

Trade Compliance and the Food Safety Modernization Act (FSMA)

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Overview of U.S. International Trade Compliance Landscape

- **Imports** – customs laws and other agency requirements affecting imports.
- **Exports** – restrictions on persons, goods and technical information – 1) what, where and to whom, and 2) how and when an export must be reported.
- **Exports - Anti-bribery Laws** – U.S. Foreign Corrupt Practices Act (FCPA). OECD Anti-bribery Convention, U.K. Anti-bribery Act, and local laws of the destination country may also apply.

U.S. trade laws, particularly export controls and FCPA, have extra-territorial reach over U.S. persons and U.S. goods (broadly defined) anywhere on the globe.

The U.K. Anti-bribery Act may have a broader extra-territorial reach than the FCPA – almost any connection with the U.K. may trigger jurisdiction.

Export Compliance – Destination, Person and Commodity Based Controls

- Embargoed destinations – Cuba, Iran (Food & Medical exceptions), Syria, Sudan.
- Treasury (OFAC) Specially Designated and Blocked Nationals (SDN) and Blocked Persons.
- Export Administration Regulation commodity & destination based licensing requirements and embargoed persons.

Export Compliance – Destination, Person and Commodity Based Controls

- You must know your customer:
 - Who are they – is the company, its owners or officers sanctioned or embargoed?
 - Where are they located? Is the destination restricted or embargoed?
 - How will they use your product? Is the use reasonable under the circumstances?
 - Will they re-export it? If so, where?

Export Compliance – Anti-bribery Laws

- Foreign Corrupt Practices Act – may not directly or indirectly bribe a foreign government official (includes management of state owned enterprises) to obtain or retain business, business benefit or unfair advantage.
- These terms are interpreted broadly by the DOJ.
- Facilitating payments exception is a trap for the unwary.
- Excessive business entertainment or travel related expenses may be considered bribes.
- Books and records of public companies must accurately identify all transactions - including unlawful bribes.

Relationship of FSMA to International Trade Compliance

FSMA will shift responsibility to importers - requires controls to ensure imported food is safe.

U.S. Customs laws require an importer to exercise reasonable care.

Reasonable Care requires the use of reliable procedures to, among other requirements, ensure that imported merchandise complies with other agency requirements.

FSMA

- Importer responsible for ensuring that its foreign suppliers have adequate preventive controls to ensure imported food is safe.
- Importer is the person in the U.S. who purchased the food being offered for import, or consignee (if no owner at time of import).
- If no U.S. owner or consignee at time of entry, the importer is the U.S. agent or representative of the foreign owner or consignee (e.g. a non-resident Canadian importer).

Compliance with U.S. Customs Laws

- Importer of Record - responsible for using *reasonable care* to enter, classify and determine the value of imported merchandise **and to provide any other information necessary** to enable CBP to properly assess duties, collect accurate statistics, and determine whether **other applicable legal requirements have been met.**

Short List Import Compliance & *Reasonable Care*

- **Documentation** – review by *Responsible* and *Knowledgeable* person to ensure accuracy and completeness.
- **Expertise** - use of “customs expert” – person knowledgeable of customs laws, i.e., customs broker, attorney or accountant.
- **Classification** - reliable procedure to ensure proper tariff classification.
- **Valuation** – reliable procedure to ensure correct valuation, generally complete price and any assists (costs not in the price but statutorily part of the value).

Short List (continued)

- **Country of Origin** – verification of place harvested, mined, or manufactured (not place of shipment) – admissibility (Cuba, Iran, N. Korea, Sudan, trade preferences and statistical reporting).
- **Conditional and Preferential Duty Regimes** – procedures to ensure all requirements are met for conditional tariff provisions, e.g., NAFTA, USGR and actual use tariff provisions.
- **Other Agency Requirements** – FDA, FCC, EPA, NHTSTA.
- **Record Keeping.**

What Every Importer Should Know About: Reasonable Care (A Checklist for Compliance)

http://www.cbp.gov/linkhandler/cgov/trade/legal/informed_compliance_pubs/icp021.ctt/icp021.pdf

C-TPAT

- Not a requirement to be a compliant importer.
- But, may provide benefits – expedited customs clearance, fewer exams, and less likelihood of comprehensive or off site examinations.

What May be Ahead for 2014 and Beyond?

- New CBP Commissioner nominated - Richard Kerlikowske – background in military, law enforcement and Office of National Drug Control Policy.
- Pledged to streamline flow & inspection of imports & exports balancing enforcement with antiterrorism efforts, completing ACE and International Trade Data System – interagency data transmission by CBP.
- Pledged to focus enforcement resources to protect consumers from unsafe and substandard products.

Conclusion

A Comprehensive Trade Compliance Program May Help:

- to ensure that import, export and FDA compliance fit together for better overall informed compliance.
- to minimize customs examinations, especially if C-TPAT is an element of the compliance program.
- to minimize the effects (time, resources, fines, professional fees) of government enforcement and penalty actions.
- soften the confrontational atmosphere if a problem is detected - *government enforcement actions are adversarial by nature* - and may lead to a better result. Companies with formal compliance policies and programs tend to be seen in a better light by government agencies than those that have no program or merely give lip service to compliance.

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Export Compliance References

- Department of Commerce, Bureau of Industry and Security (BIS) – Embargoed Persons - http://export.gov/ecr/eg_main_023148.asp
- Office of Foreign Asset Controls - Embargoed Destination Rules and Prohibited Persons
 - <http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx>
 - <http://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx>

FSMA References

- <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm359450.htm#presentations>
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- <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>
-
- <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm>
-
- <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247546.htm>
-
- <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm359450.htm#presentations>