



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Electronic Filing of Certain Import/Export Data Relating to Controlled Substances and Listed Chemicals: Announcement of the Partner Government Agency Message Set/ Document Image System Test and Request for Participants

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: General notice.

SUMMARY: The Drug Enforcement Administration (DEA) announces, in coordination with U.S. Customs and Border Protection (CBP), a pilot test of the International Trade Data System (ITDS) involving the electronic submission of data related to the importation and exportation of controlled substances and listed chemicals. The pilot program will test the electronic transmission through the CBP's Automated Commercial Environment (ACE) system, of data, forms and documents required by the DEA using the Partner Government Agency (PGA) Message Set and the Document Image System (DIS). The data, forms and documents will be transmitted for review by the DEA. CBP's PGA Message Set and DIS enable importers, exporters, and brokers to electronically transmit data required by the DEA directly to ACE. This electronic process will replace certain paper-based processes currently used during the pilot program for pilot participants.

DATES: The test will commence no earlier than August 1, 2016, and will continue until concluded by publication of a notice in the *Federal Register* ending the test.

Applications to participate may be submitted throughout the duration of this test.

FOR FURTHER INFORMATION CONTACT: For PGA-related questions, contact Elizabeth McQueen at *elizabeth.mcqueen@cbp.dhs.gov*. For technical questions related to the ACE or Automated Broker Interface (ABI) transmissions, or the PGA message set/DIS data transmission, contact your assigned client representative. Interested parties without an assigned client representative should direct their questions to Steven Zaccaro at *steven.j.zaccaro@cbp.dhs.gov* with the subject heading “*DEA Message Set/DIS Test FRN-Request to Participate*.” For DEA-related questions, contact Cathy A. Gallagher, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

To Apply: Any party seeking to participate in this test should contact their CBP client representative. Interested parties without an assigned client representative should send a request to Steven Zaccaro at *steven.j.zaccaro@cbp.dhs.gov* with the subject heading “*DEA Message Set/DIS Test FRN-Request to Participate*.” Applications will be accepted throughout the duration of this test. Applicants should identify the DEA-regulated commodities they intend to import or export and the ports they intend to use to import or export those commodities. Applicants will be notified by CBP/client representatives of the date they may begin participating in this test. Any applicant who provides incomplete information or otherwise does not meet participation requirements will be notified by email and given an opportunity to resubmit a request to participate. To be eligible to apply for and participate in the pilot, an applicant must be a self-filing importer or broker

who has the ability to file ACE Entry and Entry Summaries certified for cargo release using a software program that has completed ACE certification testing for the PGA Message Set and DIS, and, if an exporter, must have the ability to file electronically in the Automated Export System (AES) or in ACE AESDirect.

SUPPLEMENTARY INFORMATION:

Background

The Customs Modernization provisions in the North American Free Trade Agreement Implementation Act (Pub. L. 103-183, 107 Stat. 2057, 2170, December 8, 1993) provide the Commissioner of CBP with authority to conduct limited test programs or procedures designed to evaluate planned components of the National Customs Automation Program (NCAP), which includes ACE. The PGA Message Set/DIS test described in this notice is in furtherance of the NCAP goals.

This test is also in furtherance of the International Trade Data System (ITDS) key initiatives to achieve the vision of ACE as the “single window” for the U.S. Government and trade community, set forth in section 405 of the Security and Accountability for Every Port Act of 2006 (“SAFE Port Act”) (Pub. L. 109-347, 120 Stat. 1884, 1929, Oct. 13, 2006), and section 107 of the Trade Facilitation and Trade Enforcement Act of 2015 (Pub. L. 114-125, 130 Stat. 122, 135, Feb. 24, 2016). The purpose of ITDS, as stated in section 405 of the SAFE Port Act, is to eliminate redundant information requirements, efficiently regulate the flow of commerce, and effectively enforce laws and regulations relating to international trade, by establishing a single portal system, operated by CBP, for the collection and distribution of standard electronic import and export data required by all participating Federal agencies. CBP is developing ACE as the “single window” for

the trade community to transmit electronically all required information related to the cargo imported or exported and to comply with the ITDS requirement established by the SAFE Port Act. On October 13, 2015, CBP promulgated an interim final rule providing that, as of November 1, 2015, ACE is a CBP authorized Electronic Data Interchange (EDI) system which may be used for the filing of entries and entry summaries. 80 FR 61278. On February 29, 2016, CBP published a notice in the *Federal Register* stating that effective March 31, 2016, electronic entry summaries for specified entry types must be filed in ACE, and that effective May 28, 2016, electronic entries for specified entry types must be filed in ACE. 81 FR 10264.

Executive Order 13659 of February 19, 2014, *Streamlining the Export/Import Process for America's Businesses*, 79 FR 10655 (Feb. 25, 2014), requires that by December 31, 2016, the ITDS "single window," have the operational capabilities to serve as the primary means of receiving from users the standard set of data and other relevant documentation (exclusive of applications for permits, licenses, or certifications) required for the release of imported cargo and clearance of cargo for export, and to transition from paper-based requirements and procedures to faster and more cost-effective electronic submissions to, and communications with, participating U.S. Government agencies.

Partner Government Agency Message and Document Image System

On December 13, 2013, CBP published in the *Federal Register* a notice announcing an NCAP test called the Partner Government Agency (PGA) Message Set test. 78 FR 75931. The PGA Message Set is the data needed to satisfy the PGA reporting requirements. ACE enables the message set by acting as the "single window" for the electronic transmission to CBP of trade-related data required by the PGAs. Once

validated, the data will be made available to the relevant PGAs involved in regulating the importation or exportation of the cargo import, export, and transportation-related decision making. The data will be used to fulfill cargo entry requirements and may allow for earlier release decisions and more certainty for the importer in determining the logistics of cargo delivery. Also, by virtue of being electronic, the PGA Message Set will eliminate the necessity for the submission and subsequent handling of most paper documents.

On April 6, 2012, CBP announced the DIS test (77 FR 20835) allowing any party who files an ACE entry/cargo release or ACE Entry Summary certified for cargo release to submit electronically digital copies of specified CBP and PGA forms and documents via a CBP-approved EDI. On January 30, 2015, CBP modified the DIS test to allow specified Animal and Plant Health Inspection Service forms and documents to be transmitted as attachments to an email. 80 FR 5126. On October 15, 2015, CBP announced it would permit any DIS eligible form or document to be submitted as an attachment to an email. 80 FR 62082. As CBP frequently updates the list of forms and documents eligible to be transmitted using DIS, the complete list will be maintained on the CBP Web site, at the following address: <http://www.cbp.gov/trade/ace/features> under the DIS tab. Only eligible documents and forms required for the release of cargo or requested by CBP should be transmitted using DIS. Forms and documents transmitted using DIS may be transmitted without a prior request from CBP or the relevant PGA. ACE will automatically acknowledge every successful DIS transmission. This automated acknowledgement of successful transmission does not mean the correct or required form or document was transmitted as it occurs prior to any review of the

transmitted form or document. Any DEA form or document submitted via DIS is an electronic copy of an original document or form, and both the original and the imaged copy are subject to the CBP recordkeeping requirements of 19 CFR part 163, DEA recordkeeping requirements found in 21 CFR parts 1304, 1310, 1312 and 1313, and any other applicable PGA recordkeeping requirements. For purposes of the pilot, every form or document transmitted through DIS must be legible and must be a complete, accurate, and unaltered copy of the original document. *See* 19 CFR 101.9(b). For more information and the rules, procedures, technical requirements and terms and conditions applicable to the DIS, please see the DIS *Federal Register* notice at 80 FR 62082 (Oct. 15, 2015).

Current Paper Based Procedure

Current DEA regulations require applications for permits, declarations, and other required notices and reports to be filed utilizing designated forms which can be filed in paper form or by electronic means. During the pilot, the DEA import and export application and filing processes will continue to remain separate from (and in advance of) the ITDS single window. Entities will continue to use the DEA application and filing processes; however, the processes will be electronic rather than paper. After the DEA's approval or notification of receipt as appropriate, the DEA will transmit the necessary information electronically to the ITDS and the registrant or regulated person.

In support of ITDS and the use of CBP's PGA Message Set and DIS, the DEA will utilize an automated system to ensure compliance with import and export regulations. The DEA's system will electronically transmit reference data to CBP, expediting the

conditional release of shipments for the purpose of inspection, prior to the final release into the commerce of the United States.

PGA Message Set/ACE Filing

Once deployed, ACE/ITDS will replace the Automated Commercial System (ACS), the current EDI. ACE will be the official “single-window” system of record.” ACE will require that all data related to cargo release be submitted electronically using either the PGA Message Set or DIS.

The DEA and/or CBP will analyze the PGA Message Set data, forms and documents transmitted using DIS to determine whether inspection of a shipment is required. The data in ACE will also enable CBP to make the determination that a shipment may be conditionally released for inspection.

Pilot Program Details

The DEA is authorized by the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*), as amended, to regulate and collect information on the importation and exportation of controlled substances and listed chemicals. Under applicable DEA regulations, the importation of these DEA-regulated commodities into the customs territory of the United States from any place outside thereof (but within the United States), or into the United States from any place outside thereof, or the exportation of these DEA-regulated commodities from the United States typically requires the submission of one or more of the following DEA forms:

(1) DEA Form 35 – Permit to Import

(2) DEA Form 36 – Permit to Export

(3) DEA Form 161 – Application for Permit to Export Controlled Substances

(4) DEA Form 161R – Application for Permit to Export Controlled Substances for Subsequent Reexport

(4) DEA Form 236 – Controlled Substances Import/Export Declaration

(5) DEA Form 357 – Application for Permit To Import Controlled Substances

(6) DEA Form 486 – Import/Export Declaration for List I and List II Chemicals;

(7) DEA Form 486A – Import Declaration for Ephedrine, Pseudoephedrine, or Phenylpropanolamine.

This notice announces DEA's plan to conduct a test concerning the electronic transmission of the data contained in these forms to ACE using the PGA Message Set and the transmission of certain DEA permits, forms and documents using DIS. This new DEA PGA Message Set and DIS capability will satisfy the DEA data and electronic document requirements for any CBP entry filed electronically in ACE. As noted above, this test also applies to the exportation of the commodities subject to this test and requires the electronic submission of required export data through AES in Automated Export System Trade Interface Requirements (AESTIR) or American National Standards Institute (ANSI) X12, or in ACE AESDirect using an ACE portal, bulk upload or weblink. The AES DEA data elements are documented in Appendix Q of the AESTIR Implementation Guidelines (Appendix Q) and in the ACE AESDirect portal view. The

Web site to Appendix Q is <http://www.cbp.gov/document/guidance/aestir-draft-appendix-q-pga-record-formats>.

This new capability will also enable the trade community to have a CBP-managed “single window” for the electronic submission of data and documents required by the DEA during the cargo importation/exportation and review process. The technical requirements for submitting DEA data elements are set forth in the supplemental Customs and Trade Automated Interface Requirements (CATAIR) guidelines for the DEA. These technical requirements, including the ACE CATAIR chapter, may be found at the following link: <http://www.cbp.gov/trade/ace/catair>.

The list of forms and documents, including DEA documents, which may be transmitted using DIS may be found at <http://www.cbp.gov/trade/ace/features> under the DIS tab. The DEA permits, forms and documents eligible to be transmitted using DIS include DEA forms 35, 36, 236, 486 and 486A.

This test will apply to any entry filed in ACE at any port of entry and to cargo imported or exported using any mode of transportation. As a condition of the pilot, entries filed in ACE with the PGA Message Set must be transmitted using a software program that has completed ACE certification testing. *See* 19 CFR 101.9(b). This test will apply to all cargo regulated by DEA as of the date of this notice that require a CBP entry or exit.

This initial pilot will include the DEA PGA Message Set and the DIS components of ACE for imports, and the use of AES for exports. As mentioned above, DIS allows participants to transmit required PGA data to ACE through the use of electronic copies of DEA permits, forms and documents. For information regarding the use of DIS and a list

of PGA forms and documents that may be transmitted to ACE using DIS, please see [http://www.cbp.gov/trade/ace/features under the DIS tab](http://www.cbp.gov/trade/ace/features_under_the_DIS_tab).

Importers, exporters and brokers who participate in this pilot will transmit PGA Message Set data to ACE using the electronic data interchange known as the ABI, and for exports, data will be transmitted via the AESTIR or the ACE Secure Data Portal. The data elements in the PGA Message Set are generally those found on the DEA forms, permits, and declarations subject to this test. The DEA data is required in order to determine whether inspection of the shipment is required and to provide CBP with information to determine whether to conditionally release the cargo. Details related to this data will be provided to pilot participants. The DEA anticipates that this pilot program will help prepare for a successful transition from the paper-based process to the electronic entry and transmission of data to ACE.

Pilot Program Participant Responsibilities

Importers, exporters and brokers who participate in this PGA Message Set/DIS pilot will be required to:

- Submit by electronic means through the DEA Office of Diversion Control's secure network application, DEA Registered Importers/Exporters Permit Applications (DEA Forms 357, 161, 161R), and Import/Export Declarations (DEA Forms 236, 486, and 486A).
- Retrieve and print from the DEA Office of Diversion Control's secure network application, color copies of DEA issued import and export permits (DEA Forms 35 and 36).

- Obtain the required PGA Message Set Data and electronic DIS copy of the permit or declaration from the DEA registrant or regulated person.
- File, when applicable, data elements contained in Appendix Q.
- Include PGA Message Set import filings only as part of an ACE Entry or Entry Summary certified for cargo release.
- Use a software program that has completed ACE certification testing for the PGA Message Set and/or DIS.
- Transmit import filings to CBP via ACE.
- Transmit only information to CBP that has been requested by CBP or DEA.
- File export data through AES in AESTIR or ANSI X12, or in ACE AESDirect using an ACE portal, bulk upload or weblink.

Waiver of Regulations Under the Test

Pursuant to the authority of 21 U.S.C. 871(b), for the purposes of this test, the DEA waives for pilot participants those provisions of 21 CFR parts 1312 and 1313 that are inconsistent with the terms of this test. This document does not waive any recordkeeping requirements found in 21 CFR parts 1304, 1310, 1312, and 1313. For purposes of this test, those provisions of 21 CFR 1312.13(e), 1312.14(a), 1312.14(c), 1312.19(a), 1312.19(b), 1312.23(e), 1312.24(a), 1312.24(b), 1312.28(c), 1312.28(d), 1313.14(c), and 1313.23(c) that are inconsistent with the terms of this test are waived for test participants.

Paperwork Reduction Act

This change does not institute a new collection of information but instead proposes modifying the way that information is gathered. The collection of information contained

in this DEA PGA Message Set/DIS test has been previously approved by the Office of Management and Budget (OMB) in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507) and assigned OMB control numbers 1117-0009 and 1117-0023. 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 control number assigned by OMB.

Confidentiality

Data submitted and entered into the ACE Portal includes information that is exempt or restricted from disclosure by law, such as by the Trade Secrets Act (18 U.S.C. 1905). Participation in this or any of the previous ACE tests is not confidential and the name(s) of an approved participant(s) may be disclosed by CBP.

Dated: July 8, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

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