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International trade made easy

Workshop on international trade compliance

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Agenda

1. **Import Compliance**
    - FDA - Tom Sidebottom
    - Value Added Tax – Dale Bushell
    - EU perspective – Maja Kuhnt
2. **Export Compliance**
    - Export documentation & ECCN: Jeff Bernia
    - EU perspective – Maja Kuhnt
3. **Creating an International Trade compliance program**
    - Find your trade compliance score

Intro to DSG Global LLC?

- DSG Global LLC (www.dsgglobal.com) is a consulting firm focused on “International Trade compliance”.
- Headquartered in San Francisco, with team members based around the USA
- DSG Global Academy provides training on import & export topics.

How do we help our Client family?

Training & Consulting on International Trade Compliance

1. Export compliance (EAR & ITAR)
2. Import compliance
3. Cargo-Security
4. Multi-country import/export rules
5. Training

Benefits of Compliance

- Doing it right the first time is cheaper than going back and fixing it later
- Demonstrated compliance will result in fewer cargo exams, fewer penalties, fewer information requests, and fewer delays resulting in less cost
- Less cost + customs processing time = Greater competitive advantage.
- Exporting is a privilege, NOT a right!

II. Import compliance

AGENDA

1. Roles of CBP, PGA, CHB and IOR
2. FDA
3. Import process (USPS, Express, Formal Entry)
4. HTS Classification
5. Customs Valuation
6. U.S. Marking & Labeling Requirements
7. Recordkeeping
8. Penalties
9. Value Added Tax
10. EU Perspective

U.S Customs & Border Protection (CBP)

1. Assess, collect and protect the revenue.
2. Collect accurate trade statistics
3. Enforce Customs laws related to the importation of goods.
4. Protect consumers from hazardous products & industry against unfair competition from foreign manufacturers.
5. Enforcement arm for other U.S. agencies.

Participating Government Agencies (PGA)

1. U.S. Food and Drug Administration (FDA)
2. U.S. Fish and Wildlife Service (F&W)
3. U.S. Dept of Agriculture / APHIS (USDA)
4. Consumer Product Safety Commission (CPSC)
5. U.S. Department of Alcohol, Tobacco & Firearms (ATF)
6. U.S. Environmental Protection Agency (EPA)

FDA

Importer of Record (IOR)

1. The individual, firm or entity FULLY responsible for the shipment being imported
2. Must be identified for every commercial importation
3. Is the owner, purchaser, or consignee of a shipment imported merchandise
4. Must have a legal presence in the U.S.
5. Has primary responsibility to comply with U.S. Customs laws and regulations.

The Role of a Customs Broker Is One of Trade Facilitator and Information Provider.

Importing Process

- Entry Summary: CF 7501 (10 days after Entry)
- Entry documents + Duty payment
- Liquidation (approx. 1 year after Entry)

  - Protest (90 days after liquidation)
  - Court of Int'l Trade (180 days after protest)
  - Federal Circuit Court of Appeals
  - Supreme Court

Entry Documentation

Within 10 working days of arrival of freight, the following documents are required to obtain release of goods:

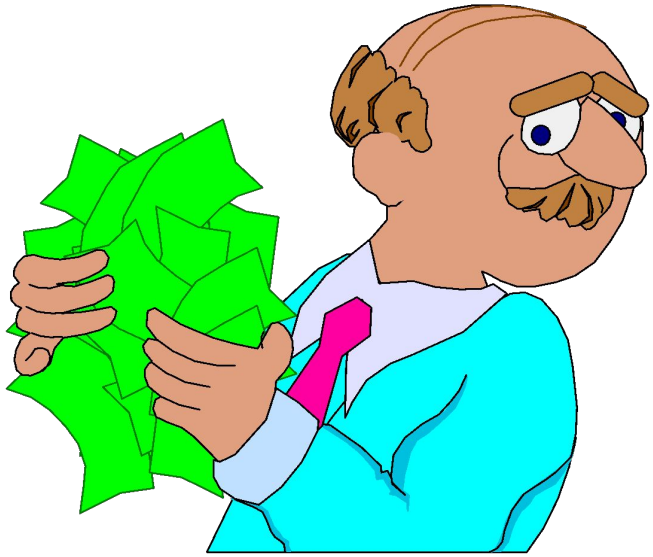
- Commercial Invoice
- Packing List
- Bill of Lading
- Carrier Manifest
- Commodity specific supporting documents (certificate of origin etc.)

Common invoice errors

- List Country of Export rather than Country of Origin
- Failure to Convert a Foreign Currency
- Use part numbers instead of complete descriptions
- Submit an invoice in a foreign language
- Failure to indicate all applicable charges
- Failure to include quantities or measures
- Failure to show manufacturer of the goods
- Failure to meet specific requirements enumerated in the regulations for certain classes of merchandise
- Failure to indicate the Terms of Sale

Duty Rates and Fees

- Customs duty, depends on HTS #
- Merchandise Professing Fee (MPF) for formal entries is ad valorem 0.3464 % (from $27.75 - $538.4 per entry). For informal entries, MPF is a set fee of $2.22, $6.66 or $9.99 per shipment.
- Harbor Maintenance fee (HMF) is calculated at 0.125% of the value of the commercial cargo imported through the ports.



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What is your Landed Cost ?

- In addition to the basic cost of an item, the ultimate cost of delivery may include
  - Inland taxes, i.e. VAT/GST
  - Entry fees, i.e. HMF/MPF
  - Customs brokerage fees
  - Cost of special packaging
  - Drayage & Ocean shipping costs
  - Port handling fees

How can importers minimize impact

1. Conduct a Tariff impact assessment (ACE account)
2. Customs valuation
3. Tariff classification
4. International Commercial Terms (Incoterms)
5. Country of Origin Rules
6. Using USMCA & Free Trade Agreements (“FTA”)
7. Duty drawback program
8. Bonded warehouses & Foreign-Trade Zones (“FTZs”)

Tariff Classification

- A higher or lower duty may apply depending on how an item is classified.
- Erroneous classification could lead to underpayment or overpayment of duties.
- For assistance:

1. Consult a Customs “expert”
2. Research binding rulings on CROSS & court cases
3. Request a binding ruling

U.S. Harmonized Tariff Schedule

Heading Subheading Tariff item	Stat. Suffix	Article Description	Units of Quantity	Rates of Duty		
				General	1 Special	2
4203		Articles of apparel and clothing accessories, of leather or of composition leather				
4203.30. 00	00	Belts and bandoliers with or without buckles	X	2.7%	Free (A, CA, E, IL, J, MX)	35%
4203.40		Other clothing accessories:				
4203.40 30	00	Of reptile leather	X	4.9%	Free (A,CA,E,IL J, MX)	35%

General Rules of Interpretation

- GRI 1 prescribes how to classify products at the 4-digit Heading level, based on the wording of the headings and the relative HS Section and Chapter Notes.
- GRI 2 prescribes how to classify both incomplete and unassembled goods, and mixtures and combinations of goods.
- GRI 3 prescribes how to classify products that are, prima facie, classifiable under two different HS headings.
- GRI 4 prescribes how to classify products that cannot be classified according to GRI's 1, 2, and 3.
- GRI 5 prescribes how to classify packaging.
- GRI 6 prescribes how to classify products at the 6-digit subheading level, based on the wording of the subheadings and the relative HS Section and Chapter Notes.

Customs Valuation

Transaction Value

- Generally, the appraised value of all merchandise imported into the United States is the transaction value of the goods.
- 95% of transactions are valued utilizing this method
- There are restrictions on the use of Transaction Value

Other Valuation Methods

In the event the merchandise cannot be appraised on the basis of transaction value, the secondary bases are considered in the following order:

(2) Transaction Value of Identical Merchandise

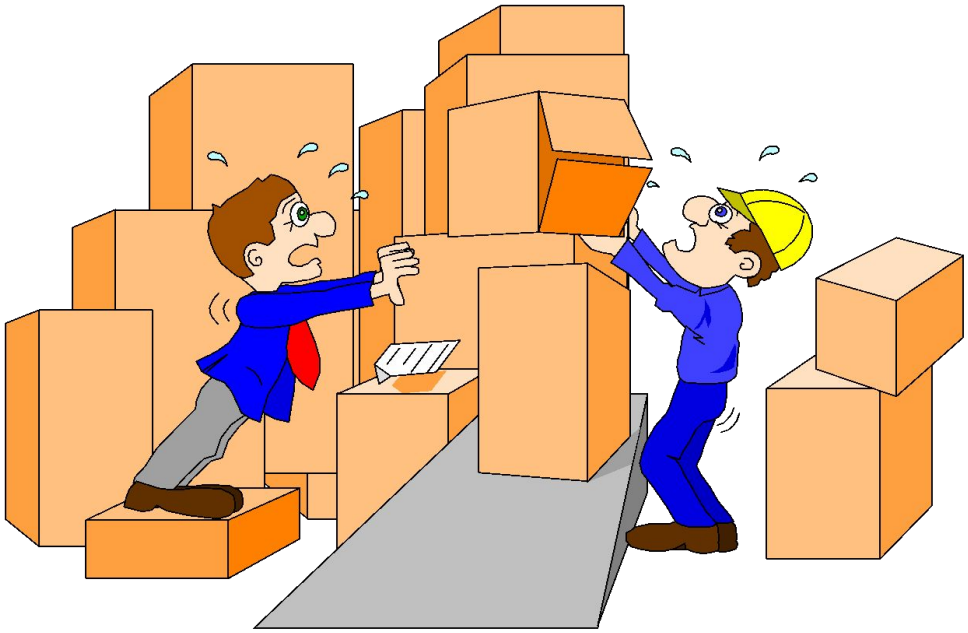
(3) Transaction Value of Similar Merchandise

(4) Deductive Value

(5) Computed Value

(6) Values if Other Values Cannot be Determined

U.S. Marking and Labeling Requirements



COUNTRY OF ORIGIN

- Not necessarily “country of exportation”
- Check the last country of “Substantial Transformation”
- Determines duty rate:
  - Most Favored Nation
  - Preferential Duty Rates
  - Embargo Countries
- For Free Trade Agreements, check the specific language for eligibility.

Marking

- General Rule: All merchandise imported for sale in the U.S. must be clearly marked (unless exempt) with the English name of the country of origin.
- The ultimate consumer in the U.S. must be able to easily find the country of origin marking and read it
- Warning! FTC Rule - Do not use “Made in USA” unless “all or virtually all” materials are sourced from USA.

Marking Exceptions

- Economically prohibitive
- Products of U.S. possessions
- Produced over 20 years prior
- Entered into warehouse
- Imported for use by importer, not intended for sale
- Articles processed in U.S. by importer
- Incapable of marking

IPR Protection

- Imported Article Bearing Name or Mark May Be Seized

<u>Example:</u>

- Counterfeit Rolex Watches
- Fake Disney apparel
- Iphones returned for repairs

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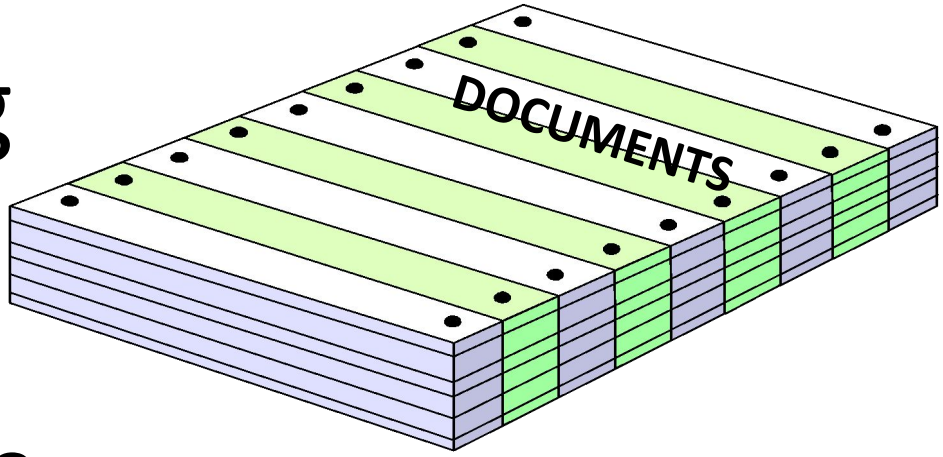
Recordkeeping

Recordkeeping



Who retains records?

Importers & their brokers/agents/carriers

What records are retained?

All documents related to and required to prepare entry of merchandise

How long must records be retained?

5 years from entry date or activity date

Penalty Actions

- Negligence: Lesser of 2 x duties or 20% of value
- Gross Negligence: Lesser of 4 x duties or 40% of value
- Fraud: 100% of domestic value

Value Added Tax

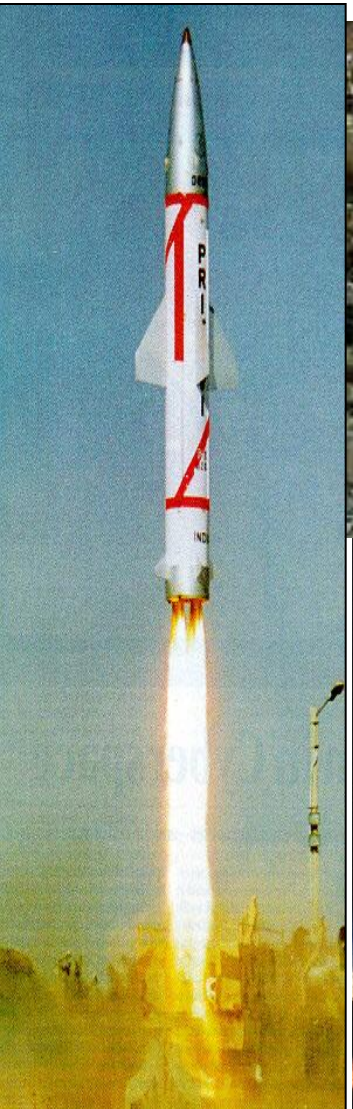
Import Topics: EU Perspective

III. Export compliance

Agencies That Regulate U.S. Exports

- **U.S. Department of Commerce – Bureau of Industry and Security (BIS)**
- U.S. Department of the Treasury – Office of Foreign Asset Controls (OFAC)
- U.S. Department of State – Directorate of Defense Trade Controls (DDTC)
- U.S. Census – Foreign Trade Division
- U.S. Department of Homeland Security – U.S. Customs & Border Protection
- U.S. Department of Energy
- U.S. Department of Justice
- U.S. Department of Agriculture
- U.S. Food and Drug Administration
- U.S. Drug Enforcement Administration
- U.S. Patent and Trademark Office
- U.S. Nuclear Regulatory Commission

Bureau of Industry and security
Office of Export Enforcement



BIS' Mission: Keep the most sensitive goods out of the most dangerous hands.

Enforcement Priorities

1. Weapons of Mass Destruction (WMD) Proliferation

2. Terrorism and State sponsorship of terror

3. Diversions to unauthorized military end-use

Examples of Dual-Use Items

Nuclear Weapons

- Centrifuges
- High-Speed/Thermal Cameras
- Mass Spectrometers
- Vacuum Pumps

Chemical Weapons

- Precursors
- Coolers
- Heat Exchangers
- Mixing Vessels

Biological Weapons

- Bacterial Strains
- Growth Media
- Fermenters
- Presses

Missiles

- Aluminium Alloys
- Composites
- Machine Tools
- Accelerometers

What is an Export?

- Export: Actual shipment or transmission of items out of the U.S.

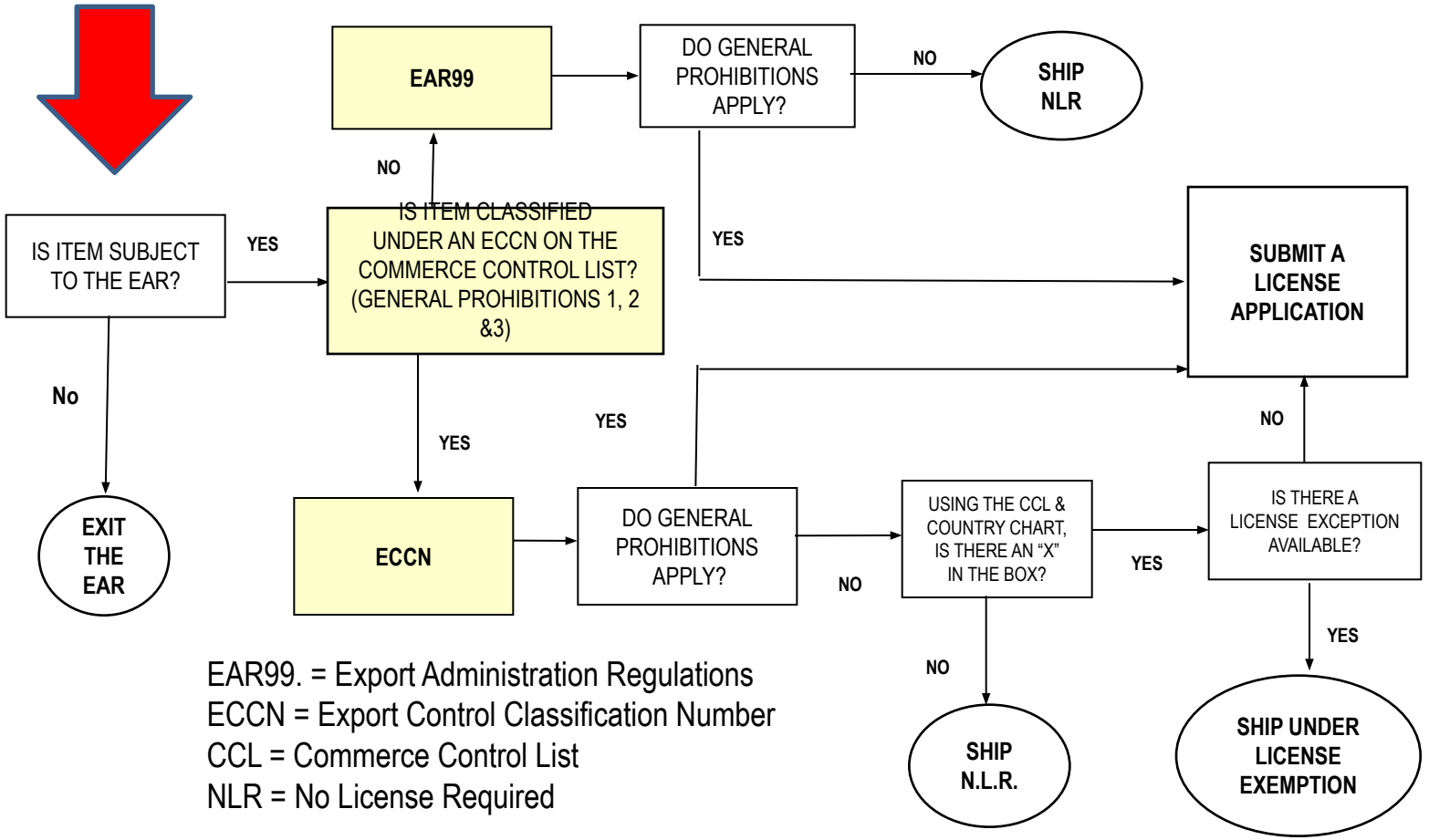
- Re-export: An item of U.S. origin or U.S. connection, exported between two foreign countries

- Deemed Export: Any release of controlled technology or source code to a foreign national

Deemed Export

- A “deemed export” is a release of technology or software source code to a foreign person in the United States.
- It is deemed to be an export to the foreign person’s most recent country of citizenship or permanent residency.
- Does not apply to US Citizens, permanent resident aliens (Green card holders), or protected individuals.
- There are deemed re-export provisions as well.

Do You Need a BIS Export License?



EAR99. = Export Administration Regulations
ECCN = Export Control Classification Number
CCL = Commerce Control List
NLR = No License Required

Five Simple Steps

Step 1: Determine Jurisdiction (State or Commerce)

Step 2: Determine Export Control Classification (ECCN) number

- If no number exists in the Commerce Control List (CCL), then the ECCN # is EAR99

Step 3: Check the 10 general prohibitions

- Denied Persons Lists, Embargoed nations, Prohibited end-uses, Knowledge violations etc.

Step 4: Check Country Chart & Reason for Control

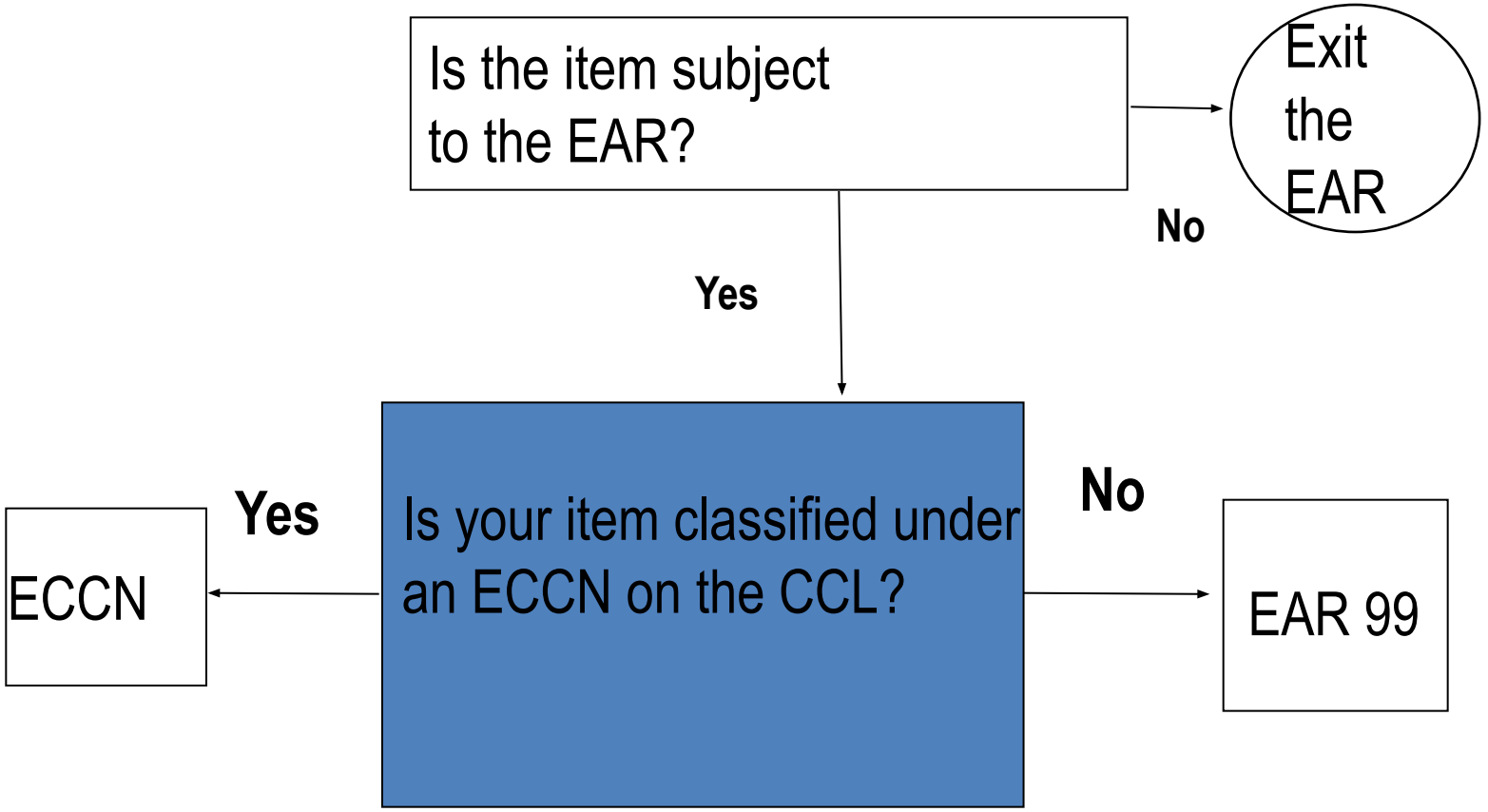
- Is there an "X" in the box?

Step 5: If yes, is a license exception available?

Step 1: Determine Jurisdiction

- Is the product or technology under the control of the EAR or ITAR?
  - Is the product clearly on the U.S. Munitions List (listed or otherwise described)
  - If ITAR controlled, it falls under DoS control
- In many cases, jurisdiction is not clear. Options:
  - DoS Commodity Jurisdiction (CJ): guaranteed safe!
  - Self Determination: follow the “Order of Review”

Step 2: Does your Item have an ECCN?



Commerce Control List (CCL)

0 = Nuclear materials, facilities and equipment and miscellaneous items

1 = Materials, Chemicals, Microorganisms and Toxins

2 = Materials Processing

3 = Electronics

5 = Telecommunications and Information Security

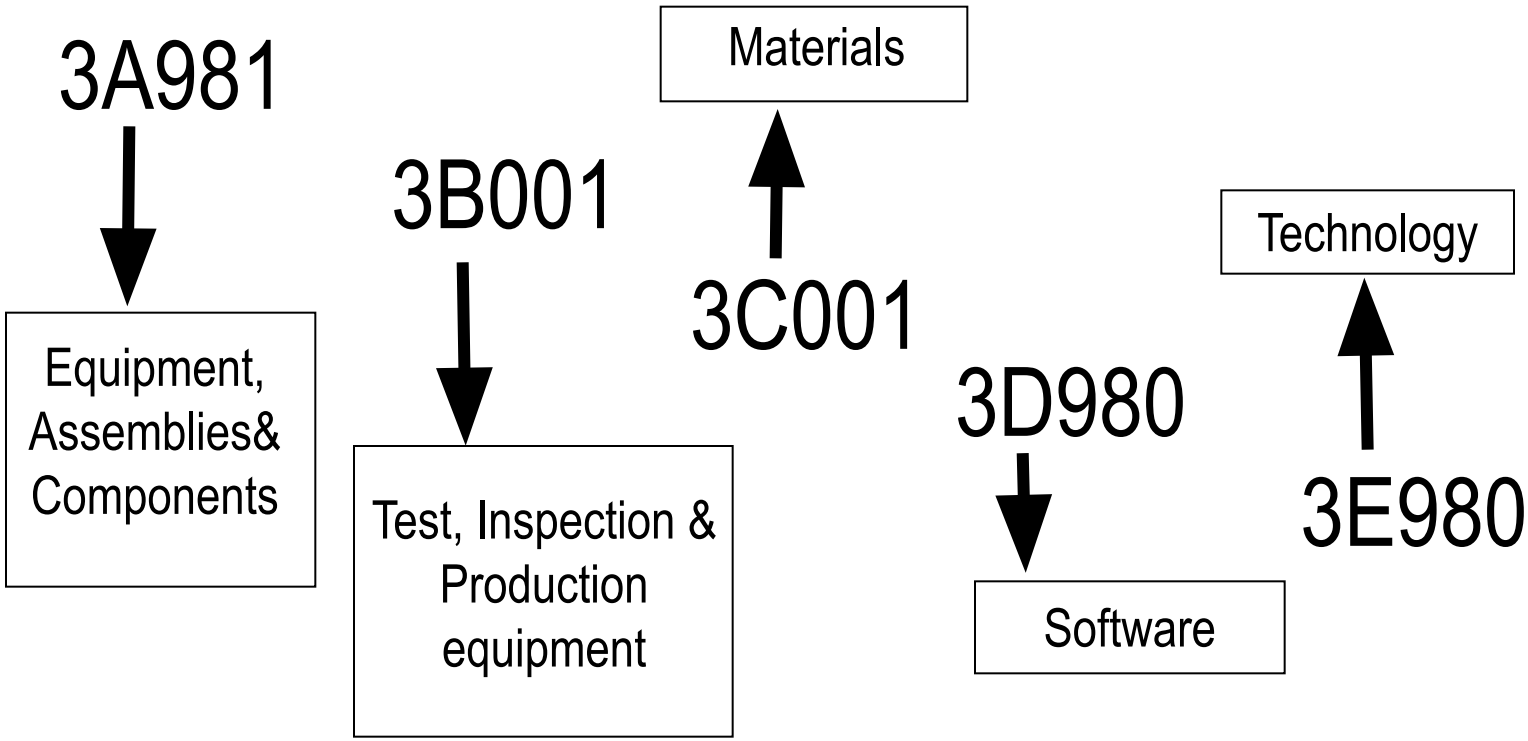
6 = Sensors and Lasers

7 = Navigation and Avionics

8 = Marine

9 = Propulsion Systems, Space Vehicles, and Related Equipment

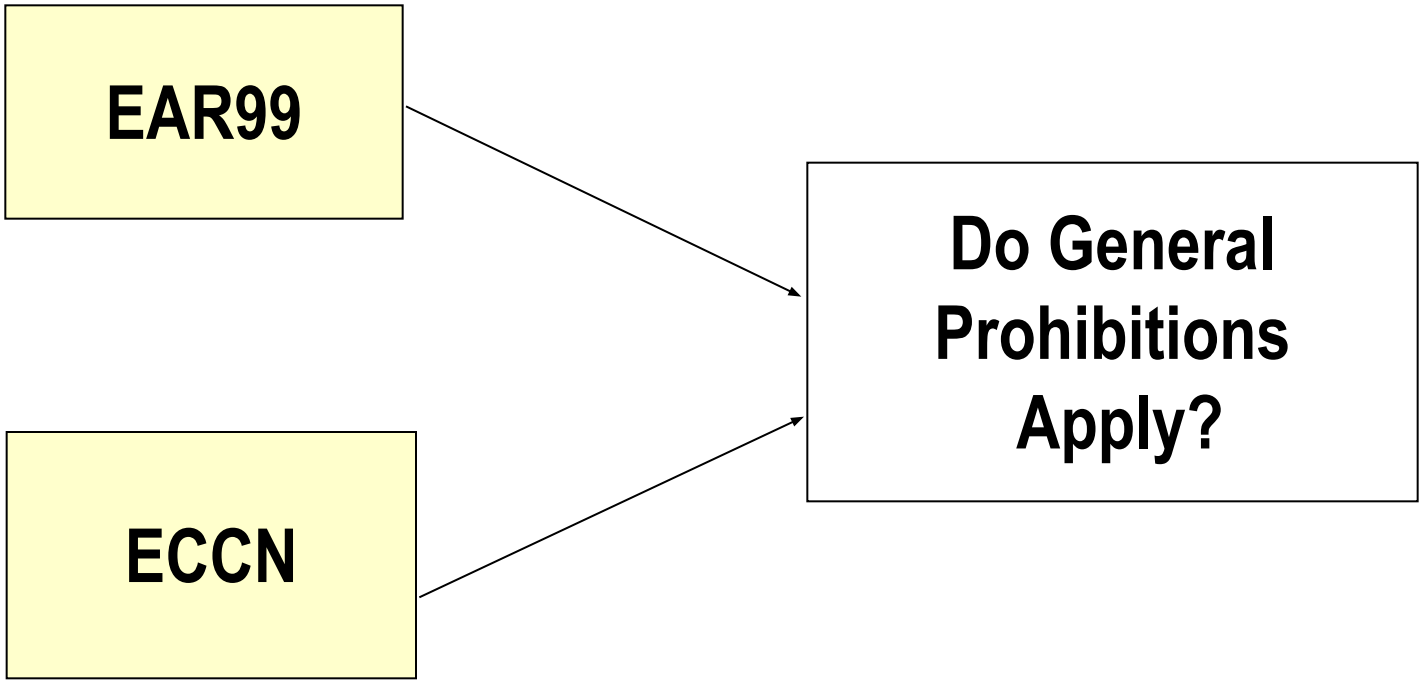
ECCN Structure



How to find your ECCN

- **Check with the manufacturer**
  - May have exported before
- **Self-determination: Work with design engineers, chemists, scientists**
  - Check the CCL alphabetical index
  - Arrive at the category and product group
  - Match characteristics of the item with ECCN and subparagraph
- **Formal BIS determination: Submit SNAP-R "CCATs" classification request to BIS to confirm**

Step 3:
Do any General Prohibitions Apply?



General Prohibitions (# 1- 10)

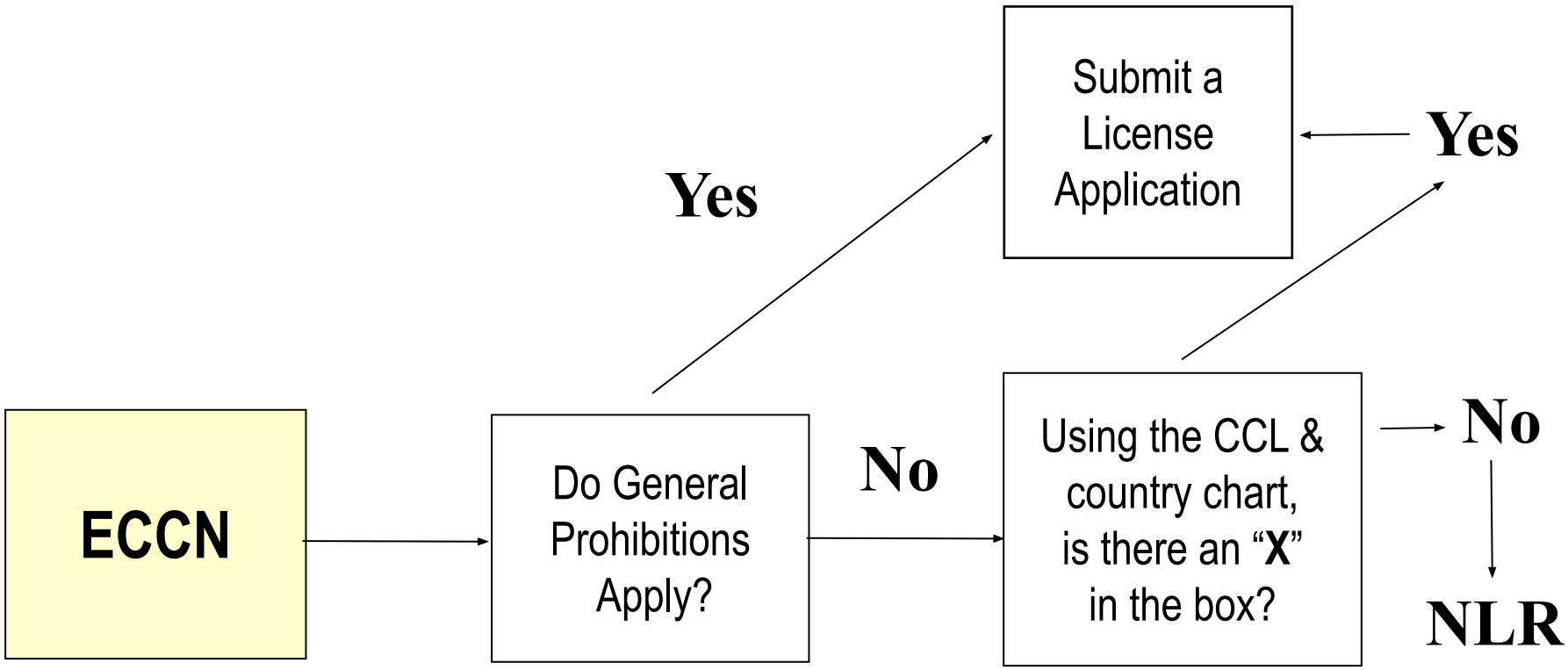
- ECCN & export license based (Prohibition 1)
- Transaction based (Prohibitions 2 thru 10).
  - Prohibited by Denial Order (Denied Parties List)
  - Prohibited end-user or end-use
  - Embargoed destinations
  - Support of proliferation activities
  - License required to transit/unlade in certain countries
  - Prohibited to violate any orders, terms, conditions of license
  - Prohibited to proceed w/ transaction if knowledge violation to occur

Consolidated Screening list

- The consolidated screening list is a list of parties for which the United States Government maintains restrictions on certain exports, re-exports or transfers of items.
- In the event that a company, entity or person on the list appears to match a party potentially involved in your export transaction, additional due diligence should be conducted before proceeding.
- The consolidated screening list includes:
  - Denied Persons
  - Unverified List
  - Entity List
  - OFAC Lists
  - Debarred List

https://www.trade.gov/consolidated-screening-list

Step 4: Check the Commerce Country Chart



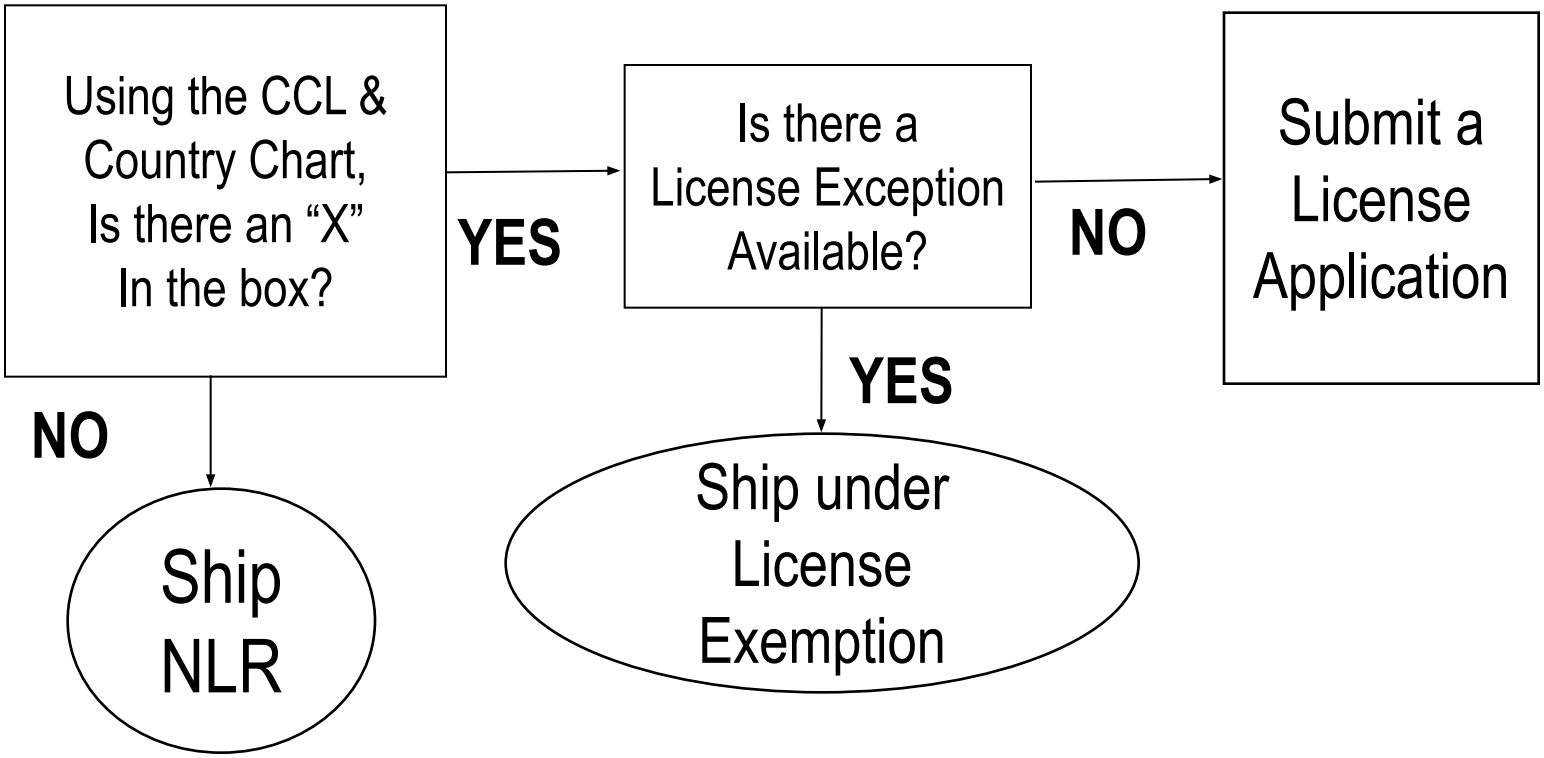
Reasons for Control

- Chemical and Biological: CB
- Nuclear Non-Proliferation: NP
- National Security: NS
- Missile Technology: MT
- Regional Stability: RS
- Firearms Convention: FC
- Crime Control: CC
- Anti-Terrorism: AT

Country Chart

Countries	Chemical and biological weapons			Nuclear nonproliferation		National security		Missile tech	Regional stability		Firearms convention	Crime control			Anti-terrorism	
Reasons for Control	CB 1	CB 2	CB 3	NP 1	NP 2	NS 1	NS 2	MT 1	RS 1	RS 2	FC 1	CC 1	CC 2	CC 3	AT 1	AT 2
Hungary [3]	X					X		X	X				X			
Iceland [3]	X					X		X	X				X			
India [7]	X			X		X		X	X				X			
Indonesia	X	X		X		X	X	X	X	X		X	X	X		
Iran [1]	See part 746 of the EAR to determine whether a license is required in order to export or reexport to this destination..															
Iraq [1]	X	X	X	X	X	X	X	X	X	X		X	X			
Ireland [3] [4]	X					X		X	X				X			
Israel	X	X	X	X	X	X	X	X	X	X		X	X	X		
Italy [3]	X					X		X	X				X			
Jamaica	X	X		X		X	X	X	X	X	X	X	X	X		
Japan [3]	X					X		X	X				X			

Step 5: License Exceptions

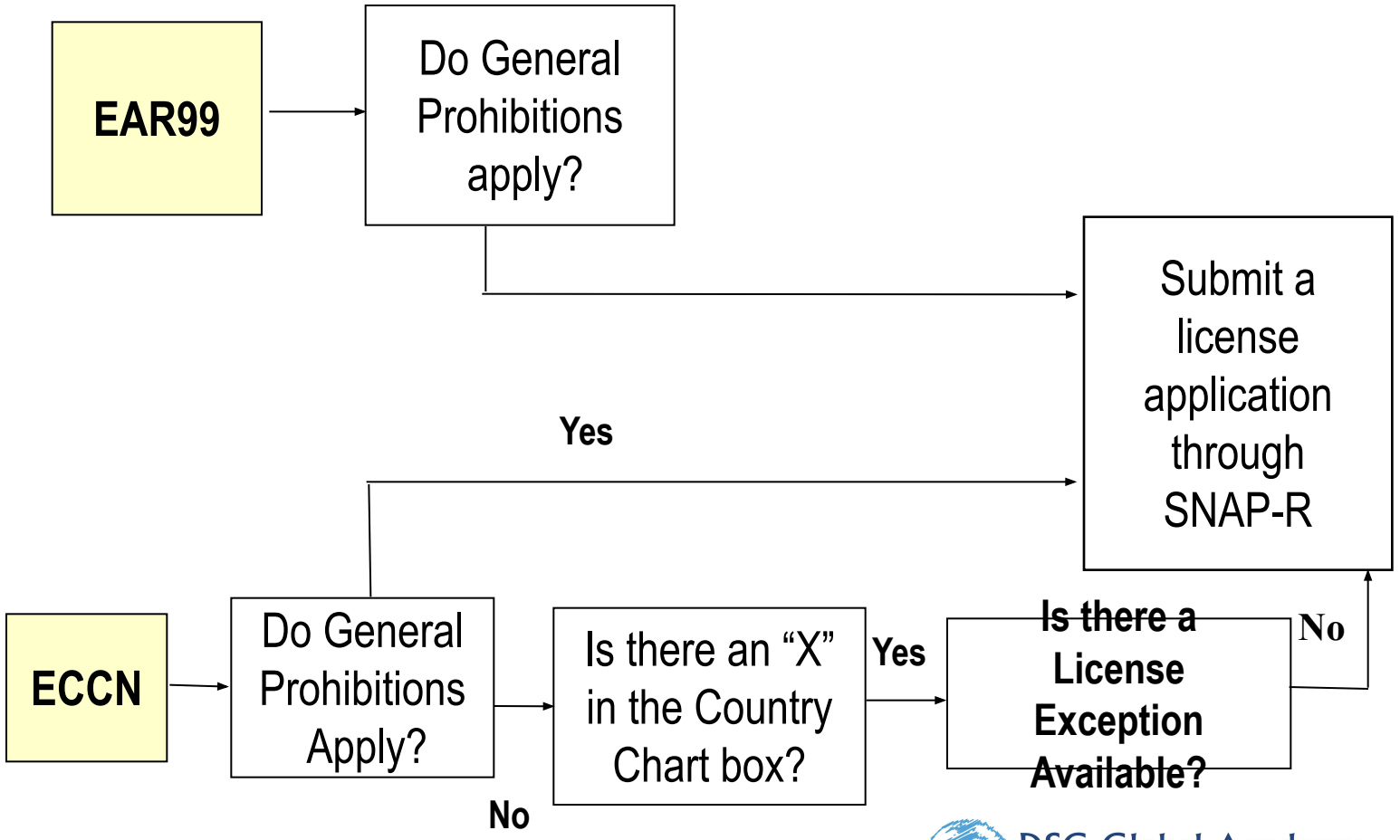


License Exceptions

- Authorization to export or re-export without an export license (Part 740 of EAR)
- Three letter symbol used for export clearance purposes

RPL	**BAG**	**TMP**	**GBS**
GOV	**STA**	**LVS**	**CIV**
GFT	**APR**	**GBS**	**TSR**
TSU	**CTP**	**CIV**	**ENC**

When Do You Need to Submit for an Export License?



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Simplified Network Application Process - Revised (SNAP-R)

- You may ask the BIS to provide you with the official classification (CCATS) by using the SNAP-R system
- SNAP-R is the online system used for most BIS purposes.
- There is no charge for requesting a classification or license from BIS.
- Each classification request is limited to 6 items.
- Allow 90 days for a CCATS (or export license) *but hope the USG response will be closer to 30 days*

Recordkeeping Requirements

- Export records must be kept for 5 years.

- Recoverable records include:
  - Proforma & CI, PL, BL/AWB, COO, NAFTA certificates
  - EEI Abstract from carrier
  - Export controls research & documentation (SNAP)
  - Sales contracts, notes and memoranda
  - All financial records pertinent to the sale
  - All other correspondence pertinent to the transaction

HOW VIOLATIONS HAPPEN IN GOOD COMPANIES

- Overwhelmed by end of quarter orders and processing
- New personnel using outdated go-by documentation
- Export manager on vacation (cross train back up personnel)
- Lack of communication with sales staff and foreign distributors.
- Absence of an ECP or written policies or controls.

Look Out for “Red Flags”!

REMEMBER: Export compliance requirements are mandatory, NOT optional!!!

- Your V.P. of Sales says; “I dont care what list they are on, we need this sale!”
- Employees need to know how to handle red flags (training, internal contacts, escalation, etc.)
- It doesn’t look right, sound right, read right – THEN, Review, Re-evaluate and Refrain from the transaction

Fines and Penalties

Violations of the EAR or ITAR may be subject to both criminal and administrative penalties.

1. **Criminal Penalties:**
   - Under the Export Control Reform Act of 2018 (50 USC 4801-4852) (ECRA), criminal penalties can include up to 20 years of imprisonment and up to $1 million in fines *per violation*, or both.

2. **Civil Penalties:**
   - As of January 15, 2025, under the EAR the maximum administrative monetary penalty is $374,474 per violation or twice the value of the transaction, whichever is greater.

3. **Denial of Export Privileges**

When is an EEI Filing Required?

- Merchandise that is valued more than US$2,500 per HTS or Schedule B being sent by the USPPI to the same consignee on the same day using the same conveyance
- Merchandise, regardless of value, which requires an export license/permit
- Hardware & technology that is subject to the International Traffic and Arms Regulations (ITAR)
- Exporters or their representatives now need to file their EEI through the Automated Commercial Environment (ACE).

When is an EEI Filing not required?

- An EEI filing is not required for shipments from the U.S. to Canada unless the merchandise is subject to ITAR, requires an export license or permit, is rough diamonds or transiting Canada for another foreign destination.
- An EEI filing is not required for shipments to Guam, American Samoa and the North Mariana Islands
- Other exemptions or exclusions as listed in the Foreign Trade Regulations

Penalties for EEI non-compliance

- Civil penalties increased for late filing - $1,100 per day up to a maximum of $10,000
- New criminal penalties were implemented for filing false and/or misleading information, up to $10,000 or imprisonment for not more than five years, or both, for each violation.
- These penalty provisions are administered by U.S. Customs and Border Protection (CBP).

Export Topics: EU Perspective

IV. Creating an International trade compliance program:

Using the Trade Compliance Scorecard Method™ to identify & manage risks

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Trade Compliance Scorecard Method™

Step 1: Evaluate

Here is the link to the Trade Compliance scorecard quiz: https://www.dsgglobal.com/trade-quiz

- 10 Administrative elements
- 10 Technical elements (Imports)
- 10 Technical elements (Exports)

Step 2: Develop a Compliance Improvement Plan

Step 3: Implement and Monitor the Compliance Improvement plan

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Administrative Elements

1. Management commitment
2. Organizational structure / Designated CO
3. Written procedures
4. Training
5. Recordkeeping
6. 3rd Party Management
7. Risk assessment (internal & external audits)
8. Voluntary disclosures
9. Audit readiness
10. Periodic program enhancements

IMPORT Elements

1. Tariff Classification
2. Customs Valuation
3. Related Party Issues
4. Country of Origin
5. Free Trade Agreements
6. Participating Govt agencies
7. Supply Chain Security
8. Customs duty management (ADD/CVD, Section 301/232)
9. Duty minimization strategies
10. Forced Labor (ULFPA)

EXPORT Elements

1. Jurisdiction (State / Commerce)
2. ECCN
3. Export licensing
4. Deemed Exports
5. Restricted party screening
6. Know your customer (End-use, End-user)
7. Embargoes, Sanctions, Anti-boycott
8. FCPA
9. Encryption
10. Re-exports & Technology transfer

ADMINISTRATIVE ELEMENTS

Management commitment

a. Formalize Written Policies
b. Allocate Adequate Resources
c. Promote a Compliance Culture
d. Accountability and Enforcement

Organizational structure & TCO

a. Designate someone with the overall responsibility for the import and export compliance program, in the capacity of a “Trade Compliance Officer”
b. Formal Appointment & Qualifications and Training
c. Clear Role Definitions
d. Organizational Support and Independence

Written procedures

a. Identify key compliance processes
b. Organize a Compliance Policy manual with clear procedures
c. Training and acknowledgment
d. Maintain and update

Training

a. Develop a formal & mandatory training program
b. Document attendance
c. Test & measure effectiveness
d. Update content continuously
e. Provide job-specific learning

Recordkeeping

a. Define what records are required
b. Define retention periods
c. Centralize & Standardize Record Storage & Disposal
d. Assign Ownership & accountability

3rd Party management

a. Formal Broker & Vendor oversight program: Establish key performance indices and metrics for measuring performance
b. Have a list of approved brokers and have a method to qualify existing or new local brokers.
c. Review customs broker bills periodically to ensure the best rates are used, no excess storage fees or other costs are incurred from shipping errors.
d. QBR's & Annual Broker/Vendor compliance review

Risk Assessment

a. Establish a Formal Internal Audit Program
b. Track Findings and Corrective Actions (CIP)
c. Develop a Formal Audit Response Protocol
d. Engage External Expertise Where Needed

Voluntary disclosures

a. Voluntary disclosure permits the company to correct an error, prior to discovery by the government.
b. The TCO must have a documented internal program for handling compliance problems, including reporting violations to senior management and to the regulatory authorities.
c. Prior to disclosure, all trade compliance risks should be notified to Legal.
d. Any issue with financial exposure also needs to go to the financial controller.

Program enhancements

a. Keep pace with regulatory change
b. Address emerging enforcement priorities
c. Adapt to business expansion

IMPORT ELEMENTS

HTS Classification

a. Formal classification procedure
b. Cross-functional alignment
c. Centralized classification database
d. Implement broker controls
e. Periodic classification audits
f. Request binding ruling for high risk items

Customs valuation

a. Establish a formal customs valuation policy.
b. Valuation scenarios (Prototypes, repairs, stock transfers etc) need to be documented in a Valuation policy.
c. Coordinate Tax & Customs
d. Implement “assist” tracking
e. Review royalties
f. Where pricing fluctuates, enroll in CBP reconciliation.

Related party issues

a. In related party transactions, ensure that the relationship did not influence the price and that the price includes all costs plus a reasonable profit to the foreign seller.
b. Document tax & customs transfer pricing policy
c. Train Finance & Tax teams on customs transfer pricing

Country of Origin (COO)

a. Formal origin determination policy
b. Train procurement & engineering teams on substantial transformation & assembly.
c. Maintain origin documentation
d. Conduct supplier origin audits, based on manufacturing steps & country claims

Free Trade Agreements (FTA)

a. If products are sourced from a FTA country for reduced duty, ensure that they are compliant with originating requirements, record retention, etc.
b. Maintain COO documentation / documented analysis
c. Periodic FTA audits
d. Binding rulings, where necessary

Supply Chain security

a. Work with your cross-functional team to maintain the Supply Chain Security program or CTPAT.
b. Ensure foreign supplier due diligence.
c. Prepare domestic and foreign locations for validations.
d. Also be aware of security programs (such as AEO, C-TPAT, PIP, FAST etc.) offered by local governments and participate in those programs.

Customs duty management

a. Conduct proactive HTS classification and scope analysis to identify ADD/CVD and 301/232 exposure
b. Maintain direct ACE Portal access and review ACE reports to identify duty spikes, inconsistencies, and AD/CVD flags
c. Conduct periodic internal audits of ACE data accuracy and broker performance

Duty minimization strategies

a. Duty minimization strategies may include FTA claims, First Sale, FTZ usage, drawback, and tariff engineering
b. Maintain robust documentation
c. Ensure all strategies are grounded in documented legal analysis (classification, valuation, origin)
d. Obtain binding rulings for high-risk or high-dollar strategies

Forced Labor (ULFPA)

a. CBP detains shipments under a rebuttable presumption of forced labor
b. Train sourcing compliance teams on forced labor red flags
c. Conduct documented supply chain mapping to the raw material level (i.e. formal UFLPA risk assessment framework)
d. Maintain traceability documentation (P.O, invoices, transportation, production flow charts)
e. Conduct periodic onsite supplier audits or third-party verification, if feasible.

EXPORT ELEMENTS

DSG Global Academy

International trade made easy

ECCN

- ECCN classification errors are a high enforcement risk
- Technically complex & increasingly scrutinized (especially for high-risk countries)

- <u>Ensure</u>:
  - Documented analysis
  - Technical staff/Engineering involvement
  - CCATS use
  - Continuous monitoring

Export licensing

a. Train sales, engineering, and logistics
b. Apply Country Chart + General Prohibitions analysis consistently
c. Validate eligibility before using license exceptions/exemptions
d. Maintain a centralized license tracker

Deemed Exports

a. Provide training to engineering, IT, and HR teams, before onboarding foreign nationals
b. Conduct nationality risk analysis (including dual citizenship)
c. Implement Technology Control Plans (TCPs) for physical + IT access controls
d. Apply for deemed export licenses before access is granted

Restricted party screening

a. Screen all parties to the transaction
b. Use automated screening tools with daily list updates
c. Conduct screening at multiple points: onboarding & pre-shipment.
d. Train sales, logistics, and finance teams on red flags and escalation procedures
e. Maintain an audit trail of screening results & false positive resolution

Know your customer (end-use, end-user)

a. Enhanced due diligence for high-risk destinations (e.g., China, Russia, Iran, UAE transshipment risk)
b. Screen for military, government, or state-owned enterprises
c. Perform documented end-use review for all controlled items (military, WMD, semiconductor, AI, aerospace risk)
d. Identify and verify the ultimate end-user, not just the distributor or reseller
e. Obtain end-use statements or certifications for higher-risk transactions

Embargoes, Sanctions, Boycott

a. Maintain a formal sanctions & anti-boycott compliance policy aligned with OFAC, BIS, and anti-boycott regulations
b. Detect, review (escalate) and report anti-boycott requests
c. Integrate sanctions review into sales, procurement, shipping, and payment workflows

FCPA

a. Establish a strict written anti-corruption policy to prohibit improper facilitation payments
b. Provide training to sales, procurement, logistics, and finance teams
c. Include anti-corruption clauses & annual certifications in contracts
d. Implement accounting controls and require documented approval for any gifts, hospitality etc.
e. Maintain a confidential whistleblower process

Encryption

a. If software present, perform a documented encryption analysis
b. Determine eligibility for License Exception ENC and confirm reporting requirements
c. If applicable, submit required encryption registration and annual self-classification reports

Next steps

1) Step 1. Evaluate
   - 10 Administrative elements
   - 10 Technical elements (Imports)
   - 10 Technical elements (Exports)

2) **Step 2: Develop a Compliance Improvement Plan**

3) **Step 3: Implement and Monitor the Compliance Improvement plan**

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International trade made easy

Thank you!

Please feel free to contact us for any information:

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- Tom Sidebottom, Founder & Principal Consultant, Regulatory Science Consulting, LLC., tom@regsciences.net

DSG Global Academy

International trade made easy

BSMA
Bio Supply Management Alliance
Because Life Depends On Us™

BSMA 18th Annual Summit 2026

Workshop 3: Mastering International Trade Compliance in Life Sciences

Tuesday March 17, 2026

Foster City, California

Tom Sidebottom

RS
RegulatoryScience
CONSULTING

Tom Sidebottom
Regulatory Science Consulting LLC

Contact Information:

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Biography

Tom Sidebottom lives and works in the SF Bay Area and for 30 years shares his passion to understand the regulatory pressures on industry and to work increasing compliance in the changing regulatory landscape. Tom joined the private sector in 2020 as a regulatory consultant and in 2022 established his company Regulatory Science Consulting LLC. He brings over 32-years of federal service with the U.S. Food and Drug Administration (FDA), including 11 yrs as the San Francisco Laboratory Director. During those 11 years, Tom often provided outreach through CBFANC to the broker and importer communities in the Bay Area by sharing insights into regulatory processes of imports, sharing best practices in regulatory science and how to navigate the challenges with FDA's DWPE and Import Alert products. He has a keen interest in AI and deep model learning tools to ease regulatory burdens, increase compliance and strengthen global standards of regulated products.

Contact Info:

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Objectives:

BSMA
Bio Supply Management Alliance
Because Life Depends On Us™

1. FDA's Role at the Border
2. FDA Product Categories That Affect Imports
3. Common FDA Import Errors That Cause Detentions
4. FDA Import Detention & Refusal Process
5. Best Practices for Trade Compliance Teams
6. Bonus Topic Data & AI (time permitting)

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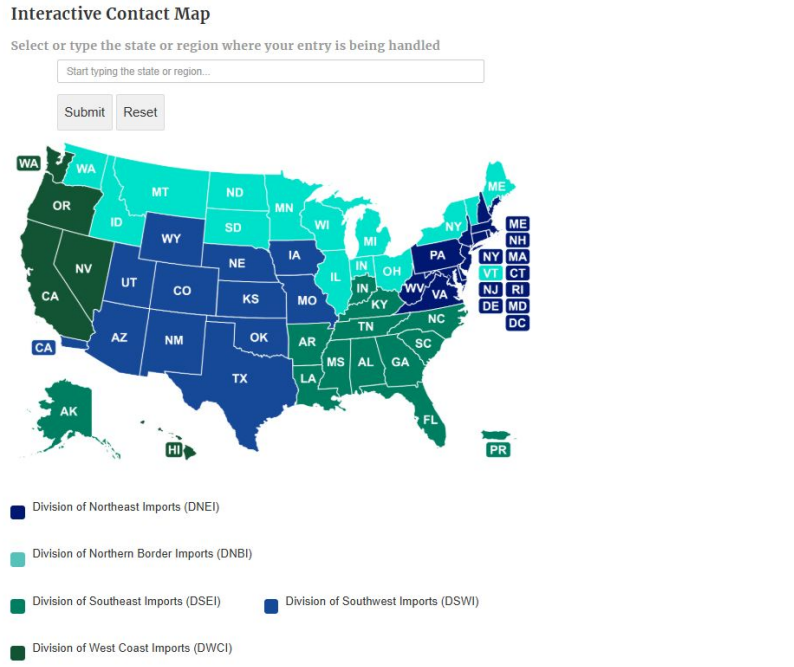
FDA's Role at the Border

- Ensure regulated products meet FDA requirements
  - ~300,000 Registered Facilities
  - ~20% of all Imports are FDA regulated products
  - ~78% API's
  - ~49 % Medical devices used in US
  - 96% Biological sale in US

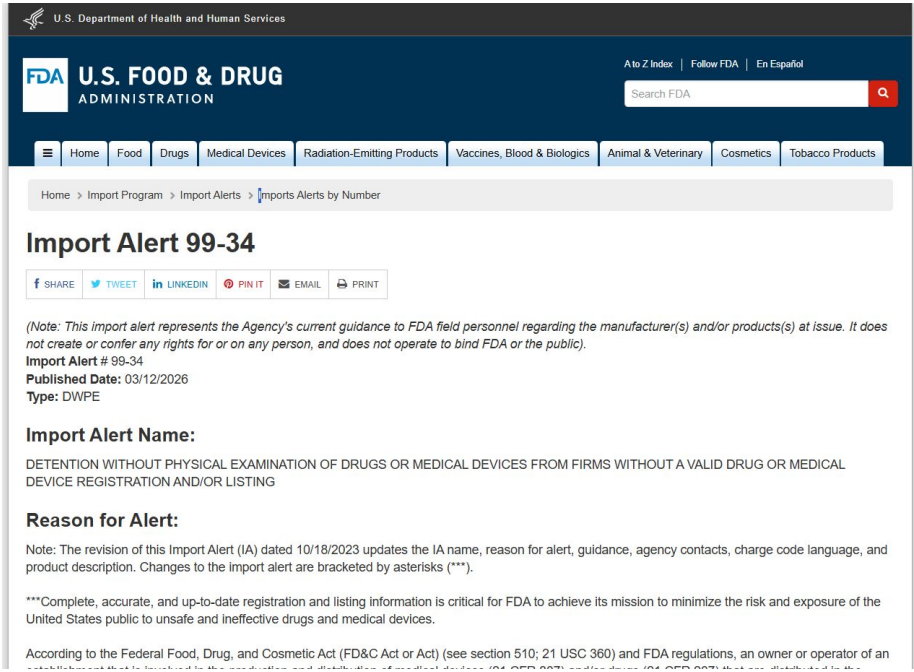
- Protect Public Health
- Entry Ports:
- Land, Air, Sea & International Mail & Courriers

- FDA Import Resources: https://www.fda.gov/industry/import-program



FDA's Role at the Border: How does that work?

- ACE filings with CBP
- ACE talks with ITACS
- ITACS Issues a Notice of Action
- FDA determines admissibility of testimony provided & affirmation of compliance
    - product code
    - manufacturer identification & registration
    - product & process registrations
    - intended use designation
- May Proceed –Detention-Refusal-Destruction-Expo
- Import Alerts
- W/L's and Administrative Penalties


U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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Home > Import Program > Import Alerts > Imports Alerts by Number

Import Alert 99-34

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

Import Alert # 99-34

Published Date: 03/12/2026

Type: DWPE

Import Alert Name:

DETENTION WITHOUT PHYSICAL EXAMINATION OF DRUGS OR MEDICAL DEVICES FROM FIRMS WITHOUT A VALID DRUG OR MEDICAL DEVICE REGISTRATION AND/OR LISTING

Reason for Alert:

Note: The revision of this Import Alert (IA) dated 10/18/2023 updates the IA name, reason for alert, guidance, agency contacts, charge code language, and product description. Changes to the import alert are bracketed by asterisks (***).

***Complete, accurate, and up-to-date registration and listing information is critical for FDA to achieve its mission to minimize the risk and exposure of the United States public to unsafe and ineffective drugs and medical devices.

According to the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act) (see section 510; 21 USC 360) and FDA regulations, an owner or operator of an

- FDA Import Resources: https://www.fda.gov/industry/import-program

FDA Product Categories That Affect Imports

FDA Product Categories that Affect Imports

- Pharmaceuticals (finished drugs)
- Active Pharmaceutical Ingredients (API
- Clinical trial materials
- Medical devices
- Diagnostic reagents
- Biological samples
- Combination products

How to start importing FDA-regulated products

- Importing FDA-Regulated Products
  Information and requirements for importing FDA-regulated products
- Entry Submission Process
  Information you need to file an entry with the FDA
- Import Systems
- Information regarding the electronic import systems the FDA utilizes to review and validate entry data and information
- FEI Portal (NEW)
  Look up a FDA Establishment Identifier (FEI) based on a firm name and address or validate an address of an FEI

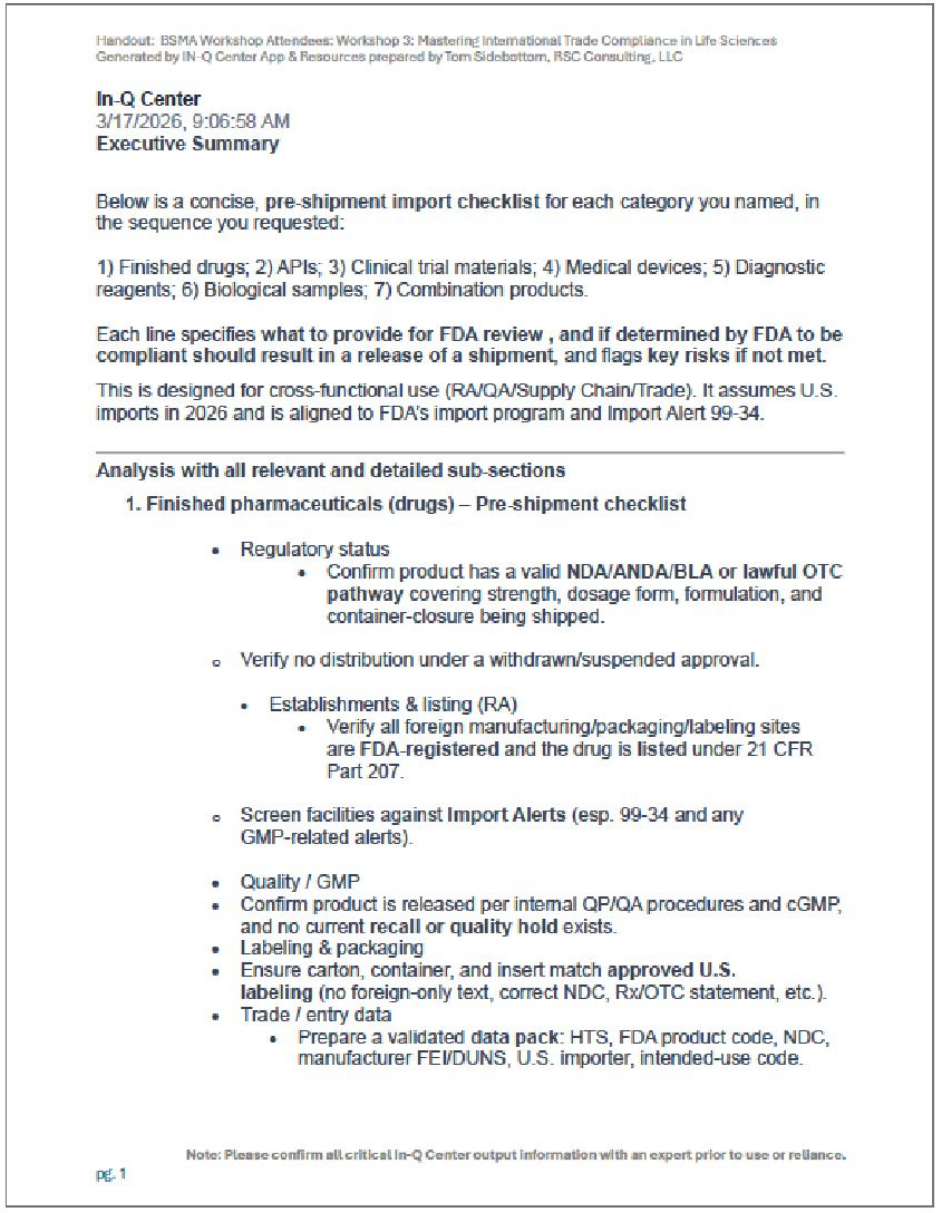
Is Your Shipment on Hold?

- Check the Real-Time Status of your Entry Now!
  Check entry status, estimated lab completion date, submit documents electronically, provide location for FDA examination, and retrieve Notices of FDA Action in ITACS
- Examination & Sample Collection
  What to expect when your product is examined/sampled by the FDA
- Actions & Enforcement
  Types of FDA actions, enforcement and compliance activities
- Import Alerts
  Overview and import alert lists by country, product and number

FDA Product Categories That Affect Imports (con't)

- *When filing an entry "may not" be required:*
- **Consumption entry (CE),** formal and informal entries, in-transit entry (IT), mail entry, personal baggage entry, warehouse entry, etc.
- **Mail Entry**: "Merchandise offered for entry through the mail. Where the value of the merchandise is less than $1,000, an entry document is generally not required to be filed with Customs.

- Workshop Aid- Pre-shipment Checklist
  - Pharmaceuticals (finished drugs)
  - Active Pharmaceutical Ingredients (APIs)
  - Clinical trial materials
  - Medical devices
  - Diagnostic reagents
  - Biological samples
  - Combination products



Handout: BSMA Workshop Attendees: Workshop 3: Mastering International Trade Compliance in Life Sciences
Generated by IN-Q Center App & Resources prepared by Tom Sidebottom, RSC Consulting, LLC

In-Q Center
3/17/2026, 9:06:58 AM
Executive Summary

Below is a concise, **pre-shipment import checklist** for each category you named, in the sequence you requested:

1) Finished drugs; 2) APIs; 3) Clinical trial materials; 4) Medical devices; 5) Diagnostic reagents; 6) Biological samples; 7) Combination products.

Each line specifies **what to provide for FDA review , and if determined by FDA to be compliant should result in a release of a shipment**, and flags **key risks if not met.**

This is designed for cross-functional use (RA/QA/Supply Chain/Trade). It assumes U.S. imports in 2026 and is aligned to FDA's import program and Import Alert 99-34.

Analysis with all relevant and detailed sub-sections

1. **Finished pharmaceuticals (drugs) – Pre-shipment checklist**

- Regulatory status
  - Confirm product has a valid **NDA/ANDA/BLA or lawful OTC pathway** covering strength, dosage form, formulation, and container-closure being shipped.
- Verify no distribution under a withdrawn/suspended approval.
  - Establishments & listing (RA)
    - Verify **all foreign manufacturing/packaging/labeling sites are FDA-registered** and the drug **is listed** under 21 CFR Part 207.
- Screen facilities against **Import Alerts** (esp. 99-34 and any GMP-related alerts).
- Quality / GMP
- Confirm product is released per internal QP/QA procedures and cGMP, and no current **recall or quality hold** exists.
- Labeling & packaging
- Ensure carton, container, and insert match **approved U.S. labeling** (no foreign-only text, correct NDC, Rx/OTC statement, etc.).
- Trade / entry data
  - Prepare a validated **data pack**: HTS, FDA product code, NDC, manufacturer FEI/DUNS, U.S. importer, intended-use code.

Note: Please confirm all critical In-Q Center output information with an expert prior to use or reliance.

pg. 1

Common FDA Import Errors That Cause Detentions

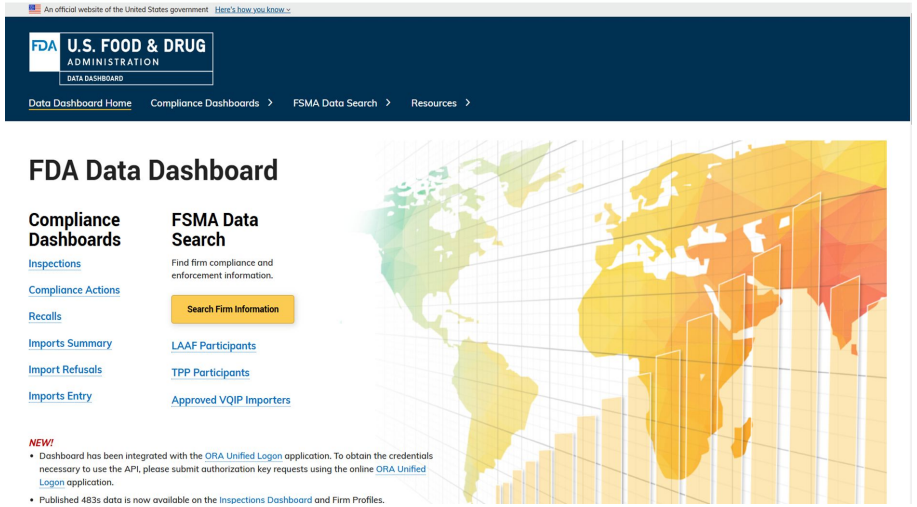
1. Missing or invalid FDA establishment registration and/or product listing
2. Unapproved or inappropriate product
   (including foreign versions of approved drugs/devices)
3. Inaccurate or incomplete entry data
   (product codes, intended use, firm identifiers)
4. Failure to respond adequately or on time to FDA detention notices
5. Non-English or non-compliant labeling
6. Products appearing adulterated (quality/safety failures)
7. Importing from firms or countries on import alerts (DWPE)
8. Misuse or misclassification of investigational or RUO/IUO products
   (Research Use Only / Investigational Use Only)
9. Poor filer performance and systemic entry submission problems
10. Failure to appreciate that “appearance” alone is enough for refusal

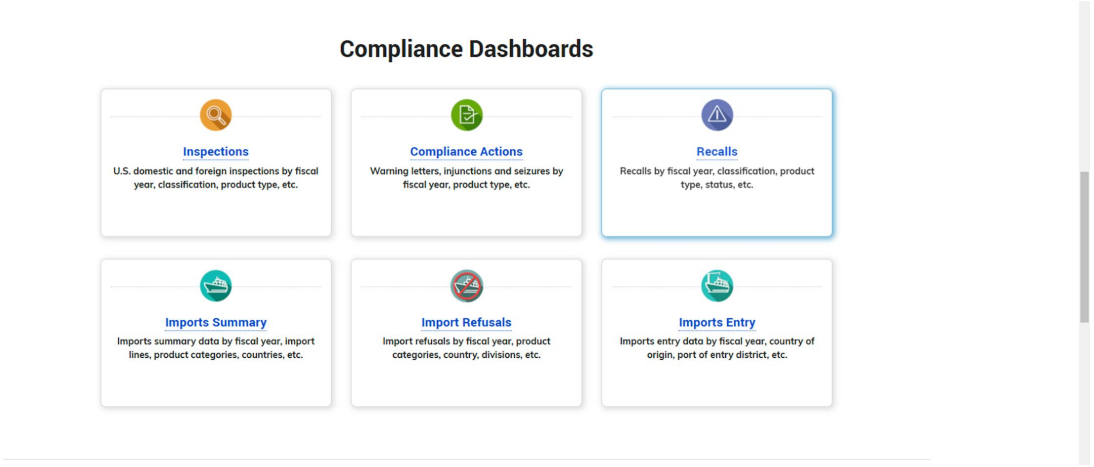
5 Best Practices for Trade Compliance Teams

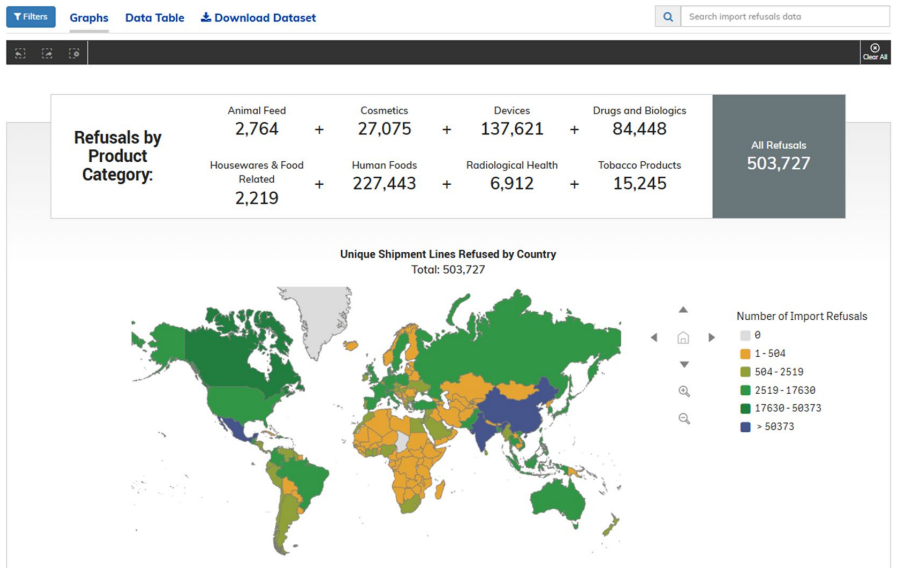
FDA-regulated imports (drugs, biologics, devices, diagnostics, combination products), trade compliance must tightly integrate **customs requirements** with **FDA admissibility**.

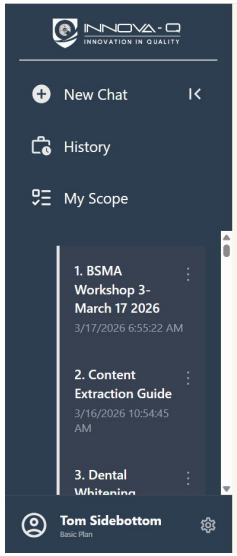
1. Centralize and control import master data (HTS, FDA product codes, FEI/DUNS, approvals, registrations).
2. Build a structured broker management and filer-quality program.
3. Embed FDA regulatory checks (approvals, registration/listing, import alerts) into pre-shipment release.
4. Standardize responses to FDA detentions and Notices of FDA Action.
5. Continuously monitor FDA/CBP changes and update SOPs and training.

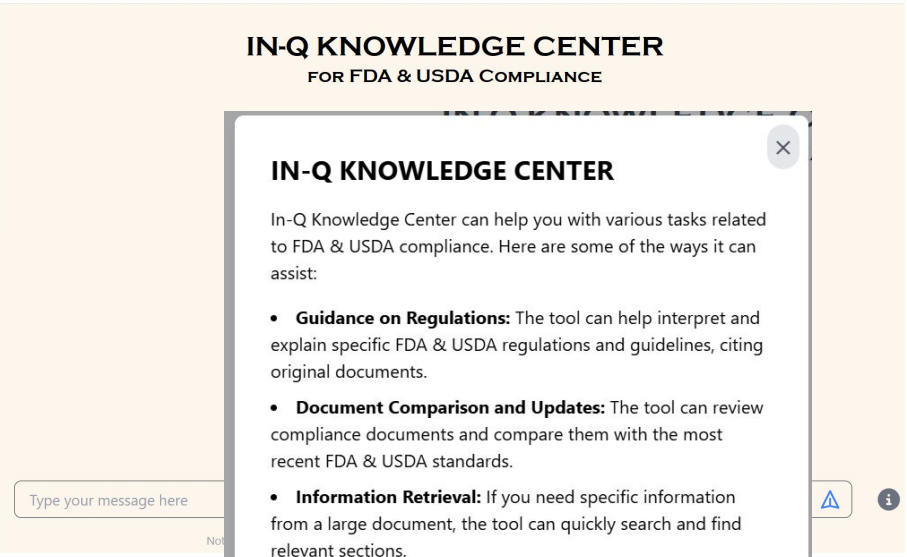
• Bonus Topic Data & AI





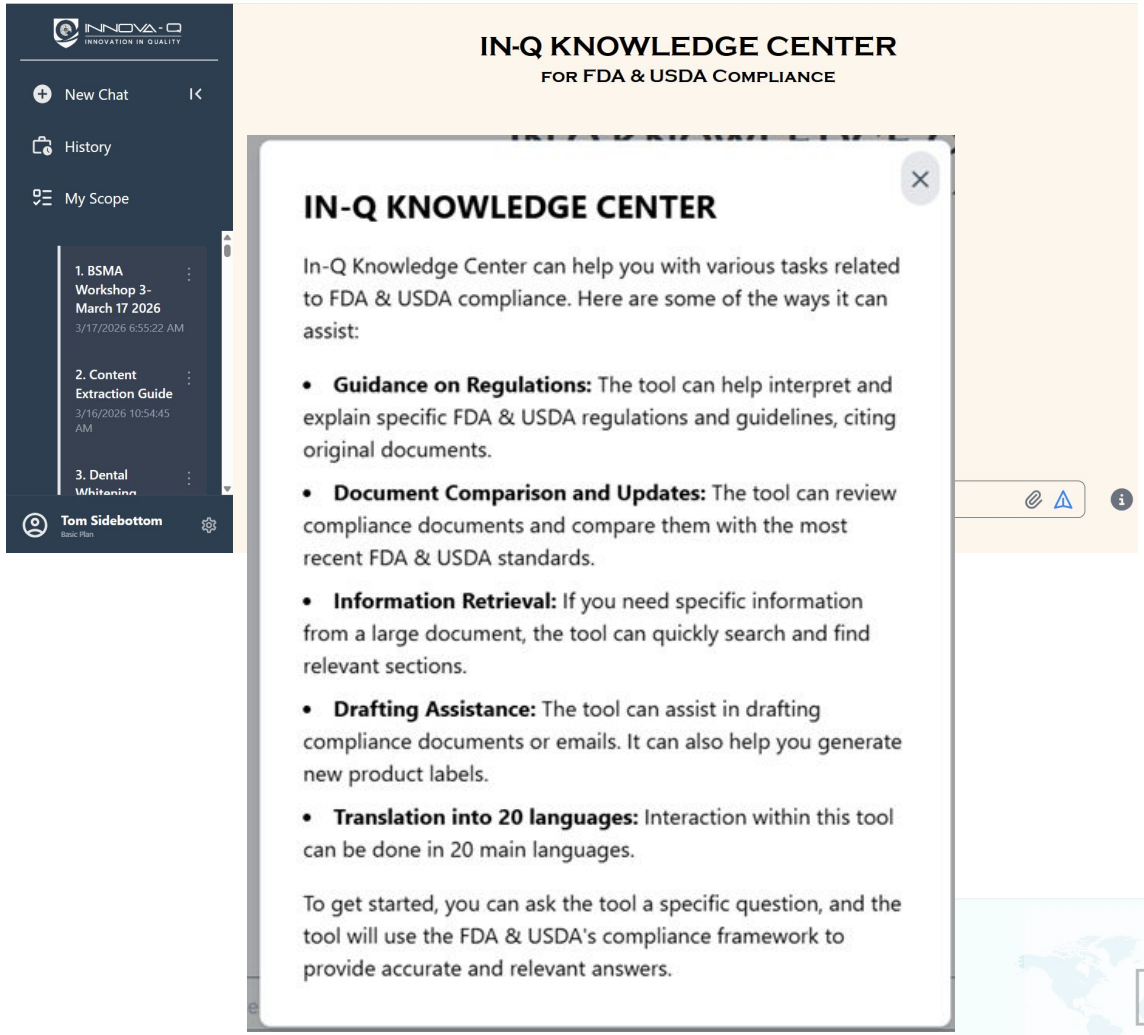






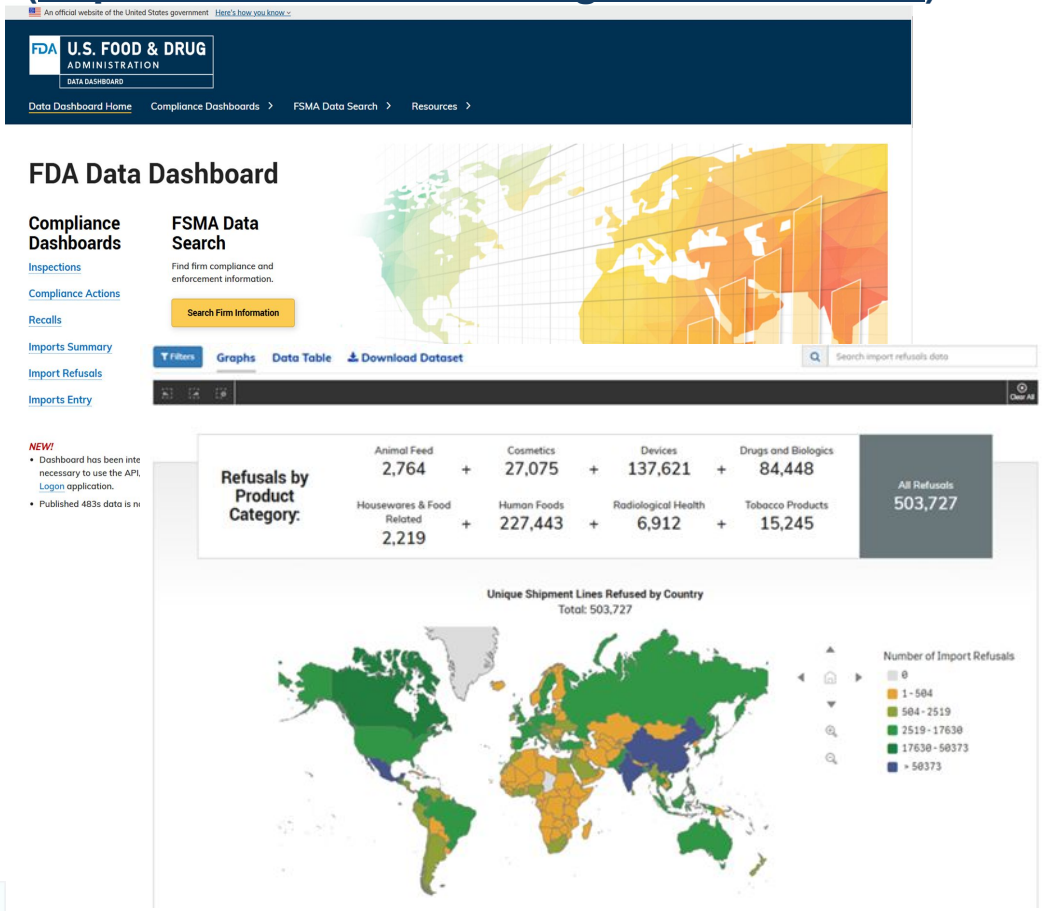
Demo AI & Data

- **IN-Q Knowledge Center**
  (https://inq-center.innovaqual.com)



FDA Data Dashboard

(https://datadashboard.fda.gov/oii/index.htm)



FDA Dashboard Links

- Import Data:
  - Summary: https://datadashboard.fda.gov/ora/cd/impsummary.htm
  - Refusals: https://datadashboard.fda.gov/ora/cd/imprefusals.htm
  - Entries: https://datadashboard.fda.gov/ora/cd/impentry.htm
- LAAF: https://datadashboard.fda.gov/ora/fd/laaf.htm
- FSMA Firms & Suppliers: https://datadashboard.fda.gov/ora/fd/fser.htm
- 3rd Party Certifiers: https://datadashboard.fda.gov/ora/fd/tpp.htm

Prepared by Tom Sidebottom, RSC Consulting LLC.

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BMSA Workshop – VAT Recovery & Compliance

VAT Recovery and Compliance Obligations on Global Trials/Studies

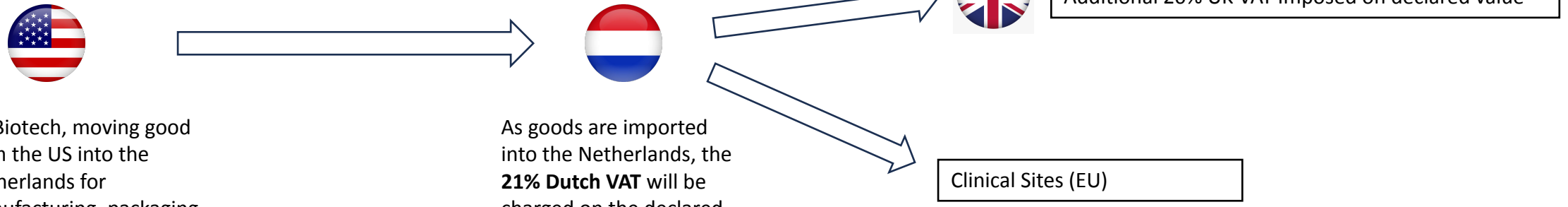
VAT IT reclaim.

Foreign VAT exposure often results from VAT incurred on:

Import VAT

Beyond the initial R&D phase, clinical trials often require the movement of products, including APIs, medicines, and biological materials like plasma and tissue samples. Conducting trials across multiple jurisdictions can lead to substantial import VAT costs when bringing these goods into a country for processing or testing, many of which may be recoverable.

Example:



US Biotech, moving good from the US into the Netherlands for manufacturing, packaging, etc.

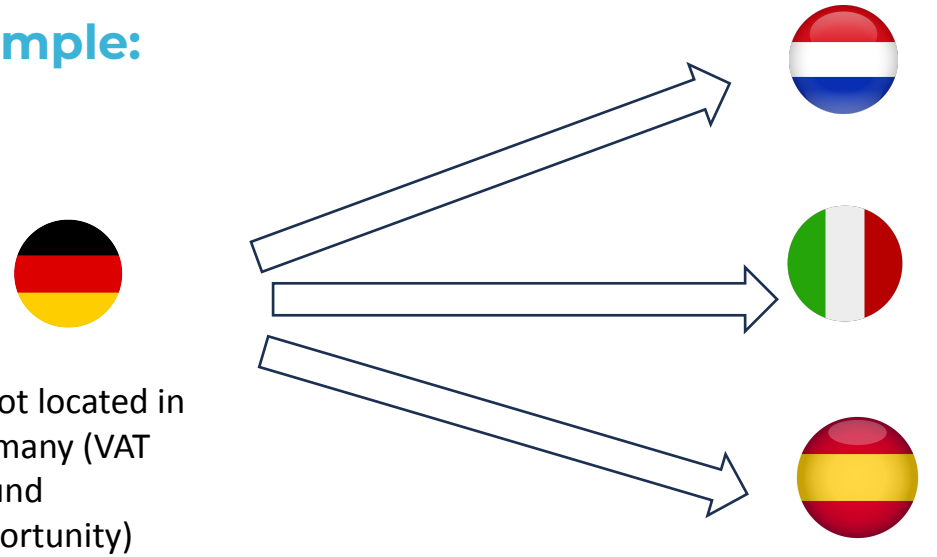
As goods are imported into the Netherlands, the **21% Dutch VAT** will be charged on the declared value of the goods

VAT Compliance & Reporting obligations as a result of Intra-EU movements:

Intra-EU Reporting Obligation (Only applicable for the EU)

- Ownership of Goods is the trigger
- Must VAT Register in each country and report the movement
- Compliance opens the door to VAT refund opportunity.
- Penalties and Fines for non-compliance (Shipments held up + fines - Horror story)

Example:



VAT Reporting Obligation in all 4 countries!

VAT Compliance & Reporting Scenarios

Most common scenario: “My CMO, CRO or CDMO is handling this.”

- Your CMO, CRO or CDMO helps you move the goods and execute necessary services; however, they are not nor can they report these movements as they DO NOT own the goods.
- Each CDMO has its own methods of movement to negate VAT charges upfront (PVA, Article 23, 56B, etc.).
- Ownership and Intra-EU movements trigger the reporting and registration obligation.
- Examples: CDMO’s – review your agreements to see who has ownership of the goods.

Foreign VAT exposure –
Other Areas of VAT that can be reclaimed

MEETINGS, EVENTS, CONFERENCES, CONVENTIONS & TRADE SHOWS

Tradeshows, meetings, events and conferences in the pharmaceutical industry generates huge spend which may be eligible VAT for recovery.

VAT on event registration, attendance fees, transport costs, accommodation and other expenses are just some of the expense categories where a VAT saving could be made.

OTHER HIGH VALUE EXPENSES

- Specialized labelling, packaging and distribution costs
- Destruction of samples, trial material and out of date products according to safety standards
- Drug marketing costs
- Travel and entertainment (domestic & foreign)
- Comparator sourcing
- API costs
- Research and Project Costs

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Dale Bushell – Director, Pharmaceuticals

Email: dale.bushell@vatit.com

Phone: +1 (757) 617 6329

arvato

What are the main import & export compliance topics in the European

Maja Kuhnt | Arvato SE – BSMA

17.03.2026

BSMA Annual Summit 2026

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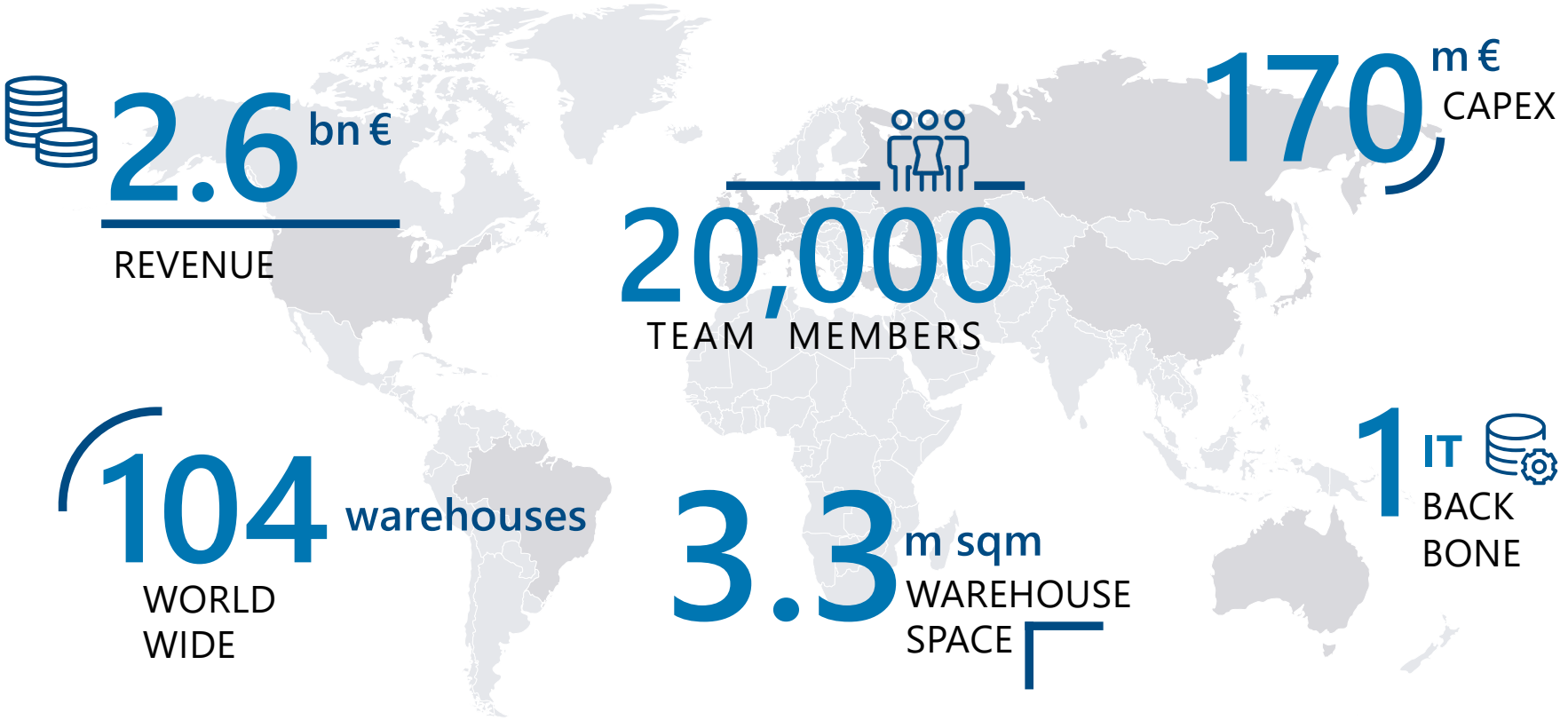
KEY FIGURES 2024

- **€19 bn** group revenues
- **€3.1 bn** operating EBITDA
- **> 75,000** team members
- **> 50** countries

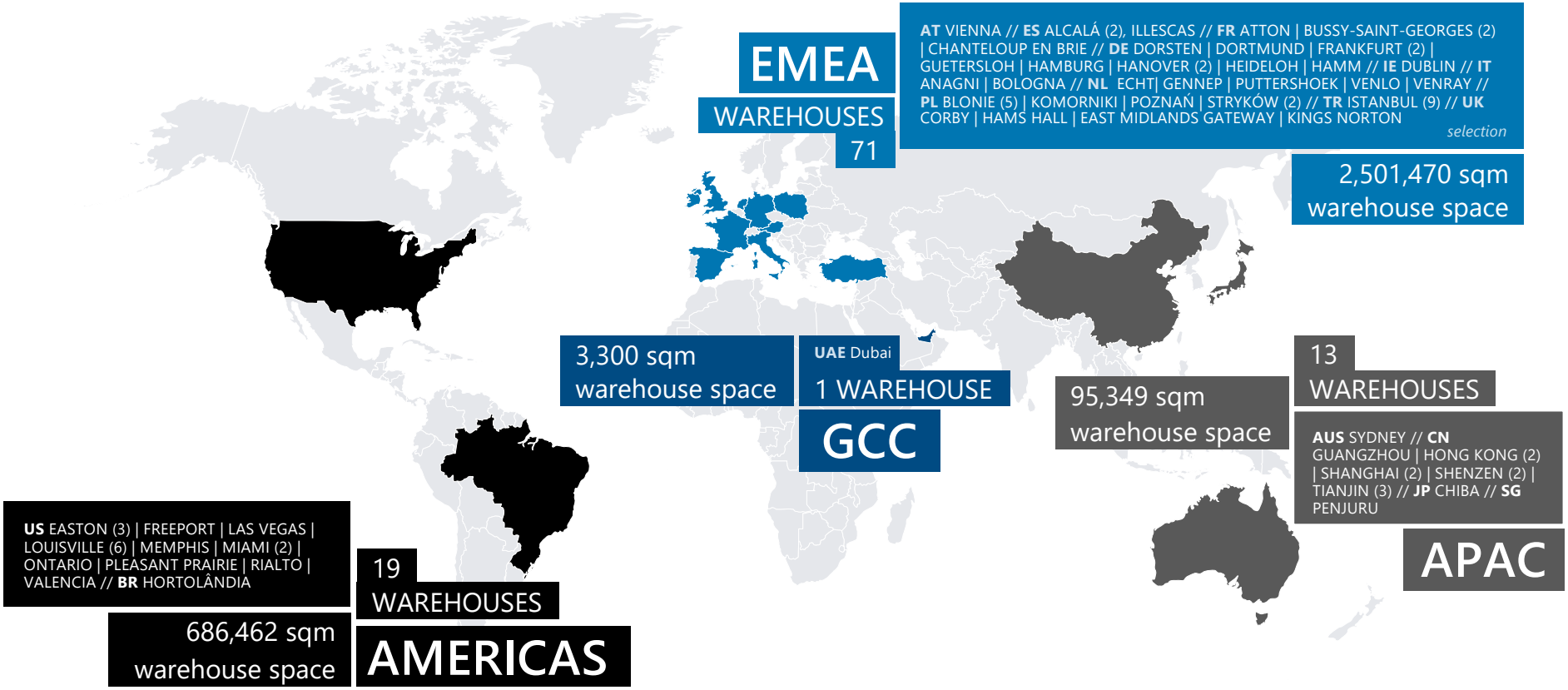
Arvato at a glance 2024

104 warehouses in 17 countries, totaling 3.3 million square meters worldwide



Our global footprint 2024

104 warehouses in 17 countries, totaling 3.3 million square meters worldwide



BSMA Annual Summit 2026

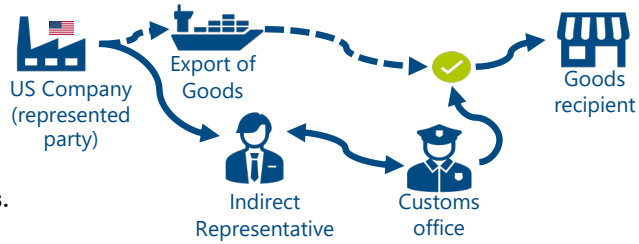
Who is presenting…?

Maja Kuhnt
(Director Competence Center
Group Customs & Trade)

I am a European customs specialist with over 20 years of experience in customs for different industry sectors. Since joining Arvato in 2013, I have supported major healthcare and pharmaceutical companies implementing customs processes in the European Union. I later served as a Team Lead and now oversee Group Customs activities across Europe, including authority interactions, compliance policies, and risk assessments.

BSMA Annual Summit 2026

What are the main import compliance topics in the European Union that Life-sciences, pharma, clinical trial companies need to be aware of?



Import VAT &
Representation in the EU

Imports into the EU are subject to import VAT in the country where customs clearance takes place.
VAT is **not harmonized** within the EU, and the applicable rates vary slightly between the individual Member States.

The company liable for duties and VAT must be **established in the EU**.
Non-EU resident companies may appoint a representative for customs clearance and import VAT when the importer cannot present an EORI number associated with EU residency. This is referred to as **indirect representation.** The indirect representative is jointly and severally liable for any customs duties and import VAT.

Country of Origin &
Preferential documents

With over 40 agreements covering 70+ countries correct origin determination is crucial when benefiting from free or reduced duty rates in the EU
Determining the correct **origin rules per agreeement** and the appropriate **wording** for origin declarations can be challenging, given that the EU has more than 50 years history of free trade agreements with different rules and contracting parties.

As customs offices intensify their inspections on preferential treatment, the following represent the most frequent errors:

- Formal errors (e.g. incorrect wording)
- Wrong origin statement/declaration (e.g. REX instead of EUR.1)
- Miscalculated origin (e.g. not all costs incluced or not sufficiently processed)

What are the main import compliance topics in the European Union that Life-sciences, pharma, clinical trial companies need to be aware of?

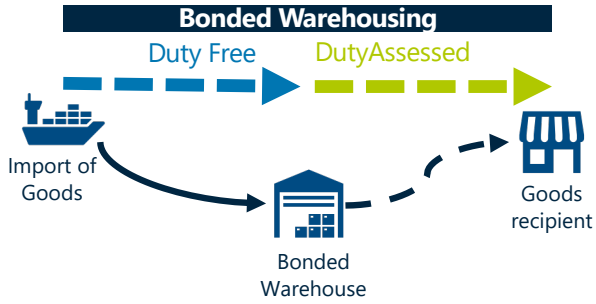
Special Customs Procedures

The UCC (Union Customs Code) provides the legal framework for simplified procedures and special customs procedures that can offer duty relief or deferment, such as:

- Inward processing
- Temporary storage
- Bonded warehousing

All procedures require proper warehouse handling and **accurate tracking of goods** from inbound to outbound. Material master data and a reliable IT system are crucial, as all inbound and outbound activities are transmitted to customs. Customs and the warehouse owner must have identical stock figures, and **cycle counts** are carried out regularly together **with the customs authority**.
Inventory discrepancies can result in the assessment of customs duties and VAT.

The warehouse or procedure holder must be established in the EU and may be a customs representative.



BSMA Annual Summit 2026

What are the main export compliance topics in the European Union that Life-sciences, pharma, clinical trial companies need to be aware of?

EU Sanctions &

Re-export controls

The EU has a comprehensive sanctions regime that covers not only transactions with sanctioned countries, but may also affect transactions involving **non-sanctioned countries**.

Sanctions are published by the EU and are legally binding for all Member States.
Although Member States may issue their own administrative guidelines for implementation, the legal basis is identical across all 27 countries.

A solid **internal control system (ICS)** and an effective communication process are required to prevent **circumvention** through non-sanctioned countries.
Inadequate screening procedures, missing internal controls or documentation, as well as the absence of end-use and end-user checks, are considered organizational negligence or a breach of supervisory duties by management.

Re-exports pose an additional risk and are often a challenge for companies.
The EU provides guidance on internal monitoring processes and contractual arrangements to support compliance.

What are the main export compliance topics in the European Union that Life-sciences, pharma, clinical trial companies need to be aware of?

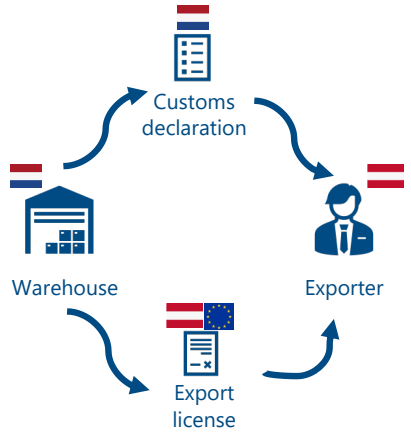
Export Licensing Procedures

The EU export control system operates under a **two-layer structure**:
1.EU-level rules – a harmonized legal framework, a common EU Dual-Use List, and standard authorisation types.
2.National-level implementation – Member States issue licences, enforce compliance, and apply penalties.

The EU provides several pre-approved EU General Export Authorisations (EUGEAs) that are valid across all Member States for low-risk destinations or items, reducing administrative burden and improving regulatory harmonization.

Be aware that an export license may need to be obtained in the **Member State where the exporter is established**, which may differ from the country where the goods physically leave the EU. This can therefore differ from the customs exporter indicated on the export declaration.

For non-EU-based exporters, the regulatory risk shifts automatically to the EU-based customs broker, as only an EU-established entity can act as the customs exporter even though there is no representation possible.

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