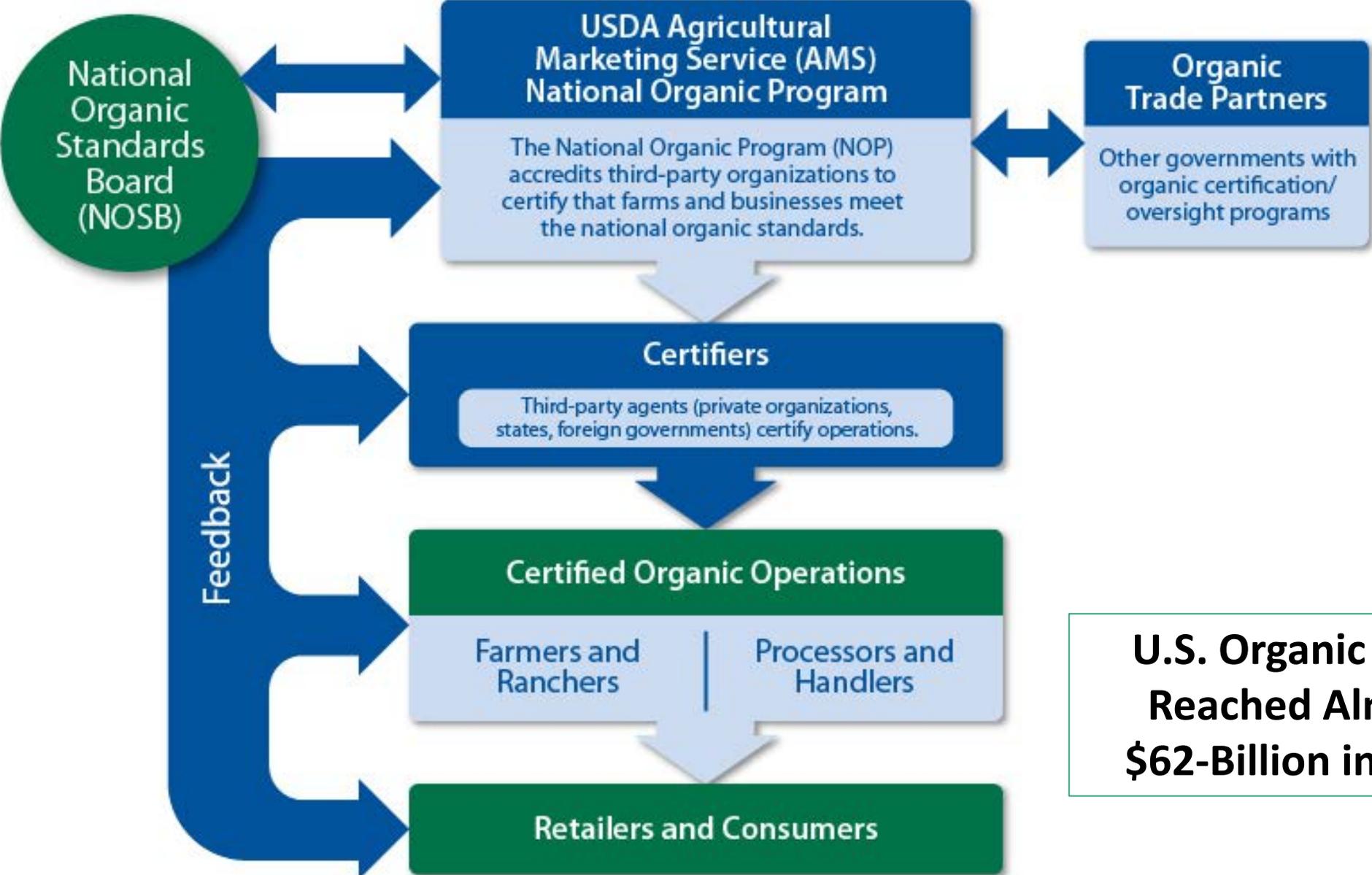
October 2021



The National Organic Program (NOP)

- **Mission:**
Protect the integrity of USDA organic products in the United States and 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

The Public-Private Partnership of Organic Certification and Oversight



U.S. Organic Sales Reached Almost \$62-Billion in 2020



National Organic Program Goals

- 1** **Strong Organic Control Systems**
Trusted People, Processes, and Rules
- 2** **Robust Enforcement**
Consistent and Fair Market for All
- 3** **Develop Standards**
Open, Transparent, Collaborative Processes
- 4** **Engage Partners and Stakeholders**
Advance Initiatives & Clarify Requirements

Inter-Agency Coordination to Oversee Organic Imports



- Launched Organic Import Certificate in Customs and Border Protection (CBP) Import System (ACE) (April 2020)
- NOP Staff in CBP Commercial Targeting and Analysis Center
- Completing Trademark Process for USDA Organic Seal
- New Data Technology Projects
 - Import Certificate Generator
 - Data Visualization
 - Automation of Data Checks to Align Certificates and CBP Data

Recent Enforcement Successes: Import Oversight



Uncertified Imports from India

- CBP data on imports used to learn about feed imports from India.
- We compared data with business records required under USDA organic regulations.
- Analysis led to the identification of two exporters shipping to U.S. without organic certification
- Led to large civil penalty and increased monitoring data from importer.

Illegally Labeled Olive Oil

- Suspended organic operation continued to ship olive oil labeled as organic to U.S.
- CBP processes and authorities used to deny entry into U.S.
- Involved collaboration of CBP, Ports, and USDA

Policy: Strengthening Organic Enforcement Rule



**Transforming the organic regulations to meet market needs:
Increasing accountability and visibility**

Fewer Exemptions

Increase
Handler
Certifications

Import Certificates

Electronic
Certificates for
all Imports

Enhanced Oversight

Strengthen
Accreditation
and Certification
Oversight

Strengthening Organic Enforcement Status



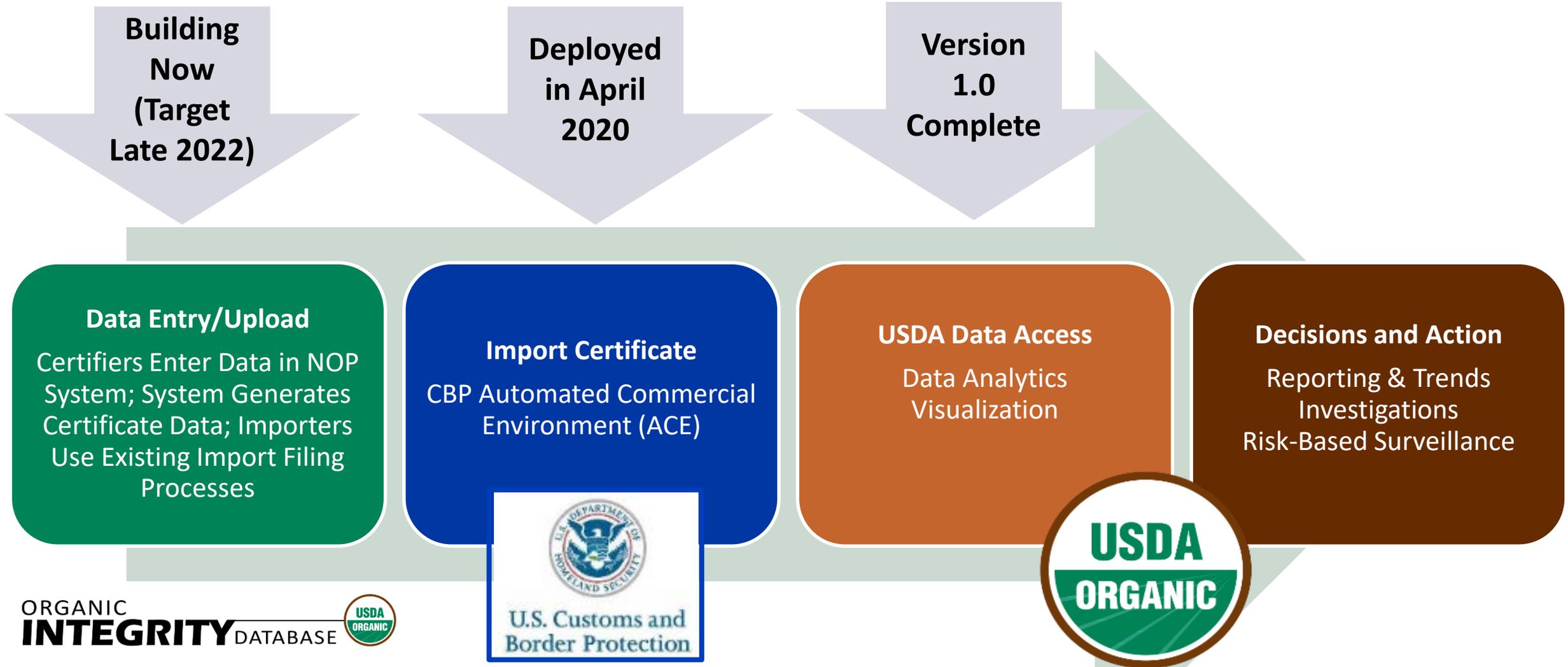
More Information: <https://www.ams.usda.gov/rules-regulations/strengthening-organic-enforcement-proposed-rule>

Electronic Organic Import Certificates

- New electronic oversight tool and process for USDA National Organic Program
- Responds to increasing complexity and length of organic supply chains
- Supports organic integrity by combatting fraud and increasing the traceability of organic products
- Supports organic enforcement to protect the USDA organic seal

Electronic organic import certificates will provide critical organic import data, improving oversight of organic imports

Technology: Import Certificates “To Be”



Key Stakeholders and Actions



Organic INTEGRITY Database: Lists Certified Operations
TO BE: Certifier Generates Import Certificate Data

Organic Certifiers Provide Certificate/Data TO
Final Certified Exporter (Shipment, Monthly, Seasonal)

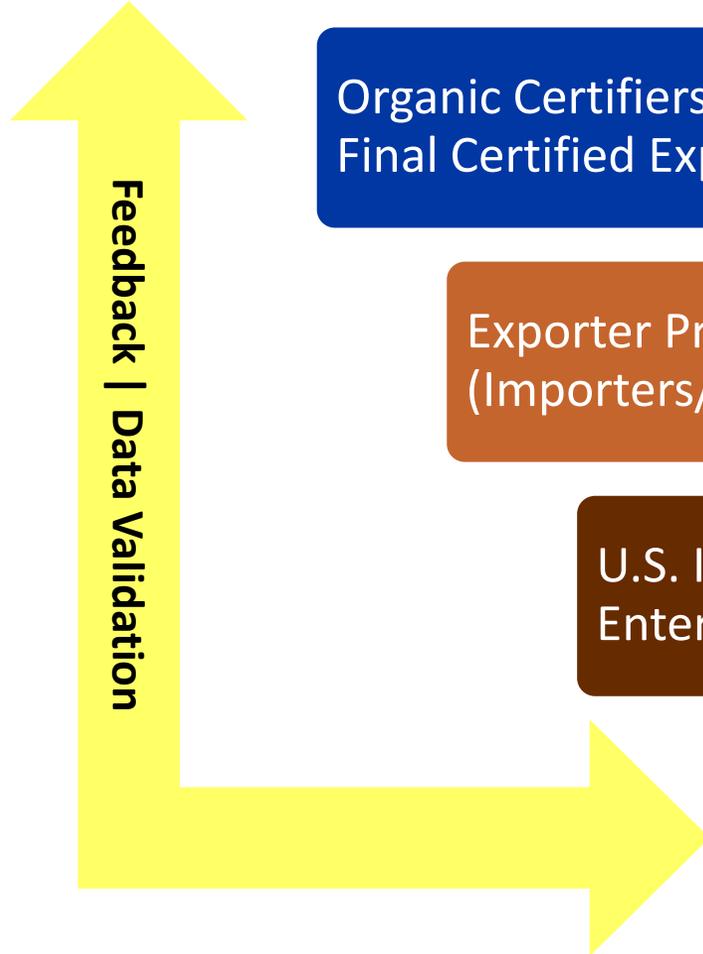
Exporter Provides Certificate/Data to Trade Filers
(Importers/Brokers)

U.S. Importers / Customs Brokers File Entries in ACE:
Enter Organic Import Certificate Number



USDA Receives ACE Data |
Validates Against Approved INTEGRITY Certificates

Feedback | Data Validation



Questions?

National Organic Program

Mission:

Protect the integrity of USDA organic products in the United States and throughout the world

Vision:

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



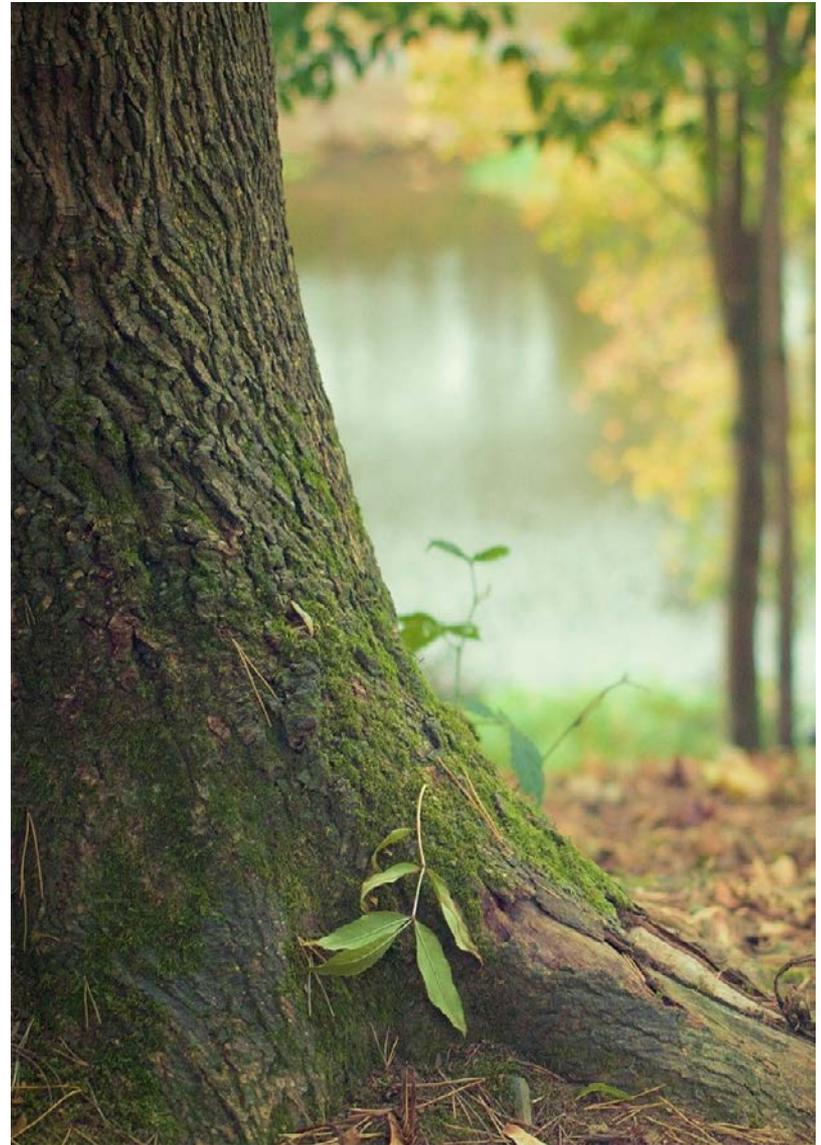


**Animal and Plant Health
Inspection Service**

Plant Protection and Quarantine

**Bob Baca
Lacey Act Program**

October 2021





Topics



Lacey Act Overview



Phase Six Products



The Path Ahead



Lacey Act Overview



Deforestation

Company Name		
Profit and Loss Statement		
Years Ending: _____		
Revenue	2016	2015
Sales revenue	\$ 150,000	\$ 175,000
(Ditto sales returns and allowances)		
Service revenue	\$ 50,500	\$ 75,000
Interest revenue		
Other revenue		
Total Revenues	\$ 200,500	\$ 250,000

Revenue Loss



Greenhouse Gas Emissions



Loss of Biodiversity



Corruption and Violence



The Cost of Transnational Crime

Transnational Crime	Estimated Annual Value (US\$)
Counterfeiting	\$923 billion - \$1.13 trillion
Drug Trafficking	\$426 - \$652 billion
Human Trafficking	\$150 billion
Illegal Logging	\$52 - \$157 billion
Illegal Fishing	\$15 - \$36 billion
Illegal Mining	\$12 - \$48 billion
Crude Oil Theft	\$5 - \$12 billion

“Transnational crime will continue to grow until the paradigm of high profits and low risks is challenged.”



Lacey Act Declaration

Declarations must include:

- Importer information
- Scientific names of plants
- Country of harvest
- Quantity of plant material

Everything is driven by HTS
(Harmonized Tariff Schedule)
codes

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 0570-0349. The time required to complete this information collection is estimated to average 0.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0570-0349
EXP. 04/2022



UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
PLANT PROTECTION AND QUARANTINE

PLANT AND PLANT PRODUCT DECLARATION

SECTION 1 – Shipment Information

1. ESTIMATED DATE OF ARRIVAL (MM/DD/YYYY)	2. ENTRY NUMBER
3. CONTAINER NUMBER(S) <input type="checkbox"/> See Attachment	4. BILL OF LADING
6. IMPORTER'S NAME	5. MANUFACTURER IDENTIFICATION CODE (MIC)
8. IMPORTER'S ADDRESS	7. CONSIGNEE'S NAME
9. CONSIGNEE'S ADDRESS	
10. DESCRIPTION OF MERCHANDISE	

SECTION 2 – Compliance with Lacey Act Requirements (16 U.S.C. 3372(f))

For each article or component of an article, provide the following:

11. HTS NUMBER <small>(no dashes/symbols)</small>	12. ENTERED VALUE	13. ARTICLE/COMPONENT OF ARTICLE	14. PLANT SCIENTIFIC NAME <small>Genus Species</small>	15. COUNTRY OF HARVEST	16. QUANTITY OF PLANT MATERIAL	17. UNIT	18. PERCENT RECYCLED

I certify under penalty that, to the best of my knowledge and belief, the information furnished is true and correct.

<small>PREPARED BY (printed)</small>	<small>PREPARED BY (signature)</small>	<small>EMAIL ADDRESS</small>	<small>TELEPHONE NUMBER</small>	<small>DATE (MM/DD/YYYY)</small>
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PPQ FORM 505
MAR 2019

(NOTE: Knowingly making any false statement in this Declaration for importation may subject the declarant to criminal penalties in accordance with 16 U.S.C. 3373(d).)

(Previous editions are obsolete.)



Lacey Act Implementation Schedule

- Since 2009, five phases of products were listed that require a Lacey Act import declaration



- On October 1, 2021, Phase 6 became effective



Phase Six Products

Chapter 42

Various trunks, cases, suitcases of wood



Chapter 92

Several musical instruments and parts



Chapter 96

Monopods, bipods, tripods, and similar articles



Phase Six Products

Chapter 33

Various essential oils

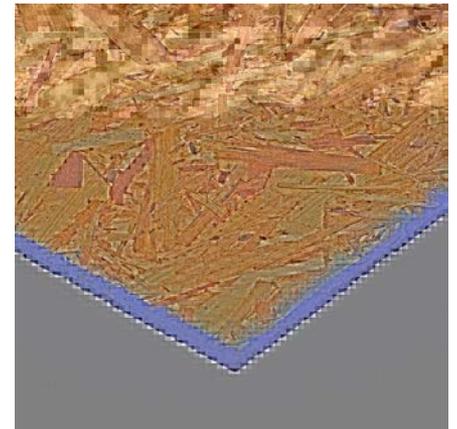
Does not include essential oils of “other”



Chapter 44

Oriented strand board (OSB)

Cases, boxes, crates, drums, containers, pallets





Phase Six Products

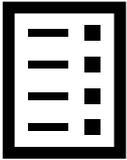
Chapter 4415

- Does not include pallets and crates that are carrying products in commerce.
- Does not include used, repaired, recycled or reclaimed products.
- Only new products, making formal entry, will require a declaration

All products in the tariff codes listed in Phase Six require a declaration as of October 1, 2021.



The Path Ahead



Outreach and Guidance



Letters of Non-compliance
& Wood Identification



Products Requiring a Declaration



USDA, APHIS

Lacey Act Program

Lacey.Act.Declaration@usda.gov



*Promoting responsible harvest to save the
world's forests*



FWS ACE Updates

OCTOBER 15, 2021

RHYAN TOMPKINS (ACE COORDINATOR)

FWS ACE Mandatory filing date

Current Extended Pilot Phase

- CERT and PROD environments are Open to all ACE Filers at all FWS authorized ports
- FWS HTS Flags enforced with a “warning” severity

SE90 Message Type Code: 13 Message Identifier Code: PU2 Narrative Message Text: PGA DATA MSNG FOR HTS - NO ACTION REQ

Tentative Mandatory Date: TBD

- Filers using ACE must enter FWS data (or disclaim)
- Filers will always have the option to file via eDecs

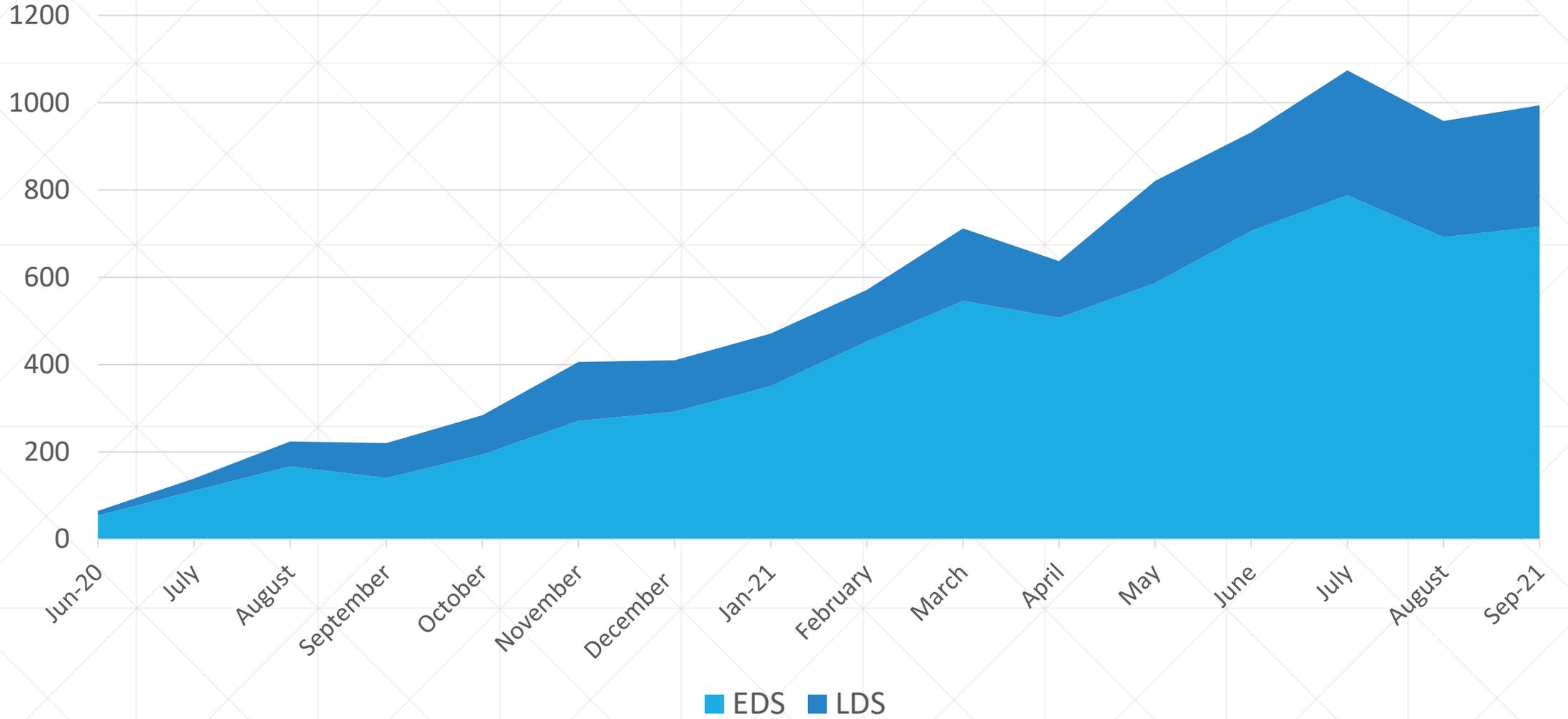


Status of FWS ACE Filings

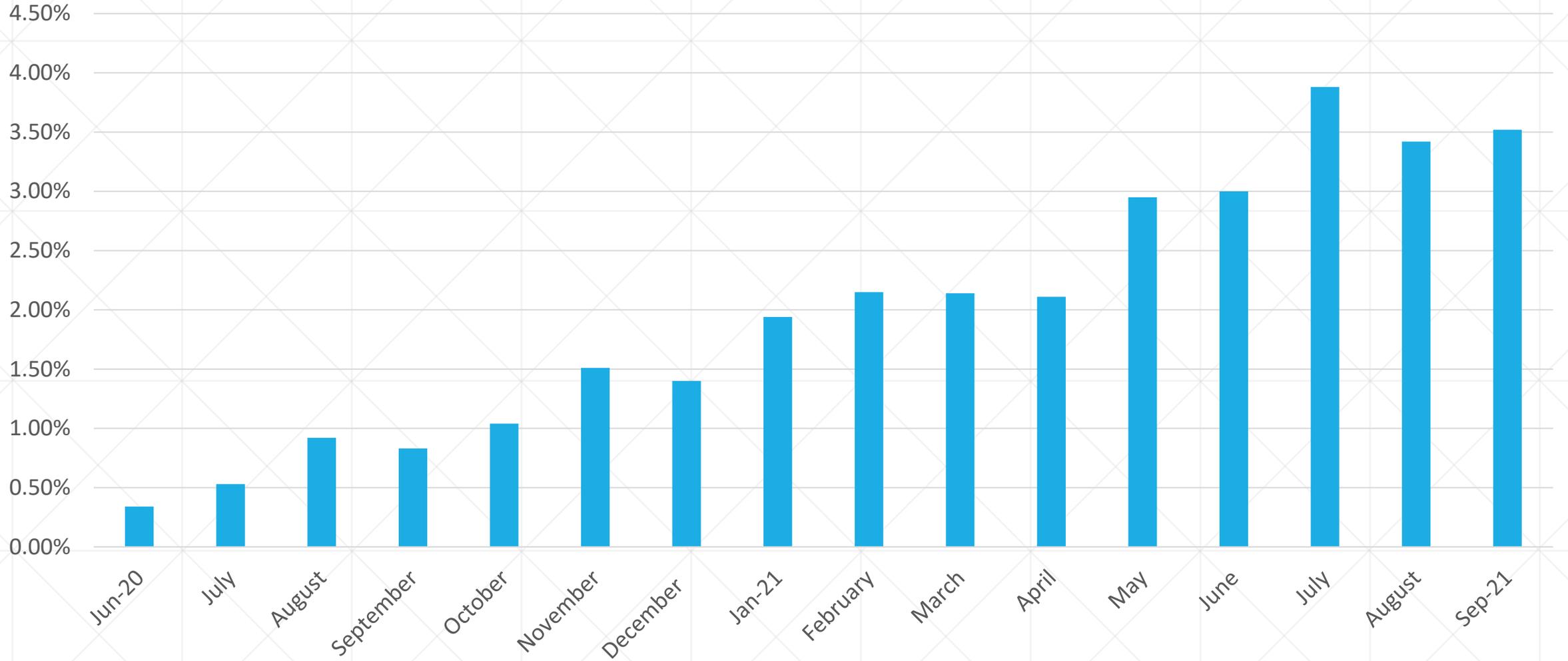
- Over 10,000 ACE entries processed
- Over 120 separate filers
- Current filings
 - 60% EDS
 - 40% LDS



FWS ACE Entries EDS vs. LDS



Percentage of ACE Entries per Total FWS Declared Imports



fwsole_ace_support@fws.gov

Additional Resources

[FWS' Import/Export webpage](#) or email lawenforcement@fws.gov for general FWS requirements and import/export questions.

FWS Implementation Guide: <https://www.cbp.gov/document/guidance/us-fish-and-wildlife-service-ace-requirements>

FWS Message Set Samples: <https://www.cbp.gov/document/guidance/ace-fws-message-set-samples>

FWS Tips for Trade: <https://www.cbp.gov/document/publications/ace-tips-trade-when-filing-us-fish-and-wildlife-service-data>

Contact fwsole_ace_support@fws.gov with any questions regarding the ACE FWS Message Set

A FWS ACE webpage is in development to provide further guidance.

