

Border Interagency Executive Council

External Engagement Committee FDA Single Window Progress Webinar

Date: Tuesday, March 24, 2015
Time: 2:00 p.m. – 3:00 p.m.
Link: <https://dhs.adobeconnect.com/biecpga/>
Phone: 877-873-8017, code 7414370



Time	Topic	Presenter
02:00 pm	Welcome and introductions:	Bruce Harsh, Department of Commerce Maria Luisa Boyce, CBP
02:05 pm	Overview of the PGA/FDA Single Window process:	Elizabeth McQueen, ACE Business Office CBP
02:15 pm	Food and Drug Administration (FDA)	Capt. Domenic Veneziano, FDA
02:35pm	Questions and answers:	Audience

Webinar Etiquette

- If using a phone to listen, please mute it
- Please do not put your phone on hold
- Questions will be answered at the end of the presentation
- Type your questions into the Q & A section
- If we are unable to get to all of the questions, answers will be provided at a later date

Thank You



Border Interagency Executive Council
External Engagement Committee PGA Pilot Webinar

Single Window and the Automated Commercial Environment (ACE)

Partner Government Agency (PGA) Onboarding



Elizabeth McQueen
Branch Chief, International Trade Data System (ITDS)

March 24, 2014



U.S. Customs and
Border Protection

AUTOMATED COMMERCIAL ENVIRONMENT/INTERNATIONAL TRADE DATA SYSTEM U.S. SINGLE WINDOW FOR TRADE



INTERNATIONAL TRADE

- In FY2013, U.S. trade accounted for \$2.4 trillion in imported goods and \$1.6 trillion in exported goods

ACE / ITDS

- Executive Order establishes deadline of December 2016 for implementation
- ACE is the technology enabler through which Single Window processing will be achieved
- Key features to enable Single Window processing have been implemented

PARTNER GOVERNMENT AGENCIES

- 47 Partner Government Agencies
- Largely paper-based with multiple entry systems
- Nearly 200 forms required for imports and exports



Quicker data availability for Government - better identification of dangerous or prohibited shipments



Automated Agency interactions reduce paper, enable near-real time decision making by Government



Easier for industry to comply with government regulations



Reduced costs for Government and industry

Mandatory Dates for Transition to ACE

Date	Mandatory Requirement	Time Remaining
May 1, 2015	Mandatory use of ACE for electronic import and export manifest	1 week
November 1, 2015	Mandatory use of ACE for electronic Cargo Release and related Entry Summary filings	7 months
October 1, 2016	Mandatory use of ACE for all remaining portions of the CBP cargo process	20 months



Implementing the Single Window

Three enablers provide the means for Partner Government Agencies (PGAs) to participate in ACE

- **Partner Government Agency (PGA) Message Set** - Establishes a single, harmonized set of information to be collected electronically from international traders by CBP on behalf of PGAs
- **Document Image System (DIS)** - Allows trade members to supply images of needed documents electronically during the cargo import and export processes
- **Interoperability Web Services** - Provides a system-to-system pipeline for data transfer between CBP and PGAs

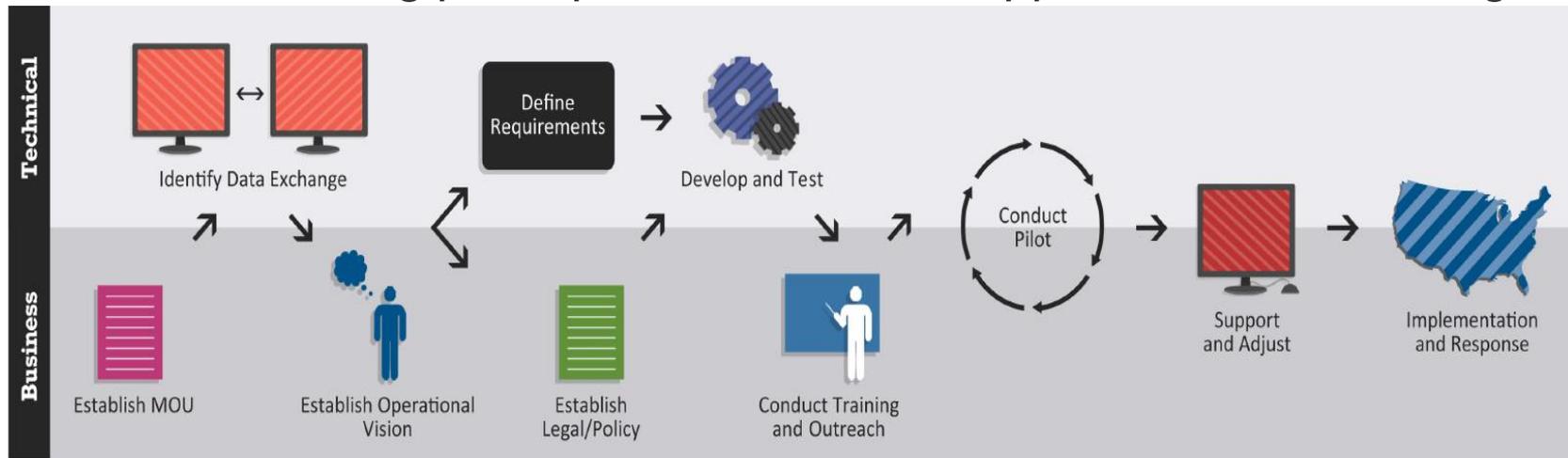
The ACE portal provides PGAs with a graphical user interface (GUI) to view the data in ACE, search on that data and run reports. The ACE portal is a consistent interface across PGAs that differs only by their particular information and processing needs.



Process for ITDS Implementation

All PGAs are onboarding to ITDS according to their data needs and authority:

- PGAs define their specific to-be process, and CBP determines the milestones necessary to onboard them to ACE
- Both sides enter into MOU agreements and develop interfaces
- Onboarding plans provide a uniform approach to onboarding



PGA Onboarding Process



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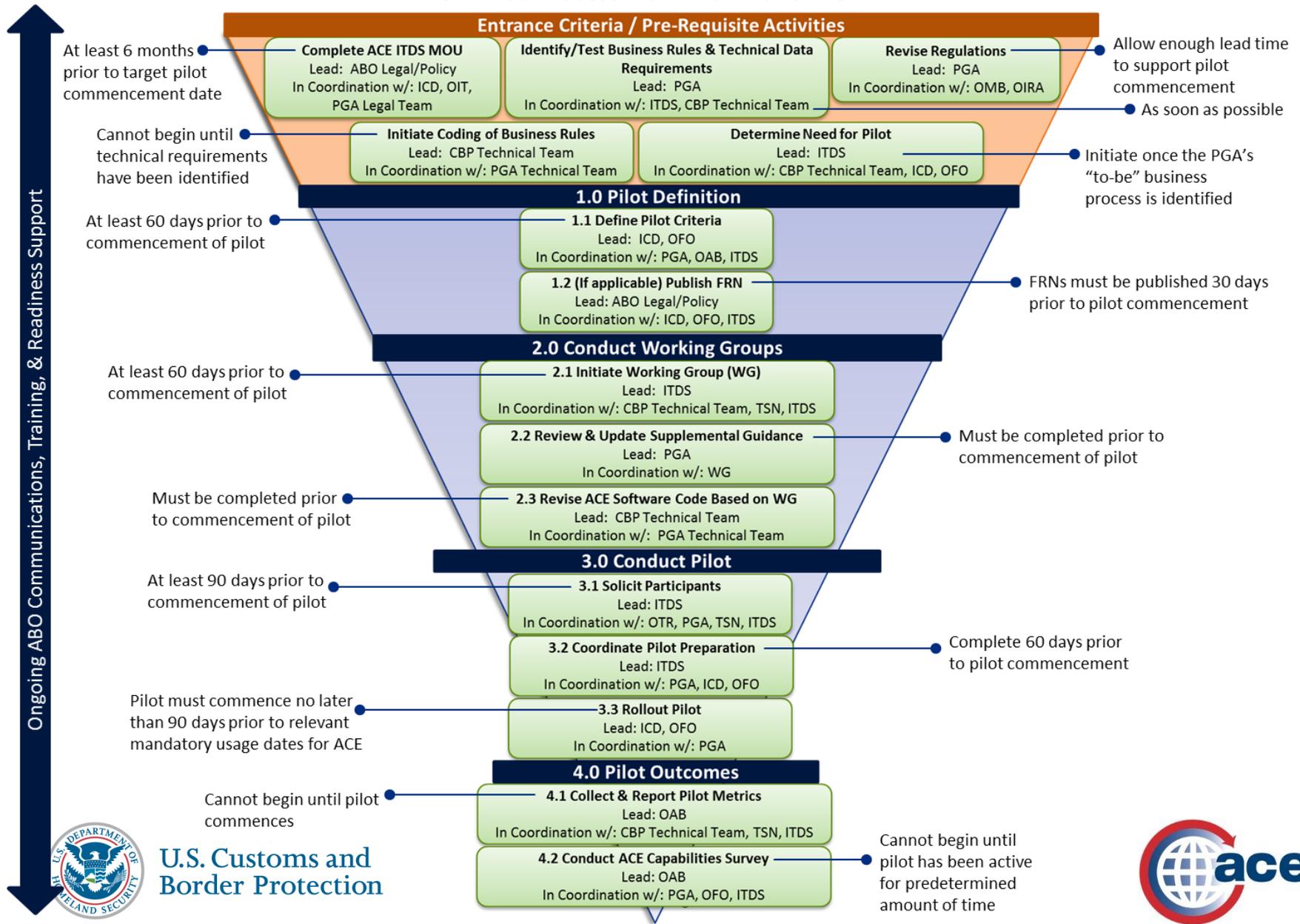
PGAs' Onboarding Plans

Each PGA's *Onboarding Plan* document will establish:

- The PGA's decisions regarding its intended use of ACE enablers:
 - Use of **PGA Message Set, Document Imaging System (DIS), or a combination** for data and document inputs.
 - Use of Interoperability Web Service (**IWS**) or **ACE portal** for data access.
 - Selection of **ACE behavior related to events**.
- Any need for a PGA to revise existing, or enact new *policies or regulations*.
- The PGA's plans to **coordinate and communicate with trade customers and vendors**, including providing training.
- Communication channels and Points of Contact (POCs) for the PGA to communicate with CBP's technical and business teams.
- PGA's plans to engage in **pilot** – or a small scale operation of the PGA's ITDS solution – to test and fully understand systematic / operational impacts



PGA Pilot Process Flow



U.S. Customs and Border Protection





BIEC External Engagement Committee

PGA Single Window Progress Update Food and Drug Administration

CAPT. Domenic J. Veneziano
U.S. Public Health Service
Director, Division of Import Operations
March 24, 2015

Division of Import Operations



- **Border Interagency Executive Council**
- **FDA Current Operational Process**
- **Changes being made and Status**



Executive Order / BIEC



- **Executive Order 13659**, *Streamlining the Export/Import Process for America's Businesses*. It had three main components;
 1. Implementing ACE/ITDS,
 2. Establishment of the Border Interagency Executive Council (BIEC),
 3. To identify regulations that need to be changed to ensure its success.

- the **BIEC's objective** is to develop policies and processes to:
 1. enhance coordination across agencies that approves the importation and exportation of goods,
 2. to enhance communication with the trade,
 3. to measurably improve supply chain processes and improve identification of illicit shipments;
 4. consult on policies and processes with the International Trade Data System (ITDS) Board of Directors; and
 5. provide to the President a report on the implementation of the duties of the BIEC on July 1, 2014 and every year thereafter until July 2016.

- **Risk Management Committee** is chaired by FDA. Its purpose is to develop common risk management principles and methods to inform agency operations associated with the review and release of cargo at the border and encourage compliance with applicable laws..



- **The Process Coordination Committee** is chaired by U.S. Customs and Border Protection (CBP). It is responsible for developing common process coordination principles and methods associated with the disposition of cargo at the border and enhance compliance with applicable laws, to streamline, harmonize and improve coordination associated with the import or export of cargo where feasible and appropriate
- The BIEC charged both the Risk Management Committee and the Process Coordination Committee with developing principle documents that will inform efforts to streamline and coordinate agency operations related to import and exports.
 1. The two principle document were completed and approved by the BIEC on September 16, 2014.
 2. The two sub-committees have now been combined to look at how the principle document can be implemented. Six specific areas have been identified: data quality, targeting, holding shipments, releasing shipments, enforcement, and deconfliction.



Table-top exercises for export and import processes:



- On October 30, 2014, the Process Coordination Committee and the Risk Management Committee conducted two table top exercises for the BIEC that walked through the importation process of two separate products with multiple agency jurisdictions. The purpose of the exercise was to identify pain points and create a discussion of ways to streamline trade processes, facilitate lawful and compliant trade, and enhance compliance and enforcement efforts.
- The two exercises identified six pain points, which needed to be evaluated. They include the need to:
 1. explore timely access to import data,
 2. the potential utilization of unique facility and entity identifiers,
 3. the pivotal role of data quality and validation,
 4. transparency on agencies targeting rules,
 5. enhanced communication on hold and release decision both to agencies and the trade,
 6. and transparency between agencies on final disposition and enforcement actions.
- These “Pain Points” have been evaluated and proposed solutions identified and currently in process



- **The External Engagement Committee**, chaired by the Department of Commerce (DOC), was formed to develop a list of all relevant FACA committees and other relevant stakeholders; identify benchmarks for effectiveness with stakeholders; coordinate with existing interagency import/export administration initiatives; work with the BIEC members and the ITDS Board to make publicly available a timeline outlining the development and delivery of the ITDS capabilities, agency implementation plans, and schedules; and maintain an outreach calendar, talking points, and frequently asked questions.
- The committee is actively working on six categories identified as priorities:
 1. **pilot programs;**
 2. **creation of a website;**
 3. **improved coordination of ITDS engagement with the ITDS Board of Directors and the Automated Commercial Environment Support Office;**
 4. **industry engagement;**
 5. **Congressional engagement; and**
 6. **international engagement.**



FDA Current Import Process



- The FDA has been receiving real time import admissibility data from CBP (ACS) since 1998. Since recently we were the only agency to do so.
- A filer/broker must file an entry and an entry bond with Customs pending a decision to allow the goods into the U.S.
- Based on the HTS the entry is sent to FDA for an admissibility decision
- Investigators evaluate the admissibility of a product electronically
- Entry reviewers have several options:
 - ✓ Release the product
 - ✓ Request examination of the product
 - ✓ Request additional information or documents
 - ✓ Recommend detention of the product
- The decision is sent back through CBP to the filer/broker by FDA and FDA Notice of actions are mailed to the IOR, Filer, and Consignee



Data Quality

Additional Information



➔ **Additional Entry Data** (above what is required for CBP)

- ✓ FDA Country of Origin
- ✓ Name and address of Manufacturer
- ✓ Name and address of Shipper
- ✓ FDA Product Code

➔ **Food products require additional information (AofC):**

- ✓ Low-Acid Canned Foods (LACF)
 - (FCE) Food Canning Establishment Number
 - Approved Scheduled Process Submission ID (SID#) and container dimensions
- ✓ Acidified Foods (AF)

Process for adequate acidification

✓ **Medical products require additional information (AofC):**

✓ Human Drugs

- Drug Registration Number
- Drug Listing Number
- Investigational New Drug Application Number (IND)
- New Drug Application Number (NDA)
- Abbreviated New Drug Application Number (ANDA)

✓ Animal Drugs

- New Animal Drug Application Number (NADA)
- Abbreviated New Animal Drug Application Number (ANADA)

✓ Biological Products

- Manufacturer's US Biologics License Number
- Product Biologics License Application Number or "Submission Tracking Number" 17



Medical Products



✓ Medical Devices

- Device Registration Number
- Device Listing Number
- Device Pre-market Approval Number (PMA)
- Device Pre-Market Notification Number (510(k))
- Investigational Device Exemption Number (IDE)
- Humanitarian Device Exemption Number (HDE)

✓ Radiological Health Products – Electronic Non-Medical

- Radiological Health Product Declaration
- Model Number
- RCHSA Accession Number



Key Dates for ACE Transition

Deployment of Key ACE Capabilities

January 2015

Electronic import manifest for air and export manifest for air/ocean/rail

July 2015

All entry types delivered

July 2016

All remaining core trade processing capabilities delivered

ACE Mandatory Dates

May 1, 2015

ACE mandatory for all electronic manifest filing

Less than 3 months away

November 1, 2015

ACE mandatory for all electronic cargo release and related entry summary filing

Less than 9 months away

October 1, 2016

ACE mandatory for all remaining electronic portions of the CBP

argo process **20 months away**

1. ACE/ITDS – FDA Implementation

- a. System Development and Implementation
 - i. **IWS** launched in August 2014 and is on-going (We do have Connection)
 - ii. **PG Message Set** (data elements, Supplemental Guide, Business Rules) (**complete**)
 - iii. **DIS (on-going)**
 - iv. User Case Testing
 - v. CBP/FDA Test Plan January/March 2015
 - vi. **FDA Pilot Tests** July 2015 **TESTERS - Volunteers**
- b. Internal Outreach Activity
 - a. Currently on-going and will continue: Field staff and HQ
- c. External Outreach Activity
 - a. On-Going and will continue with the external communication committee of the BIEC
 - b. Webinars
- d. Administrative and Legal Requirements
 - a. FRNs
 - b. MOUs

Questions?



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