The Goal

Clear Customs and FDA without detention
How to Respond to an Import Detention By FDA
“Knowledge will give you power, but character respect.”
- Bruce Lee
The Import Process

Exporter find a U.S. Importer

U.S. Importer purchases the goods and must hire a Customs Broker licensed by Customs and Border Protection (CBP)

Once shipped, product information is submitted to CBP by the licensed Customs Broker

If an FDA-regulated product, then FDA is notified during the submission to CBP

CBP defers to FDA on admissibility
The Customs Entry
The Customs Entry

A. Prior Notice of Imported Food

B. “Informal” entries (less than $2,500) – no bond (includes personal entries less than $200)

C. Formal Entries
   – Computerized Entry Systems
   – Entry Information
Entry Information

All entries have the following:

- Entry number
- Entry date
- Importer identification
- Port of entry
- Vessel/voyage information
- Quantity
- Value
- Filer identification
- Harmonized Tariff Schedule (HTS) codes
- Information on foreign shipper
- Country of origin
Entries subject to FDA jurisdiction also have:

- FDA product code
- MID code of the foreign manufacturer
- MID information of the foreign shipper, including city and country, which may or may not be the same as the foreign manufacturer
- The country of origin (which may be different from the country of origin identified for CBP purposes).
- Affirmation of Compliance (A of C) codes
FDA Import Process

1. Importer, broker or other entity submits Prior Notice to FDA
2. Prior Notice System Interface (FDA)
3. ACS/ACE (CBP)
4. OASIS Prior Notice screening (FDA)
5. OASIS/PREDICT electronic admissibility screening (FDA)
6. Examine for bioterrorism or significant health risk?
   - Yes: Prior Notice requirements met?
     - Yes: FDA entry reviewer
     - No: Review for admissibility?
       - Yes: "May proceed" message
         - ACS/ACE FDA "may proceed"
       - No: "May proceed" message
9. Results of exam?
   - Pass: Initial action?
     - 1: Slated field exam
     - 2: Slated lab exam
     - 3: Detain without physical exam
   - Fail: FDA entry reviewer
10. Dashed line indicates Prior Notice may be submitted to FDA using either system.
PREDICT establishes a risk score by analyzing shipment information according to FDA-developed risk criteria, including exporter and manufacturer compliance history, product risk, etc.

Word to the Wise:
*The Best Way to Stay Out of Trouble with FDA is To Stay Out of Trouble With FDA!*
Import Alerts

“Detention Without Physical Examination”

Green lists
Red lists
Yellow Lists
Removal from Import Alert

Mmm...High Fructose Corn Syrup with Extra Mercury!!!
U.S. Food & Drug Administration

Import Alert 02-01

(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 #: 02-01
Published Date: 08/29/2013
Type: DWPE
Import Alert Name: "Detention Without Physical Examination of White or Brown Basmati Rice From India"

Reason for Alert:
From December 1, 1986, through May 31, 1987, 25 of 34 shipments of Basmati rice from India (73%) were detained for filth (rodent, insect, bird, extraneous materials). Of the 25 detentions, 12 were for rodent filth or rodent and insect filth, 12 were for insect filth or insect and bird filth. The 25 detentions represented 11 different shippers.

A review of entry data indicates that filth continues to be a problem. The detention rate for FY'95 was 28% and FY'96 was 37%. Shipments were detained from 9 different firms in FY'95 and 12 different firms in FY '96.

Guidance:
Districts may detain, without physical examination, all shipments of white or brown basmati rice from India, except those shipments from the shippers identified in the Green List or shipments of basmati rice that are specifically destined for further processing.

Contact the Division of Field Science for questions or issues concerning science, science policy, sample collection, analysis, preparation, or analytical methodology at 301-796-6600.

All requests for removal from detention without physical examination should be addressed to DIOP 301-796-0356.

Product Description:
Basmati rice

Charge:
"The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain filth (from rodents, insects, or birds, extraneous materials) [Adulteration, Section 402(a)(3)]."

OASIS Charge Code - FILTHY

Countries

INDIA

(02 D - - 07) Rice, Basmati, Processed (Packaged)

List of firms and their products that have met the criteria for exclusion from Detention without Physical Examination (DWPE) under the Import Alert (a.k.a. Green List)

INDIA

A. B. INDUSTRIES
25 MADHYA MARG SECTOR 7-C , CHANDIGARH, INDIA
02 D - - 07 Rice, Basmati, Processed (Packaged)
Notex: Exempt - 7/13/1993
Date Published: 09/10/2009

ADF Foods Limited
83 & 86 GIDC Industrial Estate , Nadiad, Gujarat INDIA
02 D - - 07 Rice, Basmati, Processed (Packaged)
Date Published: 11/27/2009

Amar Singh Chawdawala
Outside Chaltiwala Gate , Amritsar, Punjab INDIA
02 D - - 07 Rice, Basmati, Processed (Packaged)
Notex: Exempt - 2/10/1994
Date Published: 11/27/2009

Amira Pure Foods Private Limited
21st Mile Stone , Pataudi Road , Gurgaon, Haryana INDIA
02 D - - 07 Rice, Basmati, Processed (Packaged)
Date Published: 09/10/2009

http://www.accessdata.fda.gov/CMS_JA/importalert_1.html
Basic FDA Requirements

- Facilities must be registered with FDA biennially, with Designation of “US Agent” and Consent to Inspection
- Food must be labeled properly
- Good Manufacturing Practices and HACCP
- Food must not be “Adulterated”
- For shelf-stable, sealed foods, “FCE” registration and process filing may be required
- Prior Notice Before Each Entry of Imported Food
FDA Options at time of Entry

- Product is cleared, ready to be removed from the port of entry by importer

- FDA detains product for further review (possible refusal)

- FDA detains product for testing (possible refusal)

“Conditional Release”
“Released with comment”
How to Handle an Import Detention By FDA

- “Notice of Action”
- Sampling
- Opportunity to Present “Testimony”
- Reconditioning (Form 766)
- Release or Refusal
- Released “with comment”
- Re-Export or Destruction
- “Redelivery”
- Fees charged by FDA, other expenses of detention
- Legal appeals
“Notice of FDA Action”

Issued by FDA and sent to two parties:

1. Importer of Record
2. Customs Broker

Time sensitive with a respond by deadline
Questions?

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