All Together Now: The Impact of Increasing Government Agency Cross-Talk and Coordination on Import Compliance

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Benjamin L. England & Associates, LLC and FDAImports.com, LLC

- Serve FDA, USDA, and CBP-regulated manufacturers, importers, exporters, marketers and distributors.
- Combine Legal & Business Judgment with Regulatory and International Trade expertise bringing nearly 100 years of direct former government experience to our clients.
- Identify and deliver others-centric solutions to business problems involving the approval, manufacture, marketing and movement of highly-regulated goods in & out of the U.S. at all nodes of the international supply web.

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1 - FDA Intl Harmonization

- Government's Goal – protect public health
- Industry's Goal – with as little disruption and headache as possible
- Consumer's Goal – to consume with confidence

2 - De-Harmonization

- The Trump Trade Effect
- Heavy on rhetoric to force improvements/modifications in Trade Deals
  - Takes a long time
  - Creates a lot of waves
- Easiest to impact outcomes by reallocating resources
  - Just *Act* like the deal was renegotiated
- Leads to JOINT AGENCY ENFORCEMENT = enough impact

PGAs Integration

Examples of Real Multi-Agency Actions

- Imported food ingredient (multiple containers / month)
  - Import Alert (pesticide residues) led to FDA refusals, which led to
  - Liquidated damages claims ($$), which led to
  - HTS classification (CBP informal inquiries) ($$), which led to
  - Request for CBP Internal Advice (potential litigation), followed by
  - USDA NOP investigation piled on (threatened loss of certification)
  - US Dept of Commerce inquiries re HTS classification
- Competitors at first unaffected
  - FDA sampling increased across industry – additional firms affected
  - Customs & Dept of Commerce began inquiries re HTS classification and possibly AD/CVD imposed by Commerce

Examples of Real Multi-Agency Actions

- Imported finished and raw goods (multiple containers/month; 2 chains)
  - FDA Import Alert issued against common supplier but targeting finished goods only
  - Extremely broad scope affecting all supply chains (even those with no prior connection to specific finished goods of concern)
  - Overly broad FDA automatic detentions – bulk, unfinished goods going into completely different markets unrelated to finished product of concern
  - HTS classification and FDA Product Coding changes raised CBP attention
  - Based upon legal representation – Government recently BLINKED

Examples of Real Multi-Agency Actions

- Imported finished and raw goods (multiple containers/month)
  - Middle-man US importer selling to major retailer
  - Routine CBP intensive examination led to questions re speciation, which led to
  - USFW notice of violation (Rosewood), which led to
  - Potential penalty actions
- Mitigating Factors
  - USFW screening is not a part of ACE – so hundreds of shipments slipped through
    - Mitigation opportunity
    - That dog is still sleeping…

3 - Tariffs & Trade in FDA Goods

- 25% Increase in Duty Rates for FDA-regulated goods from China
- HTS Chapter 29 – including various drugs and chemical products;
- HTS Chapter 30 – including specified medicaments (which currently enter duty-free), vaccines, reagents, immunological products, etc.;
- HTS Chaps 90 (84 & 85) – including various medical devices and medical device parts.

Structuring Transactions & Processing

- How you structure the transaction and the processing steps could save you duty
- *Maybe*…For Instance
  - Chinese med device components incorporated in another country
  - Chinese API formulated into finished drug in India
  - Kits containing Chinese components

Important Internal Changes

- Internal crosstalk between Reg Affairs and customs/trade staff - **Critical**
- Compliance requirements of multiple agencies may require similar datasets
  - You want to think through (and address) all potential issues the FIRST TIME -- in your documentation!
    - What the inspector or compliance officer or agent might care about – and what if another agency looked them over?
    - Make sure your shipment documentation tells a consistent regulatory narrative
- New structure means changing how your company units communicate and approach compliance (*i.e.* corporate governance and trade compliance procedures implemented and followed)

Trade, Harmonization & Integration

- Whether importing or buying domestic imports; something is crossing the border and affecting your supply chain
- Virtually no FDA-regulated articles remain unaffected by FDA imports and Customs legal and regulatory practice and policy
- Awareness is *critical* for all FDA-regulated industry

Need Help?

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FDLI Food and Drug Law Institute

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Specializing in FDA Regulatory Matters

International Harmonization Efforts

Domenic Veneziano

Independent Advisor, Import Operations

ABOUT THE SPEAKER

Domenic J. Veneziano is an Independent Advisor for Import Operations to EAS Consulting Group and owner of Veneziano Consulting. A 24 year veteran of the U.S. Food and Drug Administration (FDA) and U.S. Public Health Service (USPHS), Domenic served as the Agency's expert in Import Operations. He served as a senior FDA leader with prominent roles in the oversight of FDA's National import operations program, including the development and implementation of FDA's Targeting System PREDICT and the Import Trade Communication System, the integration of Customs and Border Protections Automated Commercial Environment with FDA's systems, and the Food Safety Modernization Act and Food and Drug Safety and Innovations Act. He has testified in federal court and before Congress, has represented the FDA for media inquiries, represented FDA on the ACE/International Trade Data System (ITDS) board of directors and the Border Interagency Executive Council. Additionally, Domenic has been the recipient of numerous awards, including the Department of Human Services Secretary's Award for Distinguished Service.

Domenic began his FDA career as a field investigator in the New England District office where he conducted domestic and foreign inspections and investigations. He was selected as a Supervisory Investigator responsible for assessing inspectional reports, evaluating findings and the evidence supporting them and endorsing the classification.

In 2003, Domenic transferred to FDA headquarters where he established, staffed and Directed FDA's first 24/7/365 operational center in response to the Bioterrorism Act of 2002. In 2005, Domenic became the Director of the Division of Import Operations and Policy where he enforced the import laws, developed and implemented field operational policy and procedures across the country covering over 320 port of entries, and advised FDA senior Executives on all issues related to import operations.

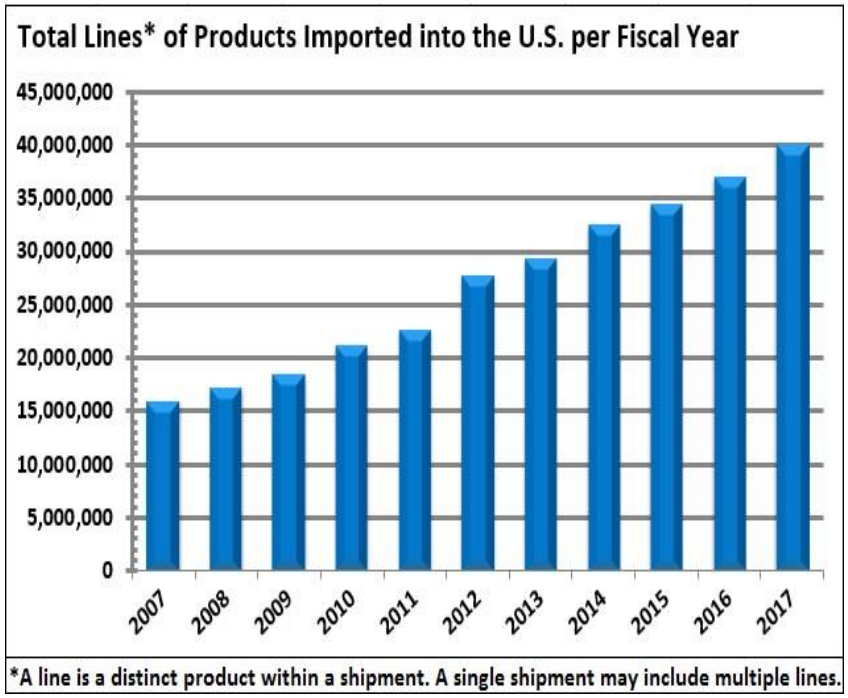
As an advisor to EAS Consulting Group, Domenic works closely with clients to provide advice to producers, importers, exporters and distributors of FDA-regulated commodities by; helping clients import products into the US and get them removed from import alert; evaluate medical device and food facilities to determine compliance with good manufacturing practice regulations and the FSMA; and by assisting them in correcting deviations found during FDA inspections or third-party audits.

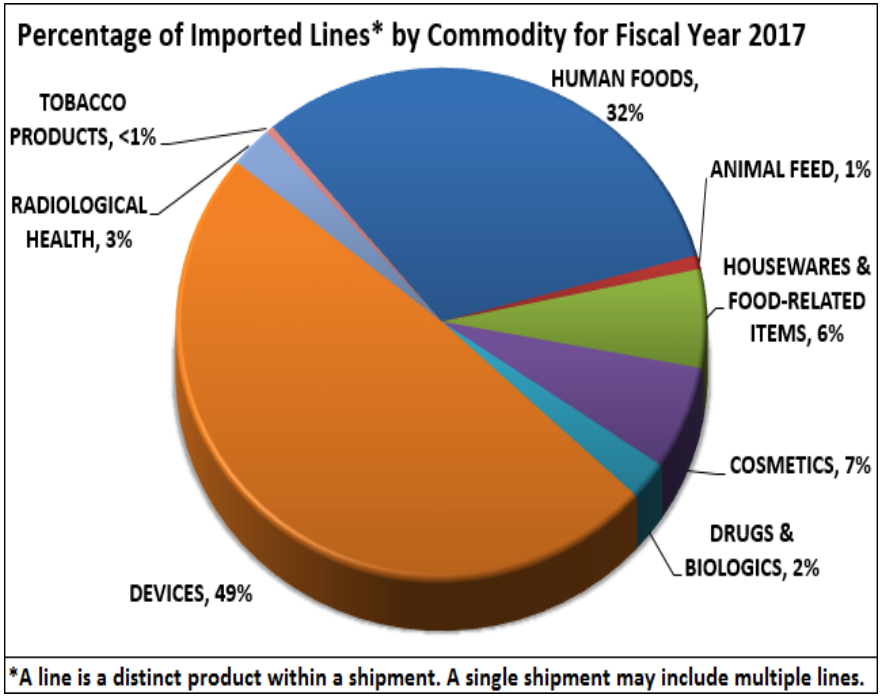
Today's Topics

- Food Safety Systems Recognition Assessments

- CCFICS: Codex Committee on Food Import & Export Inspection & Certification System

Food Safety Systems Recognition Assessments





Food is imported from over 200 countries/areas

Food Safety Systems Recognition Assessments

- **Purpose:** To identify countries that have food safety systems in place that are comparable to FDA's in order to leverage the work conducted by a foreign food safety authority in order to improve food safety.

- **Systems recognition** describes whether: (1) a country's food safety system provides a similar, though not necessarily identical, system of protections as another food safety system and (2) the country's food safety authority or authorities provide similar oversight and monitoring activities for food produced under its jurisdiction.

Food Safety Systems Recognition Assessments

PROCESS

1. FDA will conduct an internal data review of the country's compliance history.
2. FDA will arrange for a consultation meeting with the relevant food safety authority of the country.
3. Countries foreign food safety authority will complete the International Comparability Assessment Tool (ICAT).
4. In country system recognition assessment.

System Recognized Countries

- The Ministry for Primary Industries of **New Zealand**
- Canadian Food Inspection Agency and Health **Canada**
- The **Australia**n Department of Agriculture and Water Resources

CCFICS: Codex Committee on Food Import & Export Inspection & Certification System

- The Codex Alimentarius Commission (“Codex”) is an intergovernmental body with 189 members. Their purpose is to protect the health of consumers and to ensure fair practices in food trade.
- Codex is a collection of internationally adopted food standards, guidelines, codes of practice, and other recommendations to ensure fair practices in food trade and protect the health of consumers.
- FDA has been engaged in the work of the Codex since its formation in 1963

CCFICS: Codex Committee on Food Import & Export Inspection & Certification System

- CCFICS is only 1 of 10 general subject committees.
- CCFICS focuses on developing principles and guidelines for food imports and export inspections and certification systems with a view to harmonize methods and procedures which protect the health of the consumer, ensure fair trade practices and facilitate international trade in foodstuffs
- CCFICS was formed in 1992 and has issued 12 standards over that time period

CCFICS: Codex Committee on Food Import & Export Inspection & Certification System

Current Projects

- Guidance on paperless use of electronic certificates
- Guidance on the use of systems equivalence
- Guidance on regulatory approaches to third party assurance schemes in food safety and fair practices in the food trade.

CCFICS: Codex Committee on Food Import & Export Inspection & Certification System

- FDA is only 1 of several agencies that participate in CCFICS
- The development of guidance documents and principles and guidelines help lift the standards of less developed countries
- Assures that guidance documents and principles and guidelines meet FDA regulatory requirements
- Helps to ensure that products imported into the US meet Food Safety Standards
- Helps to set guidance for issues that are of interest to a specific country.

Questions?

Contact Information

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