Supply Chain Worries Keeping You Up at Night?

What You Need to Know

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Wednesday, October 15, 2014

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Transfer Pricing for Transactions between Affiliates

- U.S. Customs statutes and regulations specify that the “transaction value” as the preferred methodology for determining the customs value of imported products.

- For transactions involving affiliates, the transaction value is an acceptable methodology for determining value so long as the affiliates can establish that:
  - The circumstances of the sale indicate that the relationship between the parties did not affect the price.
  - The transaction value closely approximates the value of identical or similar merchandise determined through the use of one of the alternative valuation methodologies.
“Circumstances of the Sale” Analysis

- CBP Regulation section 152.103(I)(1)(ii): Is the intercompany transfer price consistent with normal pricing practices in the industry.

- CBP Regulation section 152.103(I)(1)(iii): Is the intercompany transfer price adequate to permit the seller to recover its costs plus a profit equivalent to the firm’s overall profit over a representative period for sales of merchandise of the same class or kind.

Alternative Valuation Methodology - “Test Values”

- Use of “test values” to establish that the intercompany transfer price constitutes a bona fide transaction value

- Does the transaction value of the imported products closely approximate:
  - The transaction value of identical or similar products in sales to unrelated purchasers in the United States.
  - The deductive value or computed value for identical or similar merchandise.
Statutory Additions to Purchase Price – Dutiable Assists

- Materials, components, parts and similar items incorporated into or added to the imported products
- Tools, dies, molds and similar equipment used in the production or manufacture of the imported products
- Merchandise consumed in the production or manufacture of the imported products
- Engineering, development, artwork, design work, plans and sketches and similar items used in the design, development, production or manufacture of the imported products

Dutiable Assists

- Recent increased emphasis on identifying and accounting for assists in determining the transaction value:
  - Increase in moving manufacturing operations abroad
  - Increase in research and development activities abroad
Dutiable Asists

- Key challenges in identifying assists
  - Test equipment
  - Engineering, research and development work
  - Master global purchase agreements
  - Apportionment of the value of assists for merchandise distributed beyond the United States

COMMERCIAL CONTRACTING ISSUES

Presented by:
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Have a Written Agreement

- Forms exchanges are unwise (except for commodities)
- UCC/CISG not well adapted to food industry issues

IP Issues

- Who owns the recipe?
- Is there critical know-how?
- Should the supplier be free to work with competitors
  - during the relationship?
  - after the relationship?
Dovetailing with Customer Commitments

- When can you change prices?
- What is the scope of your liabilities to customers?
- Recalls
- Venue/governing law

Dovetailing with Customer Commitments (cont’d)

- Breaches and *force majeure* in the context of requirements or volume commitments
- Can you go elsewhere?
  - On a spot basis only?
  - By signing intermediate or long-term contracts?
- When can you terminate?
Compliance with Pass-Through Commitments

- Confidentiality
- Inspections/certifications
- Regulatory (e.g., ingredients disclosure)

FCPA ENFORCEMENT

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Serious Consequences of FCPA Enforcement

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- 71% anticipate greater FCPA enforcement in wake of recent guidelines

Wal-Mart Says Bribe Probe Cost $439 Million in Two Years


FCPA Enforcement in the Food & Beverage Industry

- ABInBev
- ADM
- American Rice, Inc.
- Chiquita
- DIAGEO
- Kraft Foods
- Tyson
THE BASICS:

The FCPA’s Prohibitions and Essential Elements

TWO MAIN COMPONENTS:

- Anti-Bribery Provisions
- Books and Records and Internal Control Provisions
WHAT IS PROHIBITED?

- Paying or offering to pay “anything of value”
- Directly or indirectly
- To a “foreign official,” or to any other person “while knowing” that all or part of the thing of value will be paid or offered to a foreign official
- Corruptly
- For the purpose of influencing the official in some official act or to secure any improper advantage
- In order to “obtain or retain business”

“ANYTHING OF VALUE”

Examples:
- Cash or a cash equivalent
- Gifts
- Travel expenses and/or payment of personal expenses
- Services
- Golf outings or other entertainment
- Charitable donations
- Medical treatment
- Loans
- Jobs for relatives
Any officer or employee of a foreign government or any department, agency, or instrumentality thereof

- DOJ interprets instrumentality to include employees of state owned or controlled enterprises (“SOEs”)
- No distinction made as to rank or title
“OBTAIN OR RETAIN BUSINESS”

- **“Business Purpose” Test**
  - Includes payments related to the renewal of contracts, the execution or performance of contracts, or the retention of existing business

- **Examples from DOJ/SEC:**
  - Winning a contact
  - Influencing procurement process
  - Circumventing import rules
  - Gaining access to non-public bid tender
  - Evading taxes or penalties
  - Influencing enforcement actions or litigation
  - Obtaining exceptions to regulations
  - Avoiding contract termination

EXCEPTIONS & AFFIRMATIVE DEFENSES

- **Reasonable** and **bona fide** expenditures
- **Directly related** to
  - The promotion or demonstration of product or services or
  - The negotiation, execution or performance of a contract

- **Examples:**
  - Travel and expenses to visit company facilities
  - Travel and expenses for training
  - Travel and expenses for meetings
ENGAGING THIRD PARTIES

- Appropriate due diligence inquiry to expose any potential red flags
- Suggested due diligence
  - Risk-based
- Relationship should be memorialized in writing and contract should include:
  - Anticorruption reps and warranties
  - Audit rights
- Payment mechanism should be transparent and traceable – no cash
- Commission/payment should be reasonable and customary

FOOD SAFETY – RECALL/SUPPLY CHAIN ISSUES

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Greetings from Washington, DC

The President and Cabinet Send Their Regards

Margaret Hamburg, MD
Sylvia Mathews Burwell
Bo and Sunny Also Send Their Greetings

My Dog Goddard Also Says Hello
You know you have a potential problem -- when

How did that product . . . . .
get misbranded after all those people reviewed the labeling?

After you pick yourself off the floor what are you going to do??
**Survival Tips**

- **Stay calm**
  - Take a deep breath and relax.
  - You will get through it!

- **Be methodical**
  - think clearly and logically
  - fully investigate the matter **before**
    drawing conclusions or embarking on a plan
  - carefully manage the situation
    - staff
    - publicity - press
    - FDA

**Develop a Plan**

- **Decide what you are going to do**
  - Build a consensus
  - Take the responsible course of action
    - patient safety of paramount importance
  - Recall/Correction/Market withdrawal/Stock recovery
  - Decide no recall is warranted
  - Prepare appropriate communications

- **Negotiate with FDA**
  - Over what
  - Basis for negotiation
Develop a Plan

- Who is in charge of implementing the plan?
  - In house
  - Out source
- Who is in charge of following up to ensure that the plan is moving ahead?

Corrective and Preventative Action

- Can actions be taken to correct the immediate problem?
- Can the product be reconditioned?
- Must it be destroyed?
  - All lots, some lots
- What changes are being implemented to prevent recurrences
Prevention: The Cornerstone

- Comprehensive preventive controls for human and animal food facilities
- Prevention is not new, but Congress has given FDA explicit authority to use the tool more broadly
- Strengthens for prevention
- Produce safety standards
- Intentional adulteration standards

Food Safety General Approach to Preventive Controls

1. Identify Hazard
2. Understand Cause
3. Implement Preventive Controls
4. Monitor Effectiveness
5. Review & Adjust
Contents of FS Plan

1. Written Hazard Analysis
2. Written Preventive Controls
3. Written Procedures for monitoring the implementation of Preventive Controls
   - including frequency that they are to be performed
4. Written Corrective Action Procedures
5. Written Verification Procedures
6. Written Recall Plan

Examples of Compliance with Prevention Standards

- Sanitation
- Training for supervisors and employees
- Environmental controls and monitoring
- Food allergen controls
- Recall contingency plan
- Good Manufacturing Practices (GMPs)
- Supplier verification activities
Import Safety: Most Groundbreaking Shift

- Current reliance on port-of-entry inspection cannot handle increase in imported food
- Importers now responsible for ensuring that their foreign suppliers have adequate preventive controls in place
- Requires food from abroad to be as safe as domestic

Import Safety Mandates

- Sec. 301. Foreign supplier verification program
  - Requires importers to verify their suppliers use risk-based preventive controls that provide same level of protection as U.S. requirements
- Sec. 302. Voluntary qualified importer program
  - Allows for expedited review and entry; facility certification required
- Sec. 303. Certification for high-risk food imports
  - FDA has discretionary authority to require assurances of compliance for high-risk foods
Import Safety Mandates

- **Sec. 304. Prior notice of imported food shipments**
  - Requires information on prior refusals to be added to prior notice submission

- **Sec. 305. Capacity building**
  - FDA mandate to work with foreign governments to build food safety capacity

- **Sec. 306. Inspection of foreign food facilities**
  - Can deny entry if FDA access for inspection is denied

- **Sec. 201. Targeting of inspection resources**
  - Increased inspection of foreign as well as domestic facilities

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Import Safety Mandates

- **Sec. 307. Accreditation of third-party auditors**
  - FDA can rely on accredited third parties to certify that foreign food facilities meet U.S. requirements

- **Sec. 308. Foreign Offices of the Food and Drug Administration**
  - Establish offices in foreign countries to provide assistance on food safety measures for food exported to the U.S.

- **Sec. 309. Smuggled Food**
  - In coordination with DHS, better identify and prevent entry of smuggled food
Managing the Supply Chain

- Know your suppliers
  - Get references for new suppliers
  - If something in cheaper than other sources – ask why?
  - If something appears suspicious – it probably is

- Audit your suppliers

- Track and trace initiatives
  - Expensive
  - But you know where your ingredients, finished product, packaging, labeling
Thank you!

Please take a moment to fill out the survey that will appear on your screen momentarily.