Seafood Expo North America

The Future of Seafood Regulations Post FSMA

Boston Convention and Exhibition Center

March 6 – 8, 2016
Overview

- FDA Organization
  - ORA Field and Laboratories
  - FDA Foreign Offices
  - FDA Headquarters

- FY2015 Stats
  - # of lines
  - Top 10 Products
  - Top 10 Countries
  - # of Refusal
  - Top 10 Refusals
  - Time Frames

- Current assignments
  - FY2016 Stats
  - SCOPE

- PREDICT
FDA consist of 7 Centers & ORA

- Center for Biologics Evaluation and Research (CBER)
- Center for Devices and Radiological Health (CDRH)
- Center for Drug Evaluation and Research (CDER)
- Center for Food Safety and Applied Nutrition (CFSAN)
- Center for Veterinary Medicine (CVM)
- Center of Tobacco Products (CTP)
- National Center for Toxicological Research (NCTR)
- Office of Regulatory Affairs (ORA)
New Directorate Structure

Office of the Commissioner

Office of Foods
- CVM
- CFSAN

Office of Medical Products
- CTP
- CDRH
- CDER

Global Regulatory Operations and Policy
- OIP
- ORA
Responsibility

FDA responsibility

- Ensuring that food is safe, wholesome and sanitary;
- Human & veterinary drugs, medical devices & human biologics are safe and effective;
- Cosmetics and electronic products that emit radiation are safe;
- Tobacco product comply with regulations; and
- Labeling of these products honestly represent them to the users and their instructions for use are adequate

ORA Mission

- ORA protects consumers and enhances public health by maximizing compliance of FDA-regulated products and minimizing risk associated with those products
Field & HQ
Responsibilities & Activities

- Field/HQ Activities
  - DIO: Responsibilities & CBP Liaison
  - CTAC: Co-location
  - DFDT: Prior Notice Review
    - Import security reviews on food/feed identified as high risk for intentional contamination or credible evidence that something may cause death or serious injury based on prior notice screening criteria
  - Field Entry Review and Investigators
    - Electronic entry screening
    - Field examinations
    - Label examinations
    - Sample collections and analysis (testing)
Field & HQ
Responsibilities & Activities

- Field Activities (Cont.)
  - Compliance Activities
    - Detentions
    - Releases
    - Hearings and Review
    - Reconditioning Supervision & Review
    - Refusals
  - Post-Refusal
    - Export Verification
    - Witness the Destruction
  - Entry Filer Activities
    - Filer Evaluations
    - Filer Training

- Types of Port of Entries
  - Land
  - Sea
  - Mail
  - Rail
  - Air
  - Passenger
## FY 2011–2015 Seafood Lines

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lines</td>
<td>847,070</td>
<td>885,633</td>
<td>905,762</td>
<td>938,078</td>
<td>1,010,146</td>
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<tr>
<td>FY</td>
<td>Salmon, Aquac</td>
<td>Shrimp &amp; Prawns, Aquac</td>
<td>Tuna</td>
<td>Fish, N.E.C.</td>
<td>Crab</td>
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<tr>
<td>-----</td>
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<td>--------</td>
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<tr>
<td>2011</td>
<td>67,777</td>
<td>65,917</td>
<td>58,048</td>
<td>36,860</td>
<td>34,070</td>
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<td>2012</td>
<td>83,356</td>
<td>65,641</td>
<td>60,450</td>
<td>37,445</td>
<td>34,780</td>
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<td>2013</td>
<td>89,476</td>
<td>65,710</td>
<td>58,326</td>
<td>39,327</td>
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<tr>
<td>2014</td>
<td>96,911</td>
<td>71,363</td>
<td>61,892</td>
<td>41,126</td>
<td>37,556</td>
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<tr>
<td>2015</td>
<td>109,227</td>
<td>73,704</td>
<td>69,846</td>
<td>43,695</td>
<td>38,405</td>
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</table>
## FY 2011–2015 Seafood Imports by Top Ten Countries

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Canada</th>
<th>Japan</th>
<th>Mexico</th>
<th>China</th>
<th>Chile</th>
<th>Ecuador</th>
<th>Thailand</th>
<th>Indonesia</th>
<th>Vietnam</th>
<th>Korea, Rep (South)</th>
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<tbody>
<tr>
<td>2011</td>
<td>243542</td>
<td>105181</td>
<td>46494</td>
<td>55661</td>
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<td>38739</td>
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<td>27409</td>
<td>19853</td>
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<td>2012</td>
<td>235352</td>
<td>97784</td>
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<td>39842</td>
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<td>26325</td>
<td>20822</td>
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<tr>
<td>2013</td>
<td>236380</td>
<td>99083</td>
<td>59691</td>
<td>57731</td>
<td>35287</td>
<td>45881</td>
<td>42008</td>
<td>27130</td>
<td>28377</td>
<td>21226</td>
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<td>2014</td>
<td>218662</td>
<td>124209</td>
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<td>58523</td>
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<td>43334</td>
<td>31546</td>
<td>29074</td>
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<td>21156</td>
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<tr>
<td>2015</td>
<td>224,882</td>
<td>150,150</td>
<td>65,995</td>
<td>56,672</td>
<td>50,011</td>
<td>46,833</td>
<td>32,097</td>
<td>33,825</td>
<td>28,578</td>
<td>22,634</td>
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**FY 2011–2015 SEAFOOD REFUSALS**

*Refusal counts represents a unique count of lines*

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<th>FY</th>
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<th>2014</th>
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<td>1,979</td>
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## FY 2011–2015 Top Ten Seafood Products Refused

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>SHRIMP AND PRAWNS, AQUACULTURE</th>
<th>TUNA</th>
<th>SNAPPER</th>
<th>MAHI MAHI</th>
<th>SHRIMP &amp; PRAWNS</th>
<th>FISH, N.E.C.</th>
<th>SPINY LOBSTER</th>
<th>CRAB</th>
<th>ANCHOVY</th>
<th>OCTOPUS</th>
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<tr>
<td>2011</td>
<td>302</td>
<td>382</td>
<td>130</td>
<td>69</td>
<td>98</td>
<td>156</td>
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<td>113</td>
<td>158</td>
<td>70</td>
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<tr>
<td>2012</td>
<td>244</td>
<td>415</td>
<td>113</td>
<td>259</td>
<td>64</td>
<td>102</td>
<td>87</td>
<td>215</td>
<td>203</td>
<td>109</td>
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<tr>
<td>2013</td>
<td>147</td>
<td>228</td>
<td>39</td>
<td>59</td>
<td>60</td>
<td>104</td>
<td>107</td>
<td>74</td>
<td>120</td>
<td>42</td>
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<tr>
<td>2014</td>
<td>283</td>
<td>148</td>
<td>44</td>
<td>73</td>
<td>84</td>
<td>66</td>
<td>7</td>
<td>27</td>
<td>83</td>
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<tr>
<td>2015</td>
<td>358</td>
<td>180</td>
<td>166</td>
<td>133</td>
<td>97</td>
<td>78</td>
<td>64</td>
<td>46</td>
<td>45</td>
<td>37</td>
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*Represents a unique count of refusals*
### FY 2011–2015 SEAFOOD LINES BY TOP TEN REFUSAL VIOLATIONS

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>FILTHY</th>
<th>SALMONELLA</th>
<th>VET DRUG RES</th>
<th>NITROFURAN</th>
<th>MFR INSAN</th>
<th>LACKS FIRM</th>
<th>LISTERIA</th>
<th>NUTRIT LBL</th>
<th>LACKS N/C</th>
<th>NO PROCESS</th>
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<tr>
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<td>945</td>
<td>272</td>
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<td>189</td>
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<td>110</td>
<td>86</td>
<td>89</td>
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<tr>
<td>2012</td>
<td>1100</td>
<td>709</td>
<td>148</td>
<td>40</td>
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<td>108</td>
<td>76</td>
<td>50</td>
<td>101</td>
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<tr>
<td>2013</td>
<td>661</td>
<td>465</td>
<td>115</td>
<td>31</td>
<td>137</td>
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<td>57</td>
<td>38</td>
<td>38</td>
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<tr>
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<td>300</td>
<td>101</td>
<td>95</td>
<td>44</td>
<td>29</td>
<td>43</td>
<td>40</td>
<td>59</td>
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<tr>
<td>2015</td>
<td>753</td>
<td>337</td>
<td>348</td>
<td>241</td>
<td>63</td>
<td>55</td>
<td>51</td>
<td>49</td>
<td>43</td>
<td>41</td>
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</tbody>
</table>

*REFUSAL VIOLATIONS MAY REPRESENT A HIGHER COUNT. LINES MAY BE REFUSED FOR MORE THAN ONE REASON*
FY 2015 – SEAFOOD LINES
TIME FRAMES

○ Total number of lines = 1,010,146 FY15
○ Total # of samples collected = 3,914 FY15
○ % of lines sampled = 0.4% FY15
○ Total number refused = 473 FY15
○ % of lines violative based on refusal = 12.1% FY15
○ Total number reconditioned = 173 FY15
○ Total number released with comment = 168 FY15
○ Total number of actual violations = 814 FY15
○ % of violative shipments = 20.8% FY15

○ FY15 Average time between sample collection & final disposition = 21 days
○ FY14 Average time between sample collection & final disposition = 23 days

FY14
Total number of lines = 938,078
Total # of samples collected = 5,117
% of lines sampled = 0.5%
Total number refused = 361
% of lines violative based on refusal = 7.05%
Total number reconditioned = 189
Total number released with comment = 206
Total number of actual violations = 756
% of violative shipments = 14.77%
Current assignments

• No Current assignments:
• Ongoing emerging issues:
  – Illegal, Unreported, and Unregulated Fishing and Seafood Fraud (IUU)
  – Surveillance of Tuna from Indonesia for Salmonella and Decomposition.

• Sample Collection Operation Planning Effort (SCOPE)

| Import Chemotherapeutic Compliance Program | 04018 | 1000 |
| Import Pesticide Compliance Program       | 04004A | 200  |
| Import Radionuclides Compliance Program   | 04019C | 25   |
| Import Seafood Compliance Program         | 03844  | 3300 |
| Import Surveillance Mahi Mahi Sample Collection | 03844 | 500  |
| **TOTAL**                                |       | 5025 |
SEAFOOD SAMPLES – TOP TEN PRODUCTS FY 16

- TUNA
- SHRIMP, AQUACULTURE
- TILAPIA, AQUACULTURE
- SQUID
- CRAB
- SNAPPER
- SHRIMP & PRAWNS
- NON-ICTALURUS FISH, AQUACULTURE
- SCALLOPS
- MACKEREL (ALL EXCEPT SPANISH OR KING)
SEAFOOD IMPORTS
FY 2016

- Total number of lines = 414,603
- Total # of samples collected = 1,492
- % of lines sampled = 0.4%
- Total number refused = 238
- % of lines violative based on refusal = 16%
- Total number reconditioned = 19
- Total number released with comment = 55
- Total number of actual violations = 312
- % of violative shipments = 20.9%
Import Alert System:

1. It prevents potential violative products from being distributed into the United States

2. It frees up Agency resources to examine other shipments

3. Provides uniform coverage across the country

4. Places the responsibility back on the importer
   - It is the responsibility of the importer to ensure that the products he is importing in the U.S. is in compliance with our laws and regulations
36 SEAFOOD-SPECIFIC IMPORT ALERTS

16-02 DWPE of All Dried Shark Fins and Dried Fish Maws Due to Filth"
16-04 "Misbranded Seafood"
16-05 DWPE of Mahimahi Because of Histamine and Decomposition"
16-07 DWPE of Dried or Pickled Finfish from Thailand"
16-09 DWPE of Frozen Kingfish From Tri-Tee Seafood Company"
16-12 DWPE Of Frog Legs"
16-13 DWPE of Anchovy or Bagoong Products from the Philippines"
16-17 DWPE of Salmonella in Frozen Whole Fish from Thailand"
16-18 DWPE of Shrimp"
16-20 DWPE of Puffer Fish"
16-22 DWPE of Canned Shrimp from Thailand for Decomposition"
16-23 DWPE of Fresh and Fresh Frozen Lobster/Lobster Tails from India"
16-25 DWPE of Canned Crabmeat from Thailand"
16-31 DWPE of Frozen Raw and Cooked Conchmeat"
16-35 DWPE of Raw And Cooked Shrimp from India"
16-39 DWPE of Processed Seafood and Analogue Seafood (Surimi) Products for Listeria Monocytogenes
16-47 DWPE of Red Snapper from Thailand"
16-50 DWPE of Molluscan Shellfish"
16-66 DWPE of Shark and Tuna for Methyl Mercury"
<table>
<thead>
<tr>
<th>Alert Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>16-74</td>
<td>DWPE of Uneviscerated Fish or Partially Eviscerated Fish that are Either Salt-Cured, Dried, Smoked, Pickled, Fermented or Brined (excludes LACF and Acidified Products Filed Under 21 CFR 108/113 or 114)</td>
</tr>
<tr>
<td>16-81</td>
<td>DWPE of Seafood Products Due to the Presence of Salmonella</td>
</tr>
<tr>
<td>16-95</td>
<td>DWPE of Canned Tuna Due to Decomposition</td>
</tr>
<tr>
<td>16-100</td>
<td>DWPE of Langostinos Due to the Presence of Staphylococcus Aureus and E. Coli/Coliforms</td>
</tr>
<tr>
<td>16-105</td>
<td>DWPE of Seafood and Seafood Products from Specific Manufacturers/Shippers Due to Decomposition and/or Histamines</td>
</tr>
<tr>
<td>16-114</td>
<td>DWPE of Frozen Shrimp Imported by Sigma International, Inc., St. Petersburg, Florida</td>
</tr>
<tr>
<td>16-118</td>
<td>DWPE of Salted Jellyfish and Dried Squid from Hang Loong Marine Products, Hong Kong</td>
</tr>
<tr>
<td>16-119</td>
<td>DWPE of Fish and Fishery Products for Importer and Foreign Processor (Manuf) Combinations</td>
</tr>
<tr>
<td>16-120</td>
<td>DWPE of Fish/Fishery Products from Foreign Processors (Mfrs.) Not in Compliance with Seafood HACCP</td>
</tr>
<tr>
<td>16-121</td>
<td>DWPE of Processed Seafood Products Due to E. Coli</td>
</tr>
<tr>
<td>16-124</td>
<td>DWPE of Aquaculture Seafood Products Due to Unapproved Drugs</td>
</tr>
<tr>
<td>16-125</td>
<td>DWPE of Refrigerated (Not Frozen) Raw Fish and Fishery Products that are Vacuum Packaged or Modified Atmosphere Packaged or Packaged in a Material that is not Oxygen-Permeable Due to the Potential for Clostridium Botulinum Toxin Production</td>
</tr>
<tr>
<td>16-127</td>
<td>DWPE of Crustaceans Due to Chloramphenicol</td>
</tr>
<tr>
<td>16-128</td>
<td>&quot;Misbranded Catfish&quot;</td>
</tr>
<tr>
<td>16-129</td>
<td>DWPE of Seafood Products Due to Nitrofurans</td>
</tr>
<tr>
<td>16-131</td>
<td>DWPE of Aquacultured Catfish, Basa, Shrimp, Dace, and Eel from China- Presence of New Animal Drugs and/or Unsafe Food Additives</td>
</tr>
<tr>
<td>16-133</td>
<td>DWPE of Tuna from Moon Fishery India PVT Ltd.</td>
</tr>
</tbody>
</table>
PREDICT (Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting) is the FDA’s electronic screening tool for import operations that replaces the legacy screening tool in OASIS (Operational and Administrative System for Import Support). It works behind the scenes to screen all lines of imported products electronically submitted to the FDA via the US Customs and Border Protection interface.

MARCS (Mission Accomplishment and Regulatory Compliance Services) Import Entry Review is FDA’s new application used to make initial admissibility decisions, assign field work, and display the results of the PREDICT risk-based screening and database lookups.

National rollout of PREDICT began in September of 2009 to all 16 import districts and was completed in December 2011.

PREDICT is designed to calculate a customized risk score for every line in an entry. Score calculations are based on numerical weights assigned to inherent risk rules, data anomaly rules, data quality rules, and the compliance history of firms (e.g., manufacturer, shipper, and consignee) and product associated with the line.

The application of rules results in the generation of a cumulative score for a specific line. The rules can generate negative increments (good credit), neutral (no increment change), or positive increments (increased bad risk). The higher the cumulative score, the greater the identified risk.

Each line receives a percentile rank based on all other lines; increased over the past 20 days. The risk rank is designed to focus FDA’s limited resources using a risk-based approach.

Rules addressing a FDA field assignment, an Import Alert, an Import Bulletin, or District/Center requested criteria are explicitly flagged to be manually reviewed and have no impact on the calculation of the score.

The chart shows the number of FDA-regulated import lines by fiscal year.
QUESTIONS ???
Seafood Expo North America

Boston Expo Center
New England District (NWE-DO)
New England District (NWE-DO) Contact information

- **District Director:** Vacant  Stoneham, MA  DD Secretary  
  Phone: 781-587-7489

- **Director of Investigation Branch (DIB):** Lori Holmquist  
  Portland, ME  
  Phone: 207-221-0053  x  1113.

- **Import Supervisor/Import Program Manager (IPM):** Troy Petrillo  
  Stoneham, MA. Phone: 781-587-7478

- **Import Supervisor (SCSO):** Rebecca Vigue  
  Portland, ME  
  Phone: 207-221-0053  x  1120

- **Import Specialist:** Alois (Lou) Provost  
  Houlton, ME
NWE-DO Manned Port Contact information

- Houlton & Calais, ME
  Two Staff
  Supervisor: R. Vigue
  207-521-0045
  Janis Gallagher x 1113
  Lou Provost x 1116
  Import warehouse x 1119

- Highgate Springs, VT
  One Staff
  Supervisor: R. Vigue
  802-868-4725 or 4635
  Two Trainees
  Brandy Gillian x 1105

- Stoneham, MA
  Eleven Staff
  Supervisor: T. Petrillo
  781-587-7500
  Patrícia Ronan x 7571
  Steven King x 7495
New England District High volume Ports
with # of lines and highest commodities

<table>
<thead>
<tr>
<th>Port</th>
<th>Total lines</th>
<th>Product 1</th>
<th>Product 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portland, ME</td>
<td>5,504</td>
<td>Fishery/Seafood</td>
<td>Choc/Cocoa</td>
</tr>
<tr>
<td>Jackman, ME</td>
<td>4,269</td>
<td>Animal food/feed</td>
<td>Vegetable products</td>
</tr>
<tr>
<td>Houlton, ME</td>
<td>105,955</td>
<td>Vegetable products</td>
<td>Fishery/Seafood</td>
</tr>
<tr>
<td>Calais, ME</td>
<td>70,295</td>
<td>Fishery/Seafood</td>
<td>Vegetable products</td>
</tr>
<tr>
<td>Derby Line, VT</td>
<td>40,060</td>
<td>Vegetable products</td>
<td>Animal food/feed</td>
</tr>
<tr>
<td>Highgate Spring, VT</td>
<td>44,793</td>
<td>Vegetable products</td>
<td>Misc Food Related Items</td>
</tr>
<tr>
<td>Boston, MA</td>
<td>118,086</td>
<td>Alcoholic Beverages</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Logan Airport</td>
<td>196,432</td>
<td>Orthopedic</td>
<td>Gen/Plastic Surgery</td>
</tr>
<tr>
<td><strong>Total Lines for all ports 2015</strong></td>
<td><strong>620,000</strong></td>
<td></td>
<td></td>
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## New England District Import violations

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<th>Port</th>
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</thead>
<tbody>
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Flow Process

Importer files entry to the FDA (Prior Notice) and Customs Automated Commercial System (ACS) *soon to be ACE

↓

Mission Accomplishment Regulatory Compliance Services (MARCS) Import Entry review evaluates data submitted and scores entry based on data points

↓

MARCS Import Entry review system recommends: May Proceed, Exam or Detains the entry.

↓

If referred to FDA: Consumer Safety Officer (CSO) reviews entry for admissibility. CSO may release, request additional documentation, conduct field exam (Labeling, Filth, Decomposition) and/or sample entry.

↓

If entry is sampled at Port of Entry (POE) or at destination; then sample is collected and sent to FDA lab for analysis.

Time of sample completion depends on type of analysis requested.

↓

Compliance Officer (CO) reviews lab data and CSO field exam results, if negative releases entry to consignee.

Average one to three weeks from entry sampled to release.
Entry review issues

• Failure to submit additional documentation when requested (Docs required). i.e. Invoice, CBP 7501, Bill of lading, Labeling or Certifications (CFIA certs).

• Failure to submit or incorrectly submit Affirmation of compliance(s)(A of C).
  o ACC: Accession Number
  o FCE: Food Canning Establishment
  o SID: Schedule Identifier Number
  o LST: Device Listing Number
  o PMA: Device Premarket Approval #
  o PMN: Device Premarket Notification# (510K)
  o IDE: Investigational Device Exemption #
  o IND: Investigational New Drug #
  o NDA: New Drug Application#
  o NDC: National Drug Code
  o DLS: Drug Listing #
  o RAA: Rad Health Product Affirmation (FDA 2877)
Sampling Process at a truck POE

- Truck enters CBP cargo lane and is reviewed by CBP officer. If “FDA review” or “Hold” is noted CBP officer refers truck to FDA CSO.
- Driver presents entry documents and entry number to FDA CSO for review in MARCs.
- FDA CSO reviews MARC flags, IA(s) and SCOPE sampling references. CSO determines if sampling based on entry review and field exams.
- Sampling is conducted based on Investigations Operation Manual (IOM), Compliance Program manual guidance and District FY work plan.
- Sample is taken and Form FDA 472 Carrier’s Receipt of Sample is issued to driver and truck is sealed with FDA metal seal.
- Broker called for any additional entry documents and CBP 7501.
- CSO prepares collection report and packages sample for shipment via overnight carrier usually same day.
Release Issue Examples

• Failure to submit correct Product code.
• Importer entered crab meal as ingredient for animal feed. Entry was flagged by MARCs and sampled by the FDA. Importer called later and stated product was for fertilizer end use. Entry documents did not identify or indicate end use. Product code identified product for animal consumption.

• CSO made electronic requested entry docs for admissibility decision. Broker/filer called the FDA after one week asking why entry was not released.

• Compliance: Failure to submit a reconditioning proposal by within time frame. Entry refused and returned to COO.
Release Issue Examples

• Three most common compliance release issues.

• Incorrect firms declared for the Manufacturer, Shipper and consignee on entry documents. Brokers using old/outdated mid numbers or wrong mid numbers. i.e. one manufacturer had 15 FEI numbers identified because of mids used.

• Private Lab reports: must be collected and analyzed using similar collection and testing methodology. Private lab reports are incomplete or lack pertinent information.

• Labeling: Firms need to submit current labeling of products imported. Ingredient list need to be accurate and list sub ingredients i.e Butter, sub ingredients milk (allergen), salt.
Helpful websites

- Industry guidance on submission of private lab analyses to FDA may be found at the following links accessible via the FDA main web site [www.fda.gov](http://www.fda.gov):
  

  - FDA guidance provided to private laboratories is in Vol.III, Ch.7.2 of the FDA FDA Laboratory Manual, “Private Laboratory Guidance:” [http://www.fda.gov/ScienceResearch/FieldScience/LaboratoryManual/ucm173340.htm](http://www.fda.gov/ScienceResearch/FieldScience/LaboratoryManual/ucm173340.htm)
Helpful websites

- The LM also states that “Sampling should be performed in conformance with FDA-recommended sampling procedures and Compliance Programs (CPGM) [www.fda.gov/ora/cpgm](http://www.fda.gov/ora/cpgm), in addition to the Investigations Operations Manual (IOM), Ch. 4 [www.fda.gov/ora/inspect_ref/iom/iomtc.html](http://www.fda.gov/ora/inspect_ref/iom/iomtc.html)

- Guidance on sample collection & analysis may also appear in other field directives (Ex., Import Alert #16-131: [http://cms.fda.gov/vts/imports_publish/private/importalert_33.html](http://cms.fda.gov/vts/imports_publish/private/importalert_33.html))
Import Alert System

1. It prevents potential violative products from being distributed into the United States

2. It frees up Agency resources to examine other shipments

3. Provides uniform coverage across the country

4. Places the responsibility back on the importer
   - It is the responsibility of the importer to ensure that the products he is importing in the U.S. is in compliance with our laws and regulations
Import Alert System

- 275 active Import Alerts

http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm

- Import Alerts:
  - Provides guidance to the field that we have sufficient evidence to detain goods without examination

- # of Import Alerts
  - Drugs 51
  - Biologics 10
  - Foods 148
  - Devices 38
  - Tobacco 4
  - Vet meds 12
  - Cosmetics 12
Division of Import Operations (DIO) Advisory lists direct reference authorities provided to ORA from FDA’s Centers, listed by the applicable Import Alerts. FDA’s Centers grant direct reference authority to ORA for the inclusion of firms and products to Detention Without Physical Examination (DWPE) under certain circumstances. The majority of Direct references are for specific pathogens in products, i.e. salmonella and listeria monocytogenes for food products.

Products are not subject to DWPE because they are on Import Alert; they are on Import Alert because they are subject to DWPE.
Direct Reference Authorities


- IA# 16-12 – DWPE of Frog Legs
- IA# 16-17 – Salmonella in Frozen Whole Fish from Thailand
- IA# 16-18 – DWPE of Shrimp
- IA# 16-35 – DWPE of Fresh (Raw), Fresh Frozen, and Cooked Shrimp from India
Direct Reference Authorities

• IA# 16-39 – DWPE of Processed Seafood and Analogue Seafood (Surimi) Products for Listeria Monocytogenes
• IA# 16-50 – DWPE of Molluscan Shellfish
• IA# 16-81 – DWPE of Seafood Products Due to the Presence of Salmonella
• IA# 16-114 – DWPE of Frozen Shrimp Imported by Sigma International, Inc., St. Petersburg, Florida
• IA# 16-124 – DWPE of Aquaculture Seafood Products due to Unapproved Drugs
• IA# 16-127 – DWPE of Crabmeat due to Chloramphenicol
Different types of DWPE Import Alerts

Product/Firm Specific
Lists out products from specific manufacturers which appear to be violative
Often contain a “RED LIST”
Examples: 45-02, 16-81, 99-23

Product General
For products that are inherently problematic
Contain a “GREEN LIST” or none at all
Examples: 21-07, 61-07

Country- or area-wide
Geographic areas meeting certain criteria
Contain a “GREEN LIST” or none at all
Examples: 02-01, 16-131, 99-30
Removal from DWPE Importers Alert


**Summary:** In order to remove a product/firm from DWPE:

- Corrective actions must be adequate
- Verified through evaluation of actual entries
- Assurance the cause of the violation has been corrected
- Assurance of consistent compliance
Removal from DWPE Importers Alert

• Process:

Firms or importers may petition to be removed from DWPE

Industry submits the petition
FDA reviews the petition

Submit petitions to:

ImportAlerts2@fda.hhs.gov

or:

Division of Import Operations and Policy
12420 Parklawn Drive ELEM 3109
Rockville, MD 20857
Removal from DWPE Importers Alert

• Process:
  Acknowledgement sent
    Includes case number
    Includes contact person and phone/email

Reviews are done first in-first out
We do not move up in line without good reason
Reviews can take 2-3 months to process

Decision Letter sent
  Denials letters include explanation
  All denials are specifically reviewed by DIOP management
  Approval letters include our notice to field offices
  Approvals are effective immediately

Decision Letter closes the case
Removal from DWPE Importers Alert

• What to submit:
  • Corrective actions/steps to prevent future violations
  • Import Alert specific information
    o Review the import alert
    o Firms with GMP violations may need an inspection to get off an IA
  • Entry information for 5 non-violative entries:
    o US Customs Form 3461 or US Customs Form 7501
    o Invoice
    o Packing List
    o Bill of Lading
    o do not submit private laboratory results
Removal from DWPE Importers Alert

• What we review:

Corrective actions
FDA needs assurance the cause of the violation has been corrected
Inadequate corrective actions is cause for denial
Failure to submit corrective actions is cause for denial

FDA’s Internal Databases
  o We review all shipments, not just the 5 submitted
  o Product failures/refusals is cause for denial

Anything else indicated in the Import Alert
Failure to submit is cause for denial

We will always specifically ask for anything missing
QUESTIONS
Seafood Expo North America & Seafood Processing North America

March 6, 2016
Boston Convention Center
Boston, Massachusetts
The Future of Seafood Regulation Post- FSMA

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
Recognized as one of the “Best Lawyers in America” in the area of **FDA law**:
- 2009 to 2016
Do you have questions about importing/exporting?

http://www.GRCustomslaw.com
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??
Arrival → Entry to CBP and FDA → Selection of Examination by FDA → Refusal by FDA for Misbranding or Adulteration

CBP Demand for Redelivery → Proof of Destruction Under FDA Supervision on CBP Form 7512 or Proof of Exportation under CBP Supervision on CBP Form 3499

Liquidated Damages Claim by CBP for 3 Times the Value of Shipment Up to the Maximum Amount of the Import Bond → Petition Mitigation
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.
CBP focuses on detecting schemes to avoid paying customs duties as seafood products enter the country, such as transshipment to avoid antidumping duties. CBP’s import specialists review seafood import documentation on product type, value, and country of origin to ensure that importers have paid the appropriate duties. The agency also uses information provided by one of its National Targeting and Analysis Groups to help identify potentially fraudulent seafood shipments. This group analyzes data on foreign producers and importers that may be involved in transshipment schemes to avoid paying antidumping duties and works with port officials to examine these shipments as they arrive.
Mislabeling or Substituting Species

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.

A 2011 Consumer Reports Magazine study of seafood sampled from New York, New Jersey, and Connecticut found that 20% to 25% of seafood products were mislabeled.
Lacey Act and Food, Drug, and Cosmetic Act

Mislabelling of foods such as fish and shrimp is prohibited by the Lacey Act, 16 U.S.C. §§ 3372(d)(1) and 3372(d)(2), and the FDCA, 21 U.S.C. § 331. The Lacey Act, in pertinent part, makes it unlawful for a person to falsely identify any fish that has been, or is intended to be, imported, sold, purchased, or received from any foreign country or transported in interstate or foreign commerce. The FDCA, in pertinent part, prohibits the alteration or removal of the whole or any part of the labeling of food, if such act is done while such article is held for sale after shipment in interstate commerce.
Transshipment and Mislabling to Avoid Customs Duties

Transshipment occurs when foreign producers ship goods through a second country en route to the United States. Although transshipment is generally legal and commonly used in the ordinary course of business, it is illegal if done for the purpose of circumventing duties and other applicable trade restrictions. For example, shrimp from China reportedly have been shipped 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. In other cases, seafood such as Asian catfish has been mislabeled as sole specifically to avoid paying antidumping duties.
WASHINGTON—The chief executive officer of Sterling Seafood Corporation located in Cresskill, N.J., pleaded guilty today to importing falsely labeled fish from Vietnam and evading over $60 million in federal tariffs, as well as selling over $500,000 in similarly misbranded fish purchased from another importer in the United States, the Justice Department announced.

The U.S. Department of Commerce establishes antidumping duties or tariffs on certain imported products. In January 2003, an anti-dumping duty or tariff was placed on all imports of Vietnamese catfish into the United States because the Vietnamese catfish was being marketed at a significantly lower price than was market rate at the time. That initial anti-dumping order imposed a duty of up to 63.88 percent on fish.

The CEO specifically instructed the Vietnamese company to fraudulently identify the Vietnamese catfish as "grouper" on commercial contracts, purchase orders, and other documents because grouper fish was not subject to any anti-dumping duties.

The charge of importing of falsely labeled goods into the United States carries a maximum statutory sentence of two years in prison and a $250,000 fine, or twice the monetary gain derived from the offense. The second count, which charges selling misbranded fish in the United States, carries a maximum statutory sentence of three years in prison and a $250,000 fine, or twice the monetary gain derived from the offense.
19 CFR §113.62  Basic importation and entry bond conditions.

BASIC IMPORTATION AND ENTRY BOND CONDITIONS

(a) Agreement to Pay Duties, Taxes, and Charges....

(d) Agreement to Redeliver Merchandise. If merchandise is released conditionally from CBP custody to the principal before all required evidence is produced, before its quantity and value are determined, or before its right of admission into the United States is determined, the principal agrees to redeliver timely, on demand by CBP...

It is understood that any demand for redelivery will be made no later than 30 days after the date that the merchandise was released or 30 days after the end of the conditional release period (whichever is later). (See §§141.113(b), 12.73(b)(2), and 12.80 of this chapter.)

(e) Agreement to Rectify Any Non-Compliance with Provisions of Admission. If merchandise is released conditionally to the principal before its right of admission into the United States is determined, the principal, after notification, agrees to mark, clean, fumigate, destroy, export or do any other thing to the merchandise in order to comply with the law and regulations governing its admission into the United States within the time period set in the notification.
(f) Agreement for Examination of Merchandise. If the principal obtains permission to have any merchandise examined elsewhere than at a wharf or other place in charge of a CBP officer, the principal agrees to:

(1) Hold the merchandise at the place of examination until the merchandise is properly released;

…

(m) Consequence of default. (1) If the principal defaults on agreements in this condition other than conditions in paragraphs (a), (g), (i), (j), (k)(2), or (l) of this section the obligors agree to pay liquidated damages equal to the value of the merchandise involved in the default, or three times the value of the merchandise involved in the default if the merchandise is restricted or prohibited merchandise or alcoholic beverages, or such other amount as may be authorized by law or regulation.
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.
**CBP Form 301 Customs Bond**

**SECTION I**

- **Broker Filer Code:** [Blank]
- **Surety Reference Number:** [Blank]
- **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 named principal(s) and surety(s), bind ourselves to the United States in the amount or amounts, as set forth below.**

- **Execution Date:** [Blank]
- **Effective Date:** [Blank]
- **Continuous Bond:** [Blank]
- **Identification of transaction covered by this bond:** [Blank]
- **Transaction Date:** [Blank]
- **Port Code:** [Blank]

**SECTION II**

This bond remains in force for one year beginning with the effective date and for each succeeding annual period, or until terminated. The 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 shall be conveyed within the period and manner prescribed in the CBP Regulations.

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<th>Limit of Liability</th>
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**PRINCIPAL**

- **Name and Physical Address (including legal description and state of incorporation):** [Blank]
- **CBP Identification Number:** [Blank]
- **Signature:** [Blank]
- **Check Box:** [Blank]

**SURETY**

- **Name and Physical Address (including legal description and state of incorporation):** [Blank]
- **Surety Number:** [Blank]
- **Agent ID Number:** [Blank]
- **Signature:** [Blank]
- **Check Box:** [Blank]
CBP Form 3499
Application and Approval to Manipulate, Examine, Sample or transfer goods
CBP Form 7512
Transportation Entry and Manifest of Goods Subject to CBP Inspection and Permit
Seafood Expo North America & Seafood Processing North America

March 6, 2016
Boston Convention Center
Boston, Massachusetts
Seafood under Heightened Scrutiny

By: Benjamin L. England, Esq.
Founder & CEO, FDAImports.com

Boston Seafood Show 2016
Benjamin L. England, Esq.

Mr. England is the founding member of Benjamin L. England & Associates, LLC, and the owner and founder of FDAlimports.com, LLC, a consulting firm combining the services of former U.S. Food & Drug Administration (FDA) and U.S. Department of Agriculture (USDA) officials to expertly advise and counsel international and importing food, drug, medical device, and cosmetic firms.
Topics

• What happened and is happening.
• What will be in the future: Effect of FSMA on Seafood.
What happened in 2014 to 2015

- **Vet Drugs**: FDA increased the enforcement of vet drug in the seafood industry.
  - The multi-residue method enables FDA to test several drugs in single test, including sulfonamide
  - Detected sulfonamides in tilapia, but also frog legs, eel, and shrimp
  - FDA started testing sulfonamide group. For example, tilapia from Asia was hit by sulfonamide testing because foreign government permits a higher limit of the sulfonamide drugs.
What happened in 2014 to 2015

- Scombrotoxin (histamine) Fish, Canned/Pouched
  - Histamine historic area of concern for FDA and continues to be
  - Increased focused on a precooking step to ensure that the control step and monitoring is adequately validated.
What is Happening Now

• Aggressive surveillance test on all seafood, for example
  – Scallops and tuna for decomposition
  – Tilapia for unapproved drug residues
  – Expansion of sulfonamide testing into other aquaculture species
FDA is not Infallible

• FDA testing detected astaxanthin in cooked shrimp
  – Astaxanthin is an approved color additive that gives salmon its color

• Product detained and other shipments stopped under the theory that it appeared they contain an illegal color additive
FDA is not Infallible

• Astaxanthin is inherent in shrimp, not a *color additive*
  – Shrimp can be used as the source material to manufacturer astaxanthin given to salmon

• Result: Once FDA was notified of its mistake at the field level, prompt release of FDA detained and held shipments
Future – FSMA and Seafood

Seafood industry had been told FSMA will not have that big an effect

• HARPC and FSVP

“This section shall not apply to a facility if … facility is required to comply with, and is in compliance with … The Seafood Hazard Analysis Critical Control Points Program”
Future: HARPC and cGMPs

- FDA used HARPC rule to also amend cGMPs
- cGMPs apply to facilities subject to seafood HACCP
  - GMP requires mandatory training on food hygiene and food safety and record keeping for the training
Future: cGMPs and New Records

• Until recently cGMPs didn’t have recordkeeping obligations
• cGMPs requires mandatory training on food hygiene and food safety, and record keeping for the training.
Future: HACCP Importer Verification against FSVP

- Written verification procedures
  - Product specifications
  - Affirmative step
- Recordkeeping

- Hazard analysis
- Risk Evaluation
- Verification activities
  - AUDITS!
- Corrective action(s)
- Reassessment
- Recordkeeping
FDA Will Raise Seafood To Level the Playing Field

- HACCP’s verification procedures and FSVP are not equivalent (FSVP is stronger)
- FDA will not tolerate dual food safety systems
- Seafood is already considered a high-risk food
- FDA will strengthen HACCP, not weaken FSVP