

Seafood Expo North America & Seafood Processing North America

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3:30 PM – 5:00 PM

Boston Convention Center

Boston, Massachusetts

Seafood Safety and Compliance with NOAA Fisheries, FDA and U.S. Customs



Peter Quinter, Attorney

Customs & International Trade Law Group

GrayRobinson, P.A.

Mobile (954) 270-1864

Office (305) 416-6960

Peter.Quinter@Gray-Robinson.com

Skype: Peter.Quinter1



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Agenda

- FDA Import Process
- FDA Laws/Regulations
- FDA Detention and Refusal Process
- Import Alerts
- Detention Without Physical Examination

PANELISTS

- Timothy Hansen, Director, Seafood Inspection Program, NOAA Fisheries, Silver Spring, Maryland
- Domenic Veneziano, Director, Division of Import Operations, U.S. Food and Drug Administration (FDA), Rockville, Maryland
- William Scopa, Director, Interagency Collaboration Division, U.S. Customs and Border Protection (CBP), Washington, D.C.
- Christopher Hlubb, CEO and COO, Marky's Group, Inc., Miami, Florida
- Benjamin England, CEO, FDA Imports.com LLC, Glen Burnie, Maryland

Learning Objective

- Avoiding common and costly errors for seafood importation and distribution
- Latest practical experiences in food safety measures required by the federal government
- Compliance with U.S. Customs and FDA regulations and procedures to avoid detentions, delays, seizures and penalties

QUESTIONS??



Federal Food, Drug and Cosmetic Act

- Imported products must fully comply with the Federal Food, Drug and Cosmetic Act before merchandise is released by U.S. Customs and FDA.
- 21 U.S.C. 301

Detention without Physical Examination (DWPE)

- DWPE is appropriate when there exists a
 - **history of the importation of violative products,**
 - **or products that may appear violative,**
 - **or when other information indicates that future entries may appear violative**
- Detention without physical examination properly places the responsibility for ensuring compliance with the law on the importer.

Top Food Product Refusals – February 2014

Industry	Number of Refusals
16 – Fishery/Seafood Prod	161
03 – Bakery Prod/Dough/Mix/Icing	113
02 – Whole Grain/Milled Grain Prod/Starch	103
24 – Vegetables/Vegetable Products	100
28 – Spices, Flavors and Salts	98
12 – Cheese/Cheese Prod	77

¹ Available at: http://www.accessdata.fda.gov/scripts/importrefusals/ir_byProduct.cfm?DYear=2013&DMonth=2

Microbiology and Chemistry

Common lab analyses for detained products

- Nutritional Labeling
- Filth and Decomposition
- Pesticide Residues
- Salmonella
- E. Coli
- Methyl Mercury
- Nitrofurans
- Melamine
- Malachite Green
- Chloramphenicol
- Lead/Cadmium
- Fluoroquinolones
- Aflatoxin
- Sulfites
- Mold
- Heavy Metals
- Listeria
- Gentian Violet

Adulterated

- A food shall be deemed to be adulterated:
 - (1) if it bears or contains any poisonous or deleterious substance which may render it
 - Injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or
 - (2) If it bears or contains any added poisonous or added deleterious substance
 - (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance

Misbranded

- A food shall be deemed misbranded if:
 - (1) its **labeling** is false or misleading in any particular way; or
 - (2) its **advertising** is false or misleading in a material respect
 - If it is offered for sale under the name of another food
 - If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word “imitation” and, immediately thereafter, the name of the food imitated
 - If its container is so made, formed or filled as to be misleading.

Notice of FDA Action

- Products that appear (from examination or otherwise) to be violative may be detained and ultimately refused entry into the U.S.
- The standard for detention and refusal is extremely low – detention is permissible without actual observation of a product or its labeling.

Refusal

- The product then has to be exported or destroyed (in accordance with CBP Bulletin) within 90 days otherwise subject to Liquidated Damages.

Import Alert Example #1

- Import Alert: #16-81
- Published Date: May 13, 2010
- Type: DWPE (detention without physical examination)
- Import Alert Name:
 - **“Detention Without Physical Examination of Seafood Products Due to Presence of Salmonella”**
 - Reason for Alert:
 - Division of Import Operations and Policy has received recommendations from districts for detention without physical examination of seafood products due to Salmonella contamination from specific manufacturers/shippers. This import alert has been developed for seafood products from firms/countries which do not readily fit into previously existing import alerts.

Removal from Import Alert List

- FDA's Regulatory Procedures Manual
 - Chapter 9 – Import Operations and Actions
 - **9-6 – Detention without Physical Examination (DWPE)**

Removal from Import Alert List

- FDA's Regulatory Procedures Manual provides guidance to those who wish to get off the Import Alert list:
- Generally, one would need:
 - A minimum of **five consecutive non-violative commercial shipments** must enter the U.S.,
 - At least **one of the five non-violative entries should be audited by the FDA** to ensure compliance,
 - The five shipments must be **over a reasonable time period**, not one day
 - A Petition must be filed with the FDA requesting that the importer be removed from the automatic detention list

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