

Great Idea Form

Requirement Summary

GIF:	CSPO-GIF-1031	Status:	Pending CBP Change Control Board (CCB) Review	Submit Date:	September 4, 2009
Title:	ITD-023-M2.3-FDA Cargo Exam/Entry/Arrival & Release				

Origination

Requirement Initiator:	Sandra Scott, ITDS Committee Trade Co Chair
Initiator Email:	sscott@trademerit.com
Initiator Phone:	510-673-9485
Sponsor:	Kim Santos

Source:

Source:
Trade Request

Business Sponsor

Business Office:	Office of Information and Technology
Executive Director for the Business Office:	Lou Samenfink

CSPO Planning

Change to CSPO System?	
Change Planned?	Where/When Planned?
Assign to System: ACE	Assign to Release/Delivery: M2.3

Requirements Description

Business Area:	Cargo Control and Release (CCR)
Request Type:	Business Need
Impacts Trade?	Yes
Description of Change:	<p>Cargo Exam</p> <p>With the advent of the new Bioterrorism Act (BTA) regulations there now exists a two-tiered FDA clearance process under sections 21 CFR 801(a) and 801(m) for imports of food and food related products for human and animal consumption. Under the new regulations, expanded shipment and carrier required data elements must now be submitted to FDA on these types of shipments anywhere from a proposed 30 minutes prior up to a maximum 5 days prior to shipment arrival depending on the specific mode of transportation. Information is submitted electronically via ABI or FDA's web based system (PNSI). Based on this information FDA will determine whether a bioterrorist threat exists under section 801(m) and will notify Customs and Border Protection (CBP) to hold the shipment prior to crossing the border. In addition, once the entry information is submitted to FDA as required for admissibility, they will then determine whether any other admissibility risks exist under 801(a) and will notify the importer to hold the shipment prior to distribution if required.</p> <p>For FDA regulated commodities other than those described above, the required data information is submitted to FDA via ABI (and on to FDA's internal OASIS system) per current procedures. FDA then determines whether any other admissibility risks exist under 801(a) and will notify the importer to hold the shipment prior to distribution if required.</p> <p>Because no specific commodity information is required in data submitted at time of shipment arrival for FAST shipments that are not regulated under the BTA, compliance checks are based on a random sample across all of that importer's FAST shipments. In future, if additional expedited status and/or benefits programs are applied for and approved it is also</p>

	<p>possible that a reduced number of specific data elements may be required at time of entry summary under those programs for commodities that are not regulated under the BTA and compliance checks may be based on a random sample across all of an approved importers/exporters shipments. When an exam is required, however, additional cargo examination data would be collected via the ABI system according to FDA requirements.</p> <p>Entry filers will provide electronic cargo exam data within one hour of an electronic request. Based on its analysis of the cargo examination data FDA may elect to perform its own cargo examination on shipments selected for random compliance examinations.</p> <p>Entry Summary</p> <p>For FAST shipments not regulated by the BTA and released without cargo examination, specific commodity information is not submitted until entry summary data is filed. In this case, FDA data for reported commodities will be collected in the entry summary.</p> <p>Arrival/Release</p> <p>In order to avoid delays FDA staff will be available to make cargo release decisions at all hours when a motor freight port is open.</p> <p>NEXT STEPS: ITDS Committee members will follow up to determine the future vision of CBP in regards to integration of PGAs and obtaining multiple PGA approvals for expedited status and/or benefits programs (e.g., CTPAT, FAST). ITDS committee members will discuss reduced data requirements for shipments that are not covered under the BTA regulations and the operational procedures that may be required for such a benefit.</p> <p>Develop a plan to address the submission of additional cargo exam data elements electronically via ACE. Continue to follow the FDA/CBP plan for risk analysis and timing requirement integration and provide assistance in developing a plan for further integration as needed.</p> <p>Define a mechanism that will allow trade to quickly address any problems with any authorized expedited import/export process.</p>
Benefit of Change:	Allows expedited processing of legitimate known shipments and efficient designation of resources towards unknown, higher risk shipments.
Impact Assessment:	

System/Subsystem

System:	ACE	Cargo Business Area:	Import
----------------	-----	-----------------------------	--------

Implementation Requirements

Needed By Date:		Change Urgency:	
Level of Effort:		Cost Estimate:	

Sponsor Recommendation

Sponsor Recommendation:	
Sponsor Comments:	

Board Disposition

Date:	Disposition:	Comments:

Next Steps:

Next Steps:

Reasons for

Return/Deferral/Withdrawn/Rejection/Forward to PO

Reason for Return:	
Reason for Deferral:	
Reason for Withdrawal:	
Reason for Rejection:	

Reason for Forward to PO:	
------------------------------	--

Secretary Comments:

Comments:

Related Items:

CR#:	CR Name:
PTR#:	PTR Name:

Attachments

Attachments:	
--------------	--

Action Descriptions

Document History

Action History

Date:	User Name:	Note:

Update History

Date:	User Name:	Note:
