ACE Presentation for Industry

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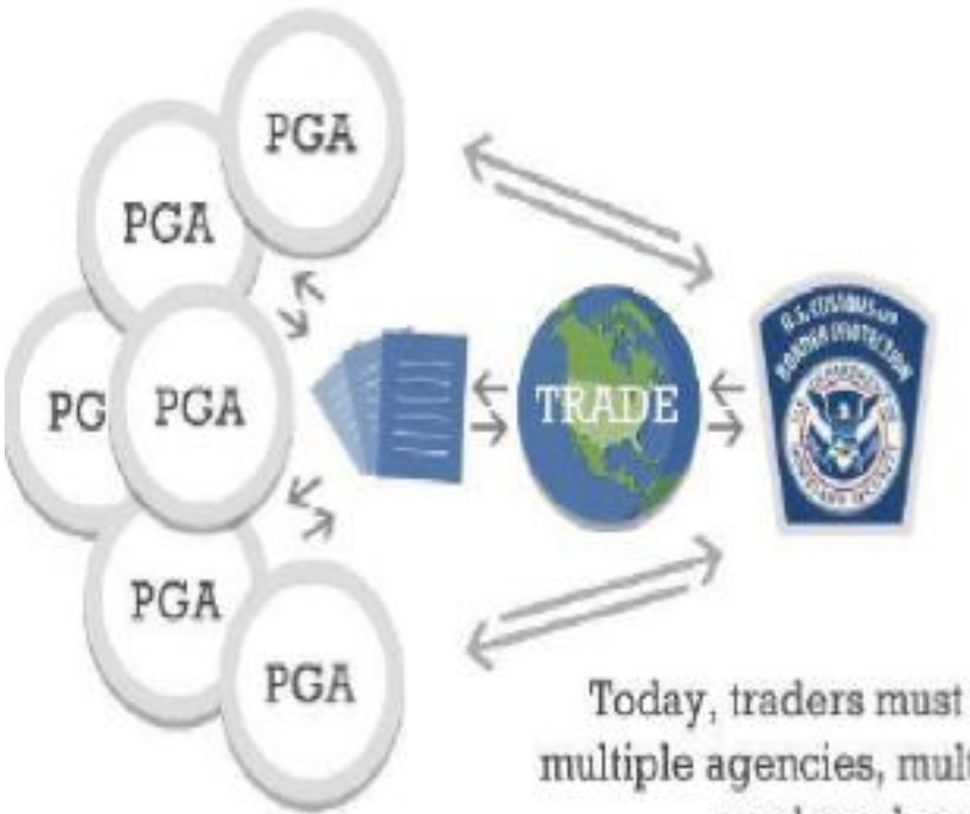
What is ACE/ITDS?

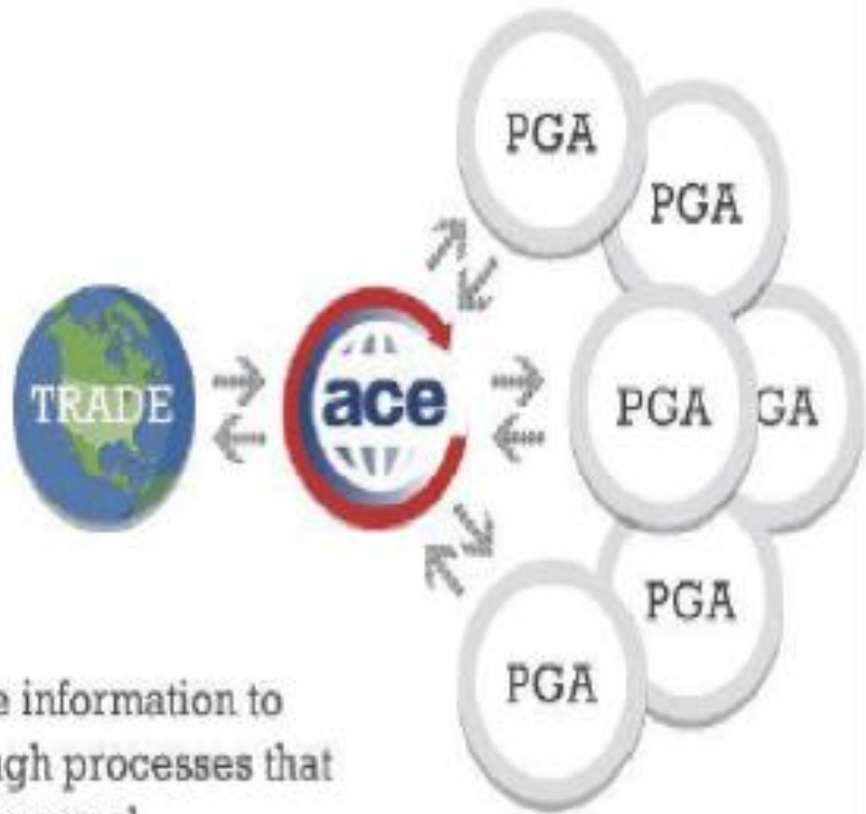
The Automated Commercial Environment/ International Trade Data System is a single access point in which industry can electronically submit information for all government agencies involved in international trade.

What is ACE/ITDS?

CURRENT FLOW OF INFORMATION



SINGLE WINDOW VISION



Today, traders must submit the same information to multiple agencies, multiple times through processes that are largely paper-based and manual.

THE SINGLE WINDOW WILL STREAMLINE THIS PROCESS.

Executive Order -- Streamlining the Export/Import Process for America's Businesses

"…reduce supply chain barriers to commerce while continuing to protect our national security, public health…"

"…the Federal Government must increase efforts to improve the technologies, policies, and other controls governing the movement of goods across our national borders…"

"…by December 31, 2016, participating agencies shall have capabilities, agreements, and other requirements in place to utilize the ITDS and supporting systems, such as the Automated Commercial Environment…"

https://www.whitehouse.gov/the-press-office/2014/02/19

ACE/ITDS

The new interface will:

- improve communication, allow FDA and other agencies to obtain data (and respond) quickly,
- process cargo more expeditiously
- enhance risk management and targeting procedures.

ACE/ITDS will mutually benefit FDA and the trade community through improved processes for submitting import data that reduce:

- costs
- the need for paper forms,
- and turnaround times.

What does ACE/ITDS mean to me?

Before cargo arrives at the border:

A single, harmonized data set is collected electronically by CBP, on behalf of all PGAs, utilizing the single window reduces duplication of efforts for the filer.

Early validation and rejection of entry filings that do not meet the PGA business rules:

Allow more time for correction of any issues.

Result in better data quality and shorter overall initial admissibility decision times for the FDA.

(Future FDA Integration) currently done via ITAS

FDA will incorporate the Document Imaging System (DIS).

Trade will have a secure data portal to electronically upload documentation for all PGAs as part of the cargo release process.

How Does ACE Change Current Business Processes?

- All entry information for all partner government agencies (PGAs) is submitted in ACE; messages from each agency are sent back to the filer
- FDA will require complete data sets at the time of transmission of the entry
- Complete and correct information will reduce the need for document requests, and improve processing times

General ACE Process, Part 1

- Importer/Filer provides entry data: [FDA]PGA Message Set sent via ACE for FDA-regulated products at the time of entry.
- Entry screened against FDA syntax business rules in ACE:
  - For filings that do not pass FDA syntax business rules, ACE will send entry filing back to filer. ACE will then provide a message to the filer on what is needed for that entry submission (e.g., specific data in the filing needs to corrected).

General ACE Process, Part 2

- Entry sent to FDA for targeting and technical validations:
  - Once a filing passes CBP syntax business rules, the entry will be forwarded to the FDA for cargo admissibility processing and FDA will provide cargo disposition messages to CBP (i.e. ‘may proceed)’ unless FDA has specific reasons to take a look at the filing/shipment.
- FDA and CBP will continue to operate as they do today at the ports of entry, with minimal change to day-to-day operations for this phase of ACE.

FDA ACE Process

Industry	CBP	FDA

1 Filer accesses ACE through the Automated Broker Interface, submits PGA Message Set to CBP

2 CBP conducts a syntax validation to ensure all mandatory data is populated; if PGA Message Set is complete, CBP will send to FDA for further processing. Entries with missing data will prompt an error message back to the filer.

3 Data is stored in & processed by OASIS, screened by PREDICT

4 FDA generates a cargo disposition message and sends to CBP*

5 CBP sends the message back to the filer

*Data that is electronically validated may be automatically "May Proceeded" dependent on risk ranking

When is ACE mandatory?

CSMS 16-000093: Updated ACE Transition Guidance

"FDA filings will continue to be allowed in ACS to provide more time for industry to transition to ACE. Further information will be provided on the mandatory filing in ACE for FDA data"

CBP and FDA are highly encouraging ACE filings and have prioritized resources to support ACE entries since March, 2016.

Current Status

- FDA began processing ACE entries in August 2015 within limited parameters; however, participation is currently open to all ports and all product types.
- 90K entries processed to date.
- Facilitating onboarding of first-time ACE filers each day.

How to Start Filing in ACE

- Get to know FDA's Requirements for importing in ACE (FDA Supplemental Guide)
- Contact your software developer & work with him/her to understand changes to your software
- Keep your ABI Client Representative informed
- To start filing in ACE for FDA, contact: ACE_Support@fda.hhs.gov

Tips for Importing Drug Products

Expedite FDA's Processing by Providing:

- Correct Product Code and Intended Use Code
- Active Ingredient Name and Dosage
- Brand Name
- Name, Address (and DUNS# if known) for:
    - Manufacturer, Shipper, Importer, Delivered To Party, and API Producer
- Affirmations of Compliance: (required based on Intended Use)
    - REG (Drug Registration)
    - DLS (Drug Listing)
    - DA (Drug Application Number)
    - IND (Investigational New drug)

Tips for Importing Medical Devices

Expedite FDA's Processing by Providing:

- Correct Product Code, Intended Use, Brand Name
- Name, Address and FEI for:
    - Manufacturer, Shipper, Importer, Delivered To Party, and Device Initial Importer (DII is no longer an AofC)
- Affirmations of Compliance: (required based on Intended Use)
    - DEV (Device Registration)
    - DFE (Device Foreign Exporter Registration)
    - LST (Device Listing Number)
    - PM# (Premarket Number - formerly PMA/PMN – if applicable)

Tips for Importing Food Products with Prior Notice

Expedite FDA's Processing by Providing:

- Correct Product Code
- Country of Production/Growth AND Country of Shipment
- Name, Address (and DUNS# if known) for:
    - Manufacturer/Grower/Consolidator, Shipper, Importer, Ultimate Consignee, PN Submitter, PN Transmitter, Owner
- Affirmations of Compliance: (required based on product/Mode Of Transportation)
    - PFR or FME (Food Facility Registration or Exemption with Reason Code)
    - VFT (Voyage, Flight, Trip Number)
    - VES (Vessel Name)
- Container Number

New Prior Notice Functionality

- Ability to file the Secure Holding Facility under trade entity “Location of Goods”
- Ability to file registration number for any trade entity to facilitate review and release of the shipment
- Ability to file contact information for each trade entity to facilitate review and release of the shipment
- Ability to file prior notice utilizing carrier name and license plate information for informal shipments
- Ability to file prior notice utilizing a Express Courier tracking number for informal shipments

Tips for Importing FDA-Regulated Products in ACE

FDA Division of Compliance Systems 2016

Diagram depicts mandatory data elements by commodity-type. For certain products, additional data elements may apply. Refer to FDA's Supplemental Guide for further specificity For more information email: ACE_Support@fda.hhs.gov

Drugs:

Intended Use Code*

Active Ingredient Name(s) & Dosage

Brand Name

Name & Address of API Producer(s), Sponsor (if applicable)

Affirmations of Compliance*

Medical Devices & Radiation-Emitting Products:

Intended Use Code

Brand Name (if available)

Name and Address of Device Initial Importer (medical devices only)

Affirmations of Compliance*

Required Data Elements for all FDA Products:

Commodity & Subtype

Product Code

Country of Production or Source

Invoice Description

Names & Addresses of Manufacturer, Shipper, Importer, Delivered To Party

Entry Point of Contact

Quantity , Packaging , Line Value

Arrival Date & Time

Biologics:

Intended Use Code

Brand or Proper Name (except for cells and tissues)

Affirmations of Compliance*

Animal Drugs & Devices:

Active Ingredient Name(s) & Dosage (drugs only)

Brand Name

Affirmations of Compliance*

Food Products requiring Prior Notice:

Country of Shipment; Place of Growth (if applicable)

Names and Addresses of PN Transmitter, Submitter, Owner, Ultimate Consignee;(in lieu of DP) Grower or Consolidator if Applicable

Contact Information for Transmitter & Submitter

Container Number

Affirmations of Compliance*

Port of Arrival

Tobacco:

Intended Use Code

Submitter

Affirmations of Compliance*

**DUNS or FEI numbers are not mandatory but are highly encouraged and may expedite processing.

*Affirmations of Compliance are mandatory in some instances but are not required for all scenarios. Cosmetics and food contact surfaces do not require any additional data elements other than those listed in the center of the diagram.

Start filing in ACE today

- If you are not yet filing in ACE for FDA, contact ACE_Support@fda.hhs.gov to get started.

- If you are already filing, increase and diversify your ACE entries.

- Deadline for full implementation is December 2016.

References

FDA Supplemental Guide: http://www.cbp.gov/ document/guidance/fda-supplemental-guide- release-16 (Full list of data elements required for admissibility)

FDA DUNS Portal: www.fdadunslookup.com (Query or request DUNS numbers for free)

Updated Resources on the FDA Website

- FDA Website ACE Page:
  - Tip Sheet
  - Updated Affirmations of Compliance
  - Updated FDA Units of Measure

- Help Desk: ACE_Support@fda.hhs.gov

FDA encourages you to start filing in ACE and continues to support you throughout this transition. We remain mindful of the overall goal of this project: to facilitate trade and reduce supply chain barriers to commerce while continuing to protect national security and public health.

Questions

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