

Seafood Expo North America & Seafood Processing North America

March 17-19, 2019

12:45 PM- 2:00 PM

Boston Convention Center

Boston, Massachusetts



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WEDNESDAY, MAY 9, 2012

FDA Import Alert: Is there Salmonella in Your Seafood?



Peter Quinter

The U.S. Food and Drug Administration (FDA) almost daily issues "Import Alerts". A recent one that affects many seafood importers was issued on May 1, 2012, is **Import Alert #16-81**, and is entitled "Detention Without Physical Examination of Seafood Products Due to the Presence of Salmonella." The Import Alert identified hundreds of specific companies from countries all over the world. Any seafood from those listed companies on the "Red List" will not be allowed to enter the United States, but instead be detained because of the suspected presence of salmonella pursuant to 21 USC 801(a) (3).

Fortunately, there is a procedure to clear the seafood through FDA for any automatically detained seafood, even if it is on the Red List. Although many people mistakenly believe that adulterated food may come from certain countries such as China, the truth is that there are hundreds of companies listed from countries including Korea, Japan, Thailand, India, Philippines, etc. An importer must establish to the FDA that the particular shipment of seafood has been tested using the Salmonella Analyses described in the Bacteriological Analytical Manual (BAM), 7th Edition (1992). Use of a private laboratory familiar with food testing for FDA import procedures must be contacted, and samples obtained, submitted, and analyzed by the food testing laboratory. A laboratory report must then be issued by the private laboratory to the FDA. Once the FDA laboratory reviews the report and determines that the particular shipment is not adulterated with salmonella, the FDA Compliance Officer at the local port where the food is being detained will authorize the release of the shipment through an FDA Notice of Action.

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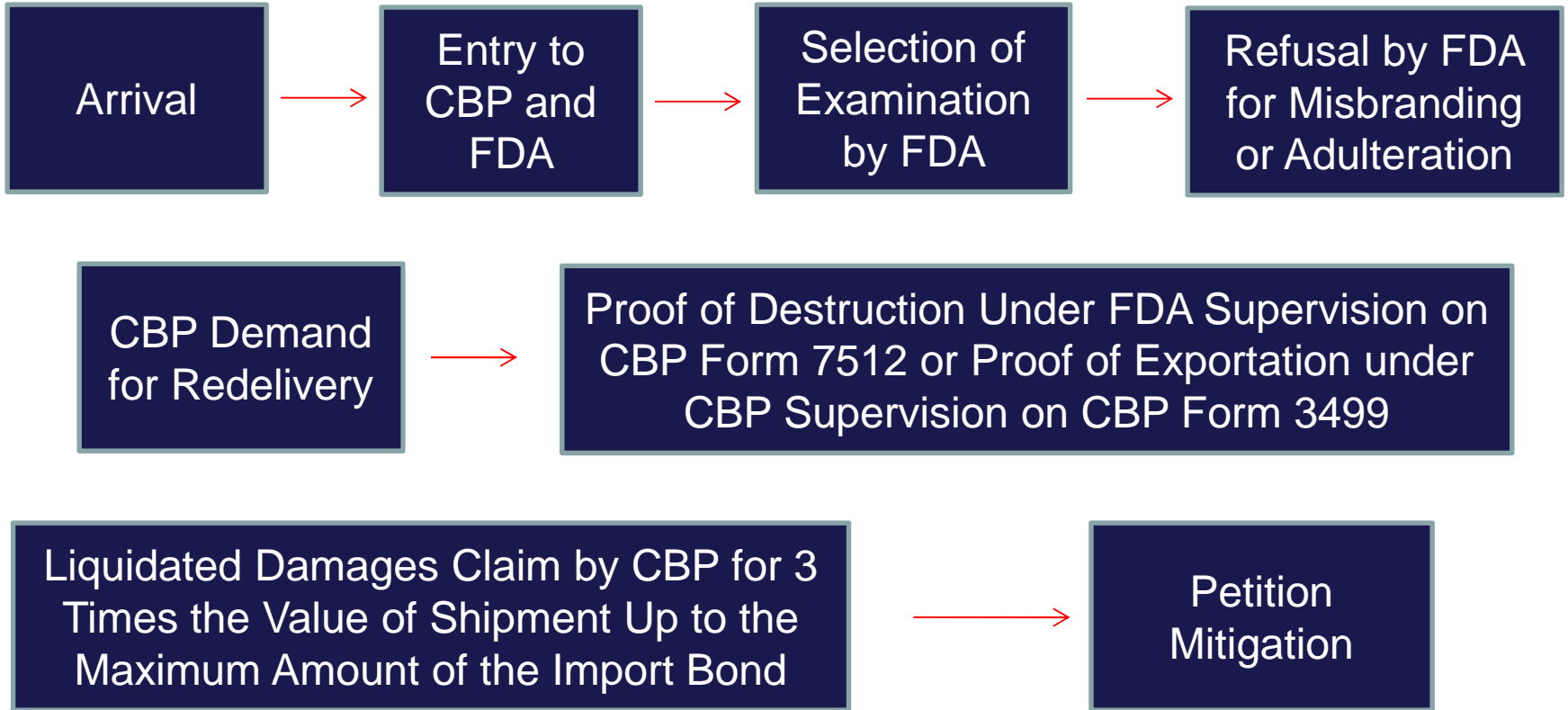
Sanction Law
Is There a "Policy Gap" in IRGC Sanctions?
1 week ago

Learning Objective

- Avoiding common and costly errors for seafood importation and distribution.
- Compliance with U.S. Government regulations and procedures to avoid detentions, delays, seizures, penalties, and criminal prosecution.

QUESTIONS??





CUSTOMS BOND
19 CFR Part 113

CBP USE ONLY	BOND NUMBER (Assigned by CBP)
--------------------	--------------------------------------

Broker Filer Code: _____ Surety Reference Number: _____

In order to secure payment of any duty, tax or charge and compliance with law or regulation as a result of activity covered by any condition referenced below, we, the below name principal(s) and surety(ies), bind ourselves to the United States in the amount or amounts, as set forth below. Execution Date

SECTION I – Select Single Transaction OR Continuous Bond (not both) and fill in the applicable blank spaces.

<input type="checkbox"/> SINGLE TRANSACTION BOND	Identification of transaction secured by this bond (e.g., entry number, seizure number, etc.)	Transaction Date	Port Code
<input type="checkbox"/> CONTINUOUS BOND	Effective Date	This bond remains in force for one year beginning with the effective date and for each succeeding annual period, or until terminated. This bond constitutes a separate bond for each period in the amounts listed below for liabilities that accrue in each period. The intention to terminate this bond must be conveyed within the period and manner prescribed in the CBP Regulations.	

SECTION II – This bond includes the following agreements. Check one box only. (Except 3a may be checked independently or with 3.)

Activity Code	Activity Name and CBP Regulations in which conditions codified	Limit of Liability	Activity Code	Activity Name and CBP Regulations in which conditions codified	Limit of Liability
<input type="checkbox"/> 1	Importer or broker §113.62		<input type="checkbox"/> 8	Detention of Copyrighted Material §113.70 -Single Transaction Only-	
<input type="checkbox"/> 1a	Drawback Payments Refunds §113.65		<input type="checkbox"/> 9	Neutrality §113.71 -Single Transaction Only-	
<input type="checkbox"/> 2	Custodian of Bonded Merchandise §113.63 (Includes bonded carriers, freight forwarders, cartmen and lightermen, all classes of warehouse, container station operators) -Continuous Bond Only-		<input type="checkbox"/> 10	Court Costs for Condemned Goods §113.72 -Single Transaction Only-	
<input type="checkbox"/> 3	International Carmer §113.64		<input type="checkbox"/> 11	Airport Security Bond Part 113 App A	
<input type="checkbox"/> 3a	Instruments of International Traffic... §113.66 -Continuous Bond Only-		<input type="checkbox"/> 12	International Trade Commission (ITC) Exclusion Bond Part 113 App B	
<input type="checkbox"/> 4	Foreign Trade Zone §113.73 -Continuous Bond Only-		<input type="checkbox"/> 14	In-Bond Export Consolidation Bond	
<input type="checkbox"/> 5	Public Gauger §113.67		<input type="checkbox"/> 15	Intellectual Property Rights (IPR)	
<input type="checkbox"/> 6	Wool & Fur Products §113.68 Labeling Acts Importation -Single Transaction Only-		<input type="checkbox"/> 16	Importer Security Filing (ISF) Part 113 App D	
<input type="checkbox"/> 7	Bill of Lading §113.69 -Single Transaction Only-		<input type="checkbox"/> 17	Marine Terminal Operator -Continuous Bond Only-	

PRINCIPAL	By checking the box you agree that you have a seal in accordance with 19 CFR 113.25 ▶	AFFIX SEAL or Check Box
Name and Physical Address (including legal description and state of incorporation)	CBP Identification Number:	<input type="checkbox"/> Check Box
	Signature	

Principal and surety agree that any charge against the bond under any of the listed names is as though it was made by the principal(s). Principal and surety agree that they are bound to the same extent as if they executed a separate bond covering each set of conditions incorporated by reference to the CBP regulations into this bond. If the surety fails to appoint an agent under Title 31, United States Code, Section 9306, surety consents to service on the Clerk of any United States District Court or the U.S. Court of International Trade, where suit is brought on this bond. That clerk is to send notice of the service to the surety at: ▶

Mailing Address Requested by the Surety

SURETY	Surety Number	Agent ID Number	
Name and Physical Address (including legal description and state of incorporation)	Signature		<input type="checkbox"/> Check Box

CBP Form 301 Customs Bond

Seafood Fraud

1. Seafood Substitution

Substituting an inexpensive species for one of higher value can be relatively easy. The differences in the taste and texture of different fish species' flesh may be subtle, and therefore it is frequently difficult to identify a species in fillet form, especially after it is prepared for consumption.

2. Seafood Short-Weighting – overglazing, soaking, and breading

3. Mislabeling Country of Origin (transshipments)

Transshipment and Mislabeling to Avoid Customs Duties

Transshipment occurs when foreign producers ship goods through a second country en route to the United States. Transshipment is illegal if done for the purpose of circumventing duties and other applicable trade restrictions.

EXAMPLES

1. Shrimp from China to the United States by way of Cambodia and Malaysia to avoid paying antidumping duties levied by the United States on shrimp imported from China.
2. Vietnamese catfish has been mislabeled as sole specifically to avoid paying antidumping duties.

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.

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.

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.

Refusal

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

REFUSAL OF ADMISSION

REDELIVERY WITH FDA VERIFICATION REQUESTED

Examination of the following products have been made and you have been afforded an opportunity to respond to a notice of detention. Because it appears that the products are not in compliance, you are hereby notified that they are refused admission.

Line ACS/FDA	Product Description
003/001	FRESH GREEN PAPAYA

Refused : 29,400 LB

FD&CA Section 402(a)(2)(B), 801(a)(3); ADULTERATION

The article appears to be a raw agricultural commodity that bears or contains a pesticide chemical which is unsafe within the meaning of Section 408(a). Product detained due to a previous violative entry. Provide private laboratory testing for pesticide Carbendazim.

For the District Director of Customs:

Jose Luis Arroyo-Acosta, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
8600 NW 36th Street, Suite 700
Miami, FL 33166

(305) 994-3040
(305) 994-3066 (FAX)
JOSE.ARROYO-ACOSTA@FDA.HHS.GOV

A request has been made to Customs to order redelivery for all the above product(s), in accordance with 19 CFR 141.113, which were conditionally released to you under terms of the entry bond. Failure to redeliver into Customs custody will result in a claim for liquidated damages under the provisions of the entry bond.

These products must be exported or destroyed under Customs supervision within 90 days from the date of this notice, or within such additional time as the District Director of Custom specifies. Failure to do so may result in destruction of the products. Distribution of the products may result in their seizure and/or injunction or criminal prosecution of persons responsible for their distribution.

You are required to have FDA verify the identification, exportation, or destruction of the above products. Contact the individual listed above to arrange for the required verification.

After completion of the exportation or destruction forward the original of the signed CF-7512 or CF3499, along with any other documents required by Customs, and a copy of this notice to:

U.S. Customs and Border Protection
8601 NW 25th Street
Room 202, Team 488
Miami, FL 33122

In addition forward copies of the signed CF-7512 or CF-3499, and any other records which document export or destruction, to the individual listed above.

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: JA

(Signature) _____

 6/12/2012
FDA COMPLIANCE OFFICER

(Signature) _____

for PORT DIRECTOR OF CBP
CBP PORT NO. 5203
MIAMI INTERNATIONAL AIRPORT

"You are ordered to redeliver this merchandise to CBP's custody. This can be accomplished by exporting or destroying under CBP supervision. Forward the original copy of the signed CBPF7512 or CBPF3499 to the CBP/FDA Joint Team 488 with a copy of this notice. Failure to comply with this notice will result in the assessment of liquidated damages."

Notice of Penalty or Liquidated Damages

DEPARTMENT OF HOMELAND SECURITY U.S. CUSTOMS AND BORDER PROTECTION		CASE NUMBER F02 201617032	
NOTICE OF PENALTY OR LIQUIDATED DAMAGES INCURRED AND DEMAND FOR PAYMENT		PORT CODE AND NAME 1703 SAVANNAH	
19 USC 1618, 19 USC 1623		INVESTIGATION FILE NO. ID: 900	
		TEAM NUMBER: 433	
<p>DEMAND IS HEREBY MADE FOR PAYMENT OF \$50,000.00, REPRESENTING LIQUIDATED DAMAGES ASSESSED AGAINST YOU FOR VIOLATION OF LAW OR REGULATION, OR BREACH OF BOND, AS SET FORTH BELOW: REDELIVERY NOTICE(CF4647) ISSUED: 03/10/2015 REDELIVERY REQUIRED: 04/10/2015</p> <p>ENTRY # 22998 KGS FROZEN TILAPIA FILLETS 22998 KGS OF FROZEN TILAPIA FILLETS WERE ENTERED ON 02/13/2015 ON ENTRY IN CONTAINER . FDA RESCINDED THE "MAY PROCEED" AND THE NOTICE TO REDELIVER (CBP FORM 4647) WAS ISSUED ON 03/10/2015. AS OF THIS TIME, REDELIVERY HAS NOT OCCURRED. DESCRIBED MERCHANDISE NOT REDELIVERED INTO CUSTOMS CUSTODY AFTER REFUSED ADMISSION BY THE FOOD AND DRUG ADMINISTRATION.</p>			
LAW OR REGULATION VIOLATED 19CFR141.113 21USC381		BOND BREACHED BOND TYPE: 1	
DESCRIPTION OF BOND: IMPORTER BROKER		FORM NUMBER:	BOND#:
NAME AND ADDRESS OF PRINCIPAL ON BOND		AMOUNT: \$50,000.00	DATE: 06/28/2012
NAME AND ADDRESS OF SURETY ON BOND			SURETY NO.
<p>IF YOU FEEL THERE ARE EXTENUATING CIRCUMSTANCES, YOU HAVE THE RIGHT TO OBJECT TO THE ABOVE ACTION. YOUR PETITION SHOULD EXPLAIN WHY YOU SHOULD NOT BE PENALIZED FOR THE CITED VIOLATION. WRITE THE PETITION AS A LETTER OR IN LEGAL FORM; SUBMIT IN (DUPLICATE) ADDRESSED TO THE COMMISSIONER OF CUSTOMS AND BORDER PROTECTION, AND FORWARD TO THE FP&F OFFICER AT: U.S. CBP FP&F OFFICE, ONE EAST BAY STREET, SAVANNAH, GA 31401</p> <p>UNLESS THE AMOUNT HEREIN DEMANDED IS PAID OR A PETITION FOR RELIEF IS FILED WITH THE FP&F OFFICER WITHIN THE INDICATED TIME LIMIT, FURTHER ACTION WILL BE TAKEN IN CONNECTION WITH BOND OR MATTER WILL BE REFERRED TO US ATTORNEY.</p> <p>TIME LIMIT FOR PAYMENT OR FILING PETITION: 60 DAYS FROM DATE OF THIS NOTICE.</p>			
SIGNATURE: TRACEY M. MARQUEZ BY <i>Tracey Marquez</i>		TITLE FP&F OFFICER (912) 447-9440	DATE 11/04/2015 (11/04/2015)

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

U.S. Department of Health and Human Services

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Page Last Updated: 09/27/2018

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Import Alert for Industry Fishery/Seafood Prod

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Fishery/Seafood Prod

DWPE = Detain without physical examination

Import Alert Number	Import Alert Type	Publish Date	Import Alert Name
16-02	DWPE	06/07/2017	"Detention Without Physical Examination of All Dried Shark Fins and Dried Fish Maws Due to Filth"
16-04	DWPE with Surveillance	09/05/2018	"Misbranded Seafood"
16-05	DWPE	09/05/2018	"Detention Without Physical Examination of Mahimahi Because of Histamine and Decomposition"
16-07	DWPE	02/23/2017	"Detention Without Physical Examination of Dried or Pickled Finfish from Thailand"
16-09	DWPE	10/06/2011	"Detention Without Physical Examination of Frozen Kingfish From Tri-Tee Seafood Company"
16-100	DWPE	10/07/2011	"Detention Without Physical Examination of Langostinos Due to the Presence of Staphylococcus Aureus and E. Coli/Coliforms"
16-105	DWPE	02/27/2019	"Detention Without Physical Examination of Seafood and Seafood Products from Specific Manufacturers/Shippers Due to Decomposition and/or Histamines"
16-114	DWPE	03/18/2011	"Detention Without Physical Examination Of Frozen Shrimp Imported By Sigma International, Inc., St. Petersburg, Florida"
16-118	DWPE	03/18/2011	"Detention Without Physical Examination Of Salted Jellyfish And Dried Squid From Hang Loong Marine Products, Hong Kong"
16-119	DWPE	03/13/2019	"Detention Without Physical Examination Of Fish And Fishery Products For Importer And Foreign Processor (Manuf) Combinations"
16-12	DWPE	07/27/2018	"Detention Without Physical Examination Of Frog Legs"
16-120	DWPE	03/04/2019	"Detention Without Physical Examination of Fish/Fishery Products from Foreign Processors (Mfrs.) Not in Compliance with Seafood HACCP"
16-121	DWPE	01/12/2018	"Detention Without Physical Examination of Processed Seafood Products Due to E. Coli"
16-124	DWPE	03/14/2019	"Detention Without Physical Examination Of Aquaculture Seafood Products Due To Unapproved Drugs"

Import Alert 16-124

Published Date: 03/14/2019

Type: DWPE

Import Alert Name:

"Detention Without Physical Examination Of Aquaculture Seafood Products Due To Unapproved Drugs"

Reason for Alert:

There has been an extensive commercialization and an increased consumption rate of aquaculture seafood products. As this industry grows, the use of unapproved new animal drugs and the misuse of approved new animal drugs in seafood raised through aquaculture also grows. The use of unapproved new animal drugs will have an impact on the safety of aquaculture products for consumers.

Guidance:

Districts may detain, without physical examination, the products from the firms identified in the attachmnet for this alert.

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

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

Product Description:

Aquaculture seafood

Charge:

"The article is subject to refusal of admission pursuant to on 801(a)(3) in that it appears to be adulterated in that it or contains a new animal drug (or conversion product of) that is unsafe within the meaning of Section 512, which violation of Section 402(a)(2)(C)(ii)."



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