



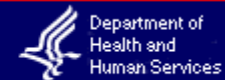
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**ON DEALING WITH**



**U.S. Food and Drug Administration**



**U.S. Customs and Border Protection**  
*Securing America's Borders* **CBP.gov**

# FDA Imports & Inspections

## Regulatory Import Processes, Liabilities & Costs

**International West Coast Seafood Show – 2006**

Presented by:

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# Topics of Discussion

- FDA's Legal/Regulatory Authorities regarding Seafood HACCP related to:
  - Interaction with GMPs
  - FDA's foreign inspection program
  - FDA's use of Customs civil enforcement authorities
  - FDA's reach into the supply chain
  - Rise of FDA/Customs Criminal Investigations

# FDA Legal/Regulatory Authorities

## FDA Inspections: HACCP Approach

- Imports Section of FDCA
- Importer Inspections & Investigations
- Seafood HACCP
  - 21 USC 342(a)(4)
  - 21 CFR Part 123
  - Guidance (and its effect)
- HACCP Record Keeping (*not* BTA)
- Foreign Inspection Authority

# FDA's Import Mandate

- FDA “shall refuse” admission to a regulated product if “it appears from the examination of samples or otherwise” to violate some substantive FDCA legal requirement.
- Preponderance of the evidence v. beyond a reasonable doubt?
- Generally FDA makes the finding of an appearance, not the courts, so FDA routinely refuses admission to products - unchallenged

# Exam of Samples “Or Otherwise”

- Legal foundation for FDA Import Alerts
- Prior compliance history – of the
  - product
  - foreign manufacturer
  - Exporter or importer
  - geographic region, or
  - country
- Examination of prior shipments
- Foreign inspections (refusal of same?)

# Lacey Act

FDA shares jurisdiction to enforce the Lacey Act, which prohibits the importation, exportation, transportation, sale, receipt, acquisition, or purchase of any **fish**, wildlife or plants taken, possessed, transported or sold in violation of *any* law, treaty, or regulation of the U.S. or any state (*includes* violations of foreign laws).

# Importer Inspections & Investigations

- Inspection Authority

- 21 USC 374(a) -- FDA officers, upon presentation of credentials & written notice (FD 482)
- Enter factory, warehouse, establishment (or vehicle to transport) in which food is manufactured, processed, packed, or held for/**after** IS Commerce
- Inspect facility, materials, product, containers, equipment, labeling
- **RECORDS** under BTA when criteria met ONLY

# Importer Inspections & Investigations

- Investigation Authority

- 21 USC 372 -- Secretary (HHS) authorized to conduct examinations and investigations through any HHS employee or agent, or through state officials
- **DOES NOT INCLUDE INSPECTIONS**, *per se*
- Commissioning of other federal agency officials *may* include inspections –if reduced to a MOU & pre-existing Joint Jurisdiction over facility
- 21 USC 372(e) – *criminal* law enforcement auth
  - *Counterfeit drugs*

# Interstate Commerce Records

- 21 USC 373 -- Carriers *and other* persons receiving food in interstate commerce must provide access for inspection and copying of records showing the interstate movement of foods or the holding of foods after interstate movement
- Subject to written request for the records
  - *Quantity, shipper, and consignee thereof*
- *No criminal liability if obtained under this provision*

# Seafood HACCP

- 21 USC 342(a)(4)
  - Food is deemed “adulterated if”
  - “it has been prepared, packed, or held under insanitary conditions whereby it *may have become* contaminated with filth, or whereby it *may have been* rendered injurious to health”
- 21 USC 371(a):
  - “Authority to promulgate regulations for efficient enforcement of [FDCA] . . . is vested in [HHS] Secretary”

# Seafood HACCP Regs

- 21 CFR Part 123
- Not intended to provide detailed training (here) or exhaustive legal analysis
- Questions, in light of previous slides
- BUT, consider:
  - *AFGE v. Glickman (USDA)*, U.S. Ct. App. (June 2000)
  - Court found HACCP under Fed Meat Insp. Act an **illegal (unconstitutional) delegation** of inspection authority to industry!

# HACCP & GMPs

- Seafood HACCP regs cite to food GMPs (21 CFR Part 110) stating:
  - Part 110 applies in determining whether the facilities, methods, practices, and controls used to process fish and fishery products have been processed “under sanitary conditions” (e.g. 21 USC 342(a)(4)) [**No Records - umbrella requirements**]
  - Purpose of Part 123 is to set the forth the “requirements specific to the processing of fish and fishery products.” [**All Records - specifics**]

# Seafood HACCP Regs

- Hazard Analysis and HACCP Plan
- 21 CFR 123.6
  - *Shall* conduct a Hazard Analysis
  - *Shall* have a HACCP plan meeting criteria
    - Written and records
  - Failure to have and implement HACCP plan = “adulteration” under 21 USC 342(a)(4)
    - Converting Sanitation umbrella requirements into mandatory specific requirements **implemented and verified (inspected) by the processor**

# Seafood HACCP Guidance

- FDA Guidance is supposed to be interpretation of HACCP regs (which, although more specific than umbrella sanitation regs – are still general)
- Specifics in HACCP Guidance are treated as a Rule...Proof?
  - Stray from the guidance and watch FDA issue
  - **FD483s**
  - **Untitled Letters**
  - **Warning Letters**

# Seafood HACCP Regs

- Corrective Action Plans
- 21 CFR 123.7
  - Where deviations to Critical Limits occur, processor *shall* have and implement corrective action plan
  - If no corrective action plan, processor *shall* follow FDA's corrective action plan (123.7(c))
  - Full **documentation** of actions taken (FDA review)
  - **Processor is self-inspecting and enforcing FDA regs and guidance . . . against self**

# Seafood HACCP Regs

- **Records, Records, Records**
- 21 CFR 123.9
  - Wherever Records are required – certain mandatory information must be included
  - (c) All records required by [Part 123] and all plans and procedures required by this part shall be available for official review and copying at all reasonable times
  - **Under WHAT AUTHORITY?**

# Seafood HACCP Regs

- Significance of lack of records authority
  - Failure to maintain “required” records results in failing to comply with the provision the record documents (= “**adulteration**” 342(a)(4))
  - Failure to provide access to records is deemed an inspection “**refusal**” – a prohibited act.
  - 123.11 requires records for sanitation *not required by Part 110!*
- **Under WHAT AUTHORITY?**

# Seafood HACCP Regs

- Significance of lack of records authority
  - MAJORITY of HACCP related 483s cite inadequate documentation *thus* substantive violation
  - Even FDA injunctions and seizures have been prompted by failure to maintain **RECORDS**
  - FDA civil actions based upon “adulteration” under 21 USC 342(a)(4) for **RECORDS VIOLATIONS!!!**

# Seafood Importers & HACCP

- 21 CFR 123.12 “Special Requirements”
  - Importer Verification
  - Product Specs PLUS affirmative steps
  - Ordinarily importers forget to design product specs or they adopt foreign processor’s product specs – often FDA deems this inadequate
  - **FDA putting foreign processor’s compliance with HACCP on the shoulder of the importer**

# Seafood Importers & HACCP

- 21 CFR 123.12(d) Evidence of compliance
  - **Absolute FLIP of FDA authority**
  - Unlikely to be sustainable under FDCA or Administrative Procedures Act (beyond the scope of statutory authority)
- 21 USC 381(a) – everything is admissible **unless FDA** has evidence of a violation
- 21 CFR 123.12(d) – everything inadmissible **unless importer** has documented evidence of compliance!

# Seafood Import Alerts

- FDA's HACCP program becomes substantive law that foreign processors must comply with and importers must document they are complying with OR
- All **future entries** are deemed adulterated because they "appear" to have been processed, packed or held under insanitary conditions whereby they *may have been* rendered injurious to health

# Seafood Import Alerts & Records

- Evidence of this purported apparent violation?
  - Lack of RECORDS (foreign processor's HACCP plan)
  - RECORD REVIEW (inadequate foreign processor HACCP plan)
  - Failure of importer to have WRITTEN (records) product specs
- **Under WHAT AUTHORITY?**
- **RESULT? Automatic detention/refusal**

# Seafood Import Alerts

Alert	Text Revised	Attachment Revised	Title/Description
16-02	05/21/1996	02/23/2006	<u><a href="#">AUTOMATIC DETENTION OF ALL DRIED SHARK FINS AND DRIED FISH MAWS DUE TO FILTH</a></u>
16-04	07/08/2004	05/04/2006	<u><a href="#">MISBRANDED SEAFOOD</a></u>
16-05	05/07/1998	04/06/2006	<u><a href="#">DET. W/O PHYS. EXAM OF MAHI MAHI DUE TO DECOMPOSITION AND HISTAMINES</a></u>
16-07	05/21/1996	06/22/2005	<u><a href="#">AUTOMATIC DETENTION OF DRIED AND PICKLED FISH FROM THAILAND</a></u>
16-08	05/21/1996	09/15/2006	<u><a href="#">DETENTION WITHOUT PHYSICAL EXAMINATION OF SWORDFISH FOR METHYL MERCURY</a></u>
16-09	06/04/1996		<u><a href="#">AUTOMATIC DETENTION OF FROZEN KINGFISH FROM TRI-TEE SEAFOOD COMPANY</a></u>
16-100	06/04/1996	08/12/1994	<u><a href="#">AUTOMATIC DETENTION OF LANGOSTINOS DUE TO THE PRESENCE OF STAPHYLOCOCCUS AUREUS AND E. COLI/COLIFORMS</a></u>
16-105	06/04/1996	03/03/2006	<u><a href="#">AUTOMATIC DETENTION OF SEAFOOD AND SEAFOOD PRODUCTS FROM SPECIFIC MFRS/SHIPPERS DUE TO DECOMPOSITION AND/OR HISTAMINES</a></u>

# Seafood Import Alerts

16-114 06/04/1996

[A/D OF FROZEN SHRIMP IMPORTED BY SIGMA INTERNATIONAL ST. PETERSBURG FLORIDA](#)

16-118 11/04/1996

[DETENTION W/O PHYSICAL EXAMINATION OF SALTED JELLYFISH AND DRIED SQUID FROM HANG LOONG MARINE PRODUCTS HONG KONG](#)

16-119 05/15/2001 07/06/2006

[DETENTION W/O PHYSICAL EXAM OF FISH AND FISHERY PRODUCTS FOR IMPORTER AND FOREIGN PROCESSOR \(MANUF\) COMBINATIONS](#)

16-12 06/05/1996 02/10/2006

[DETENTION WITHOUT PHYSICAL EXAMINATION OF FROG LEGS](#)

16-120 12/15/2000 08/14/2006

[DETEN WITHOUT PHYS. EXAM OF FISH/FISHERY PRODUCTS FROM FOREIGN PROCESSORS \(MFRS.\) NOT IN COMPLIANCE WITH SEAFOOD HACCP](#)

16-121 08/17/2004 04/19/2005

[DETENTION W/O PHYSICAL EXAM OF FROZEN COOKED SEAFOOD PRODUCTS DUE TO E. COLI](#)

16-124 11/16/2001 09/27/2006

[DETENTION WITHOUT PHYSICAL EXAMINATION OF AQUACULTURE SEAFOOD PRODUCTS DUE TO UNAPPROVED DRUGS](#)

16-125 09/25/2002 09/27/2006

[DET W/O PHY EXAM OF REFRIGERATED \(NOT FROZEN\) VACUUM PAK OR MODIFIED ATMOSPHERE PAK RAW FISH AND FISHERY PRODUCT](#)

16-127 07/14/2004 09/15/2006

[DETENTION WITHOUT PHYSICAL EXAMINATION OF CRABMEAT DUE TO CHLORAMPHENICOL](#)

16-128 05/18/2004 05/21/2004

[MISBRANDED CATFISH](#)

# Seafood Import Alerts

16-129	04/14/2005	09/08/2006	<u>DETENTION WITHOUT PHYSICAL EXAMINATION OF SEAFOOD PRODUCTS DUE TO NITROFURANS</u>
16-13	06/05/1996	04/30/1992	<u>DETENTION WITHOUT PHYSICAL EXAMINATION OF ANCHOVY OR BAGOONG PRODUCTS FROM THE PHILIPPINES</u>
16-17	06/06/1996	08/09/2006	<u>SALMONELLA IN FROZEN WHOLE FISH FROM THAILAND</u>
16-18	11/14/1996	09/28/2006	<u>DETENTION WITHOUT PHYSICAL EXAMINATION OF SHRIMP</u>
16-19	05/19/1993		<u>PROCESSED SHRIMP (CANNED)</u>
16-20	10/28/2003		<u>DETENTION WITHOUT PHYSICAL EXAMINATION OF PUFFER FISH</u>
16-21	03/05/1999	03/23/1999	<u>FILTH IN IMPORTED FRESH OR FROZEN RAW SHRIMP</u>
16-22	07/09/1996	05/10/2005	<u>DETENTION WITHOUT PHYSICAL EXAM CANNED SHRIMP FROM THAILAND FOR DECOMPOSITION</u>
16-23	07/09/1996	05/01/1992	<u>DETENTION WITHOUT PHYSICAL EXAM OF FRESH AND FRESH FROZEN LOBSTER/LOBSTER TAILS FROM INDIA</u>
16-25	07/09/1996	05/06/2005	<u>DETENTION WITHOUT PHYSICAL EXAM OF CANNED CRABMEAT FROM THAILAND</u>
16-31	06/07/1996	05/17/2002	<u>DETENTION WITHOUT PHYSICAL EXAM OF FROZEN RAW AND COOKED CONCHMEAT</u>

# Seafood Import Alerts

16-35 07/06/1995 10/12/2006

[AUTOMATIC DETENTION OF FRESH RAW FRESH FROZEN AND COOKED SHRIMP FROM INDIA](#)

16-39 11/03/1994 09/27/2006

[AUTOMATIC DETENTION OF PROCESSED SEAFOOD AND ANALOGUE SEAFOOD \(SURIMI\) PRODUCTS FOR L. MONOCYTOGENES](#)

16-47 03/03/1997

[AUTOMATIC DETENTION OF RED SNAPPER FROM THAILAND](#)

16-50 03/19/2002 04/17/2006

[DETENTION W/O PHYSICAL EXAM OF MOLLUSCAN SHELLFISH](#)

16-66 03/10/1995 10/05/2005

[AUTOMATIC DETENTION OF SHARK FOR METHYL MERCURY](#)

16-74 03/03/1997 12/16/2005

[AUTOMATIC DETENTION OF SALT-CURED UNEVICERATED FISH](#)

16-81 09/22/1992 10/13/2006

[DETENTION WITHOUT EXAM SEAFOOD PRODUCTS DUE TO SALMONELLA](#)

16-95 03/05/1993 01/13/2000

[AUTOMATIC DETENTION OF CANNED TUNA DUE TO DECOMPOSITION](#)

# Seafood Import Alerts Examples

- 16-125 VacPac and MAP (Worldwide Effect)
- Issued because of the “potential” for *C. botulinum* toxin production
- Evidence –
  - “studies” that time/temp CCPs are most effective means for controlling growth of toxin forming *C. bot*
  - “studies” that retail vacpac/MAP display cases are not maintained at adequate temperatures
- Result? FDA deems VacPac/MAP products that do not indicate time/temp abuse to the retail level adulterated FROM THE PROCESSOR on.

# Seafood Import Alerts

AAHHHH!!!!!!

**STOP THE INSANITY!!**

# Seafood HACCP Inspections

- Import Seafood Products Compliance Program Guidance Manual 7303.844
- How do I predict if I will be inspected?
  - **TOP PRIORITY:** 90% of all FDA seafood HACCP inspections of importers w/ average of (total) 100 or more entry lines /year
  - **Remaining** 10% of all FDA seafood inspections HACCP inspections of importers w/ average of (total) less than 100 entry lines/year

# Program Inspection “Priority List”

- Products with **previous “safety defects”**
- **“High Risk Products”**, which are:
  - Vac Pac/MAP (IA 16-125)
  - Fresh/Fresh Frozen Molluscan Shellfish from uncertified shippers (enforced by STATES!!)
  - Ready to Eat (e.g., pasteurized, hot/cold smoking)
  - Scombroid *species* (histamine formers) – Mahi Mahi & Tuna
  - Salt-cured, air-dried *and* uneviscerated fish
  - Stuffed Seafood Products
- Then **“Low Risk Products”** (everything else)

# HACCP Inspection Process (& Direct Reference Warning Letters)

- Walk through & diagram process
- Figure out product risk
- Review importer's *written* verification procedures
- Review affirmative steps *documents*
- Review product safety *written* specs
- Review verification *records*
- Document objectionable conditions based upon *records review*

# HACCP Reconditioning Process

- Where any reconditioning request is filed by an importer for imported seafood products, Compliance Program Guide Manual states
  - “Importer **must** supply HACCP verification documents for the detained product along with the reconditioning proposal”
    - Product Specs (written)
    - Foreign processor’s HACCP plan
  - Thus importer **must** enforce HACCP on self and on foreign processor

# HACCP Untitled Letters

- Model Untitled Letters describe what FDA expects for HACCP compliance
  - Restates FDA regs and guidance *BUT*
  - “If you disagree with FDA’s assessment, you should explain how your system is complying with the regulations. [FDA] understand[s] that there may be more than one way to verify compliance with the Seafood HACCP Regulations.”
  - ASS/U/ME

# HACCP Untitled Letters

Model Untitled Letter obviously assumes that the Seafood HACCP Regulation verification is enforceable law!!

# HACCP Warning Letters

- Model Warning Letters describe what FDA believes are repeat or significant HACCP Regulation violations
- PLUS A THREAT:
  - FDA may detain without examination your imported entries
  - FDA may refuse to issue Certificates for Export or EU Health Certificates for your products
- Purporting to shut you down!

# FDA's Foreign Inspection Program

- FDA has express authority to inspect foreign drug and device facilities (21 USC 360(i)(3))
- No such express authority *or* mandate for foreign food facilities
- Yet, if a foreign seafood facility refuses an FDA inspection, FDA uses that *as evidence* of an apparent violation of the Seafood HACCP regs – based upon HACCP records authority

# Customs' Enforcement Tools

- Importations contrary to law – 19 U.S.C. § 1595a(a)
  - Where merchandise is imported contrary to law, Customs has the authority to issue **civil monetary penalties** in the amount of the **domestic value** of goods so imported
  - Contrary to what law?
  - Includes FDCA and FDA regs
  - **HACCP violations at the border can support such penalties**

# Customs' Enforcement Tools

- Import, aid or abet importation contrary to law - 19 U.S.C. § 1595a(c)
  - Where a person imports or facilitates the importation of goods contrary to law, the imported goods and those things that facilitated the importation are subject to **Customs seizure**
  - Includes FDA regulated goods

# Customs' Enforcement Tools

- Liquidated Damages claims for **failing to redeliver** imported FDA-regulated products - 19 CFR § 141.113
  - FDA refusal of admission
  - FDA notices of sampling not complied with (failure to hold)
- Liquidated damages claims are civil claims for up to **3 times the import value** of the merchandise (limited by the bond ceiling)

# FDA's Use of Customs' Enforcement Tools

- **FDA Import Enforcement Course**
- Almost all of FDA's import inspectors, investigators and compliance officers **trained** to use **Customs' civil enforcement authorities** to enhance enforcement of FDA requirements
- FDA Regulatory Procedures direct FDA personnel to coordinate civil cases with Customs
- Proven very effective enforcement tools

# Customs' Enforcement Subject to Notice and Petition Process

- Customs must give notice of civil claims (or seizures)
- Importer has right to **petition** for relief from penalty or liquidated damages claims or for remission of seized goods
- **Petition** ordinarily must focus upon improper interpretation or implementation of FDA AUTHORITY not Customs authority

# FDA Reaches into the Seafood Supply Chain

- Vacuum Packed or Modified Atmosphere Packaging Products
- FDA/CFSAN *requires* (by rejecting foreign processor HACCP plans) use of Time & Temperature Integrators (TTI technologies) on retail packaging *to the consumer level* ensuring proper handling throughout supply chain
- Under WHAT AUTHORITY?

# TTI Technology

- Must be validated by manufacturer and verified by seafood processor
- FDA relies *entirely* upon the “Skinner & Larkin” curve, which *entirely* fails to consider temperature excursions in the shipping cycle
- BUT if there is a better way, shouldn't FDA be willing to accept it? (guidance)

# FDA-Customs Criminal Enforcement

- FDA Office of Criminal Investigations knocks on the door, if you're lucky
  - But **don't expect** a Notice of Inspection (FD482)
- Asking for records, statements, affidavits
- OCI and Customs increasingly focusing upon FDA regulated importers
- Criminal search warrants, instead of inspection notices (or administrative inspection warrants)

# FDA-Customs Criminal Enforcement

- If OCI shows up, be certain to:
  - **Call an attorney**
  - Find out why they are there – under what authority?
  - Find out exactly what they want from you before you give them anything
  - Do not necessarily grant access to the facility – if they view you as a “witness” but find something questionable, **they will leverage it against you** to get information out of you

# FDA-Customs Criminal Enforcement

- Basic Rules of Thumb for Criminal Investigations (besides calling an attorney):
  - An OCI Agent's business card, badge, or credentials is **not a search warrant** and is not a legal assertion of authority **to enter your premises**
  - Records are not within the purview of an investigation **unless** the statute or a Grand Jury subpoena grants the authority to the investigator
  - Grand Jury subpoenas should always grant time to respond

# FDA-Customs Criminal Enforcement

- OCI has recently been visiting Customs brokers seeking records related to entries
- Importer records belong to the IMPORTER and are NOT subject to disclosure (except under Customs regulations)
- Brokers should not release your records without your consent, a Customs administrative summons, or a Grand Jury subpoena
- You should notify your broker of this restriction, if you haven't already

# Additional Agenda Point

- FDA's indiscriminant use of the bully pulpit (and its willing accomplices in among the press corp)
- Spinach
- Pacific Northwest raw shellfish
- **Anyone at the oyster shucking contest should have come here instead**

# What We Discussed

- FDA's Legal/Regulatory Authorities regarding Seafood HACCP related to:
  - Interaction with GMPs
  - FDA's foreign inspection program
  - FDA's use of Customs civil enforcement authorities
  - FDA's reach into the supply chain
  - Rise of FDA/Customs Criminal Investigations

# Questions?



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