“Understanding the Regulatory Jurisdiction of Federal Agencies”

Seafood Expo North America

Boston, MA

March 6-8, 2016
U.S. Customs and Border Protection

Overview of Import Clearance/Vetting Process

Seafood Expo North America
Boston
March 2016
Current Process for Importing Goods

1. Contract
2. Purchase Order
3. Manufacture
4. CSI
5. Transportation
6. Manifest
7. Arrival/Importation
8. Entry/Immediate Delivery

- CBPF 1302
- CBPF 7509
- CBPF 7533
- Manifest
- CBPF 3461 / 3461ALT

- Notice of Redelivery
- Import Specialist Team Review
- Entry Summary Selectivity Results
- Entry Summary + Collection
- Release
- Cargo Selectivity Results
- Examination
- Detention
- Seizure
- PROTEST
- RELIQ

- Liquidation
- 1) Warehouse
- 2) Export
- 3) Destroy

U.S. Customs and Border Protection
Import Reporting

• Cargo Release and Admissibility - Merchandise must be admissible to U.S under law and regulation
  • Manifest - declaration from the person or entity bringing the merchandise to U.S.
  • Customs Declaration
  • Partner Govt. Agency licenses/certificates and reporting
  • (For cargo security vetting only: CBP security filing (10+2): SF 10 data elements + load plan = container status messages)

• Entry Summary and Payment of Duties
  • Payment of duties
  • Classification - based on description and/or examination merchandise is identified by HTS
  • Appraisal - Value is declared and assessed (price actually paid or payable)
Risk Assessment Processes

• CBP performs risk assessment on every transaction for
  • Security – Weapons of mass destruction/effect, terrorists
  • Enforcement – Narcotics, weapons, illegal persons
  • Admissibility – Meets regulatory requirements for entry for both revenue and other agencies (import safety, food safety etc)

• CBP takes action on high risk shipments
  • Non-intrusive inspection
  • Unlading and examination of shipments
  • Referral to OGA/PGAs for their examination/action
    o E.g. CBP works closely with National Marine Fisheries Service to enforce their permit requirements. (Atlantic Highly Migratory Species, Antarctic Marine Living Resource, Tuna Tracking and Verification Program)

• Importer is responsible to present the merchandise for examination and pay costs that arise
Risk Management Methods

• Systems
  • Automated Targeting System
  • Advance information to facilitate vetting
  • Automated Commercial Environment – Int’l Trade Data System (ACE-ITDS) (single window system)

• Programs
  • Customs-Trade Partnership Against Terrorism (C-TPAT)
  • Importer Self Assessment
  • Inter-agency trusted trader efforts (e.g. FDA, CPSC)

• Personnel for vetting
  • National Targeting Center-Cargo (NTCC)
  • Commercial Targeting & Analysis Center (CTAC) – interagency
  • National Targeting & Analysis Centers (NTAGs)

• Legislation
  • E.g. Trade Act of 2002 (advance cargo information for vetting)
  • PGA ITDS
Seafood Expo North America

Understanding the Regulatory Jurisdiction of Federal Agencies

Boston Convention and Exhibition Center
March 6 – 8, 2016
Seafood Regulation

Federal Food, Drug, and Cosmetic Act (FD&C)
- Sec. 402 Adulterated Food
- Sec. 403 Misbranded Food
- Sec. 801 Imports and Exports

Code of Federal Regulation (21 CFR)
- Part 110 Current good manufacturing practice in manufacturing, packing, or holding human food
- Part 113 Thermally processed low-acid foods packages in hermetically sealed containers
- Part 114 Acidified foods
- Part 123 Fish and fishery products (Seafood HACCP)
- Part 161 Fish and shellfish
Fish and Fishery Products
Hazards and Controls Guidance
Fourth Edition – April 2013

PROJECT:
FISH S.C.A.L.E.


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I. Introduction
II. Background
III. Discussion
IV. The Seafood List
V. Understanding and Using The Seafood List
VI. Principles for Determining Acceptable Market Names
VII. References

Resources for You
- The FDA Seafood List - Updates for 2012
- The FDA Seafood List - Updates for 2011
- The FDA Seafood List - Updates for 2011
Electronic Transactions of FDA Regulated Entry Lines

Entry filer

Data elements

CBP

OASIS

PN screening

801(a) screening

Prior Notice Center (foods only)

“FDA review” message

“May proceed” message

FDA district entry reviewer

“May proceed” message

FDA review message

Review?

Yes

STOP

OK?

Yes

No

No

Yes
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
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
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)
ORA Organizational Chart

Office of Regulatory Affairs Effective October 1, 2012

ACRA
Associate Commissioner for Regulatory Affairs

DACRA
Deputy Associate Commissioner for Regulatory Affairs

IT Staff
External Relations Staff
Executive Secretariat Staff

Office of Resource Management (ORM)

Office of Criminal Investigations (OCI)

Office of Operations (OO)

Senior Scientist

Audit Staff (AS)

Office of Enforcement and Import Operations (OEIO)

Office of Food and Feed Operations (OFFO)

Office of Medical Products and Tobacco Operations (OMPTO)

Office of Regulatory Science (ORS)

Office of Communications and Quality Program Management (OCQPM)

Office of Policy and Risk Management (OPRM)

Office of Partnerships (OP)

Office of Enforcement (DE)

Division of Food Defense Targeting (DFDT)

Division of Medical Products and Tobacco Program Operations (DMPTPO)

Division of Medical Products and Tobacco Scientific Staff (MPTSS)

Northeast Region (NER)

Quality Management Staff (QMS)

Risk Management Staff (RMS)

Contracts and Grants Staff (CGS)

Office of Food and Feed Operations and Inspections (DFFOI)

Division of Food and Feed Operations (OFFO)

Division of Food and Feed Operations and Inspections (DFFOI)

Division of Medical Products and Tobacco Inspections (DMPTI)

Medical Products and Tobacco Scientific Staff (MPTSS)

Medical Products and Tobacco Policy Staff (MPTPS)

Office of Regulatory Science (ORS)

Laboratory Operations and Support Staff (LOSS)

Internal Communications Staff (ICS)

Office of Medical Products and Tobacco Operations (OMPTO)

Division of Medical Products and Tobacco Operations (OMPTO)

Division of Medical Products and Tobacco Scientific Staff (MPTSS)

Project Coordination Staff (PCS)

Office of Communications and Quality Program Management (OCQPM)

Office of Regulatory Affairs (ORA Regions)

ORA Regions

Northeast Region (NER)

Quality Management Staff (QMS)

Risk Management Staff (RMS)

Contracts and Grants Staff (CGS)

Central Region (CER)

Project Coordination Staff (PCS)

Office of Regulatory Affairs (ORA Regions)

Southwest Region (SWR)

Division of Planning Evaluation and Management (DPEEM)

Office of Regulatory Affairs (ORA Regions)

Pacific Region (PAR)

Operational units shaded green are new or have been modified
STATS
**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>
</tr>
</tbody>
</table>
## FY 2011–2015 Top Ten Seafood Products

<table>
<thead>
<tr>
<th>FY</th>
<th>Salmon, Aquac</th>
<th>Shrimp &amp; Prawns, Aquac</th>
<th>Tuna</th>
<th>Fish, N.E.C.</th>
<th>Crab</th>
<th>Shrimp &amp; Prawns</th>
<th>Snapper</th>
<th>Cod</th>
<th>Lobster</th>
<th>Tilapia, Aquac</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>67,777</td>
<td>65,917</td>
<td>58,048</td>
<td>36,860</td>
<td>34,070</td>
<td>29,177</td>
<td>29,818</td>
<td>22,361</td>
<td>20,137</td>
<td>20,590</td>
</tr>
<tr>
<td>2012</td>
<td>83,356</td>
<td>65,641</td>
<td>60,450</td>
<td>37,445</td>
<td>34,780</td>
<td>33,183</td>
<td>30,774</td>
<td>22,084</td>
<td>21,967</td>
<td>24,119</td>
</tr>
<tr>
<td>2013</td>
<td>89,476</td>
<td>65,710</td>
<td>58,326</td>
<td>39,327</td>
<td>35,035</td>
<td>27,415</td>
<td>31,465</td>
<td>27,074</td>
<td>24,755</td>
<td>24,035</td>
</tr>
<tr>
<td>2014</td>
<td>96,911</td>
<td>71,363</td>
<td>61,892</td>
<td>41,126</td>
<td>37,556</td>
<td>33,971</td>
<td>30,500</td>
<td>29,107</td>
<td>24,124</td>
<td>21,855</td>
</tr>
<tr>
<td>2015</td>
<td>109,227</td>
<td>73,704</td>
<td>69,846</td>
<td>43,695</td>
<td>38,405</td>
<td>37,683</td>
<td>32,881</td>
<td>29,837</td>
<td>22,893</td>
<td>22,672</td>
</tr>
</tbody>
</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>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>243542</td>
<td>105181</td>
<td>46494</td>
<td>55661</td>
<td>16569</td>
<td>38739</td>
<td>51457</td>
<td>28671</td>
<td>27409</td>
<td>19853</td>
</tr>
<tr>
<td>2012</td>
<td>235352</td>
<td>97784</td>
<td>51747</td>
<td>57333</td>
<td>21685</td>
<td>39842</td>
<td>49176</td>
<td>26442</td>
<td>26325</td>
<td>20822</td>
</tr>
<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>
</tr>
<tr>
<td>2014</td>
<td>218662</td>
<td>124209</td>
<td>60556</td>
<td>58523</td>
<td>45501</td>
<td>43334</td>
<td>31546</td>
<td>29074</td>
<td>29509</td>
<td>21156</td>
</tr>
<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>
</tr>
</tbody>
</table>
FY 2011–2015 SEAFOOD REFUSALS*

<table>
<thead>
<tr>
<th>FY</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refusals</td>
<td>2,500</td>
<td>3,039</td>
<td>1,979</td>
<td>1,501</td>
<td>1,766</td>
</tr>
</tbody>
</table>

*Refusal counts represents a unique count of lines
## FY 2011–2015 TOP TEN SEAFOOD PRODUCTS REFUSED

*Represents a unique count of refusals*

<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>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>302</td>
<td>382</td>
<td>130</td>
<td>69</td>
<td>98</td>
<td>156</td>
<td>27</td>
<td>113</td>
<td>158</td>
<td>70</td>
</tr>
<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>
</tr>
<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>
</tr>
<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>
<td>38</td>
</tr>
<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>
</tr>
</tbody>
</table>
**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>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>795</td>
<td>945</td>
<td>272</td>
<td>10</td>
<td>189</td>
<td>107</td>
<td>104</td>
<td>110</td>
<td>86</td>
<td>89</td>
</tr>
<tr>
<td>2012</td>
<td>1100</td>
<td>709</td>
<td>148</td>
<td>40</td>
<td>280</td>
<td>39</td>
<td>108</td>
<td>76</td>
<td>50</td>
<td>101</td>
</tr>
<tr>
<td>2013</td>
<td>661</td>
<td>465</td>
<td>115</td>
<td>31</td>
<td>137</td>
<td>35</td>
<td>57</td>
<td>38</td>
<td>38</td>
<td>90</td>
</tr>
<tr>
<td>2014</td>
<td>489</td>
<td>352</td>
<td>300</td>
<td>101</td>
<td>95</td>
<td>44</td>
<td>29</td>
<td>43</td>
<td>40</td>
<td>59</td>
</tr>
<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>
</tr>
</tbody>
</table>

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

### TIME FRAMES

<table>
<thead>
<tr>
<th>Metric</th>
<th>FY15</th>
<th>FY14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of lines</td>
<td>1,010,146</td>
<td>938,078</td>
</tr>
<tr>
<td>Total # of samples collected</td>
<td>3,914</td>
<td>5,117</td>
</tr>
<tr>
<td>% of lines sampled</td>
<td>0.4%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Total number refused</td>
<td>473</td>
<td>361</td>
</tr>
<tr>
<td>% of lines violative based on refusal</td>
<td>12.1%</td>
<td>7.05%</td>
</tr>
<tr>
<td>Total number reconditioned</td>
<td>173</td>
<td>189</td>
</tr>
<tr>
<td>Total number released with comment</td>
<td>168</td>
<td>206</td>
</tr>
<tr>
<td>Total number of actual violations</td>
<td>814</td>
<td>756</td>
</tr>
<tr>
<td>% of violative shipments</td>
<td>20.8%</td>
<td>14.77%</td>
</tr>
</tbody>
</table>

**FY15 Average time between sample collection & final disposition = 21 days**

**FY14 Average time between sample collection & final disposition = 23 days**
Field & HQ
Responsibilities & Activities

• Field/HQ Activities
  ✓ DIO: Responsibilities & CBP Liaison
  ✓ CTAC: Co-location
  ✓ Prior Notice Review
    ✓ Import security reviews on food/feed identified as high risk for intentional contamination 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
QUESTIONS ???
Country of Origin Labeling (COOL)

Requirements for Fish and Shellfish

Kenneth M. Becker, USDA
North American Seafood Expo 2016
What is COOL? Who has to comply with COOL?

Purpose
• Retailers (most grocery stores and supermarkets) are required to provide consumers with country of origin information.
• COOL is a consumer information law.

Scope
• COOL is not a food safety initiative. Other agencies address food safety standards (Food Safety Inspection Service, Food and Drug Administration).
• 4,000 retail firms operate 37,000 retail store facilities across the U.S.
• Restaurants, cafeterias, farmers’ markets, and other food service institutions are exempt from COOL rules.
The COOL statute and regulations require suppliers and retailers to convey two pieces of information on fish and shellfish items sold at retail (most supermarkets and grocery stores):

- Country of Origin
- Method of production: farm-raised or wild-caught
Country of Origin Labeling (COOL)

Country of Origin

- Whole fish and shellfish, and fillets, steaks, nuggets, and any other flesh.
- Product of the U.S. – harvested in the waters of the United States or by a U.S. flagged vessel and processed in the United States or aboard a U.S. flagged vessel, and that has not undergone a substantial transformation (as established by U.S. Customs and Border Protection) outside of the United States.
Country of Origin Labeling (COOL)

Country of Origin

• An imported covered commodity shall retain its origin as declared to U.S. Customs and Border Protection at the time the product entered the United States, through retail sale, provided that it has not undergone a substantial transformation (as established by U.S. Customs and Border protection) in the United States.
Country of Origin Labeling (COOL)

Country of Origin

• If a covered commodity was imported from country X and subsequently substantially transformed (as established by U.S. Customs and Border protection) in the United States or aboard a U.S. flagged vessel, such product shall be labeled at retail as “From country X, processed in the United States.” Alternatively, the product may be labeled as “Product of country X and the United States”.

Method of Production (fish and shellfish)

Farm-Raised

Harvested in Controlled Environments

– Subjected to production enhancements
  • Protection from predators
  • Addition of artificial structures, or
  • Providing nutrients

• Includes fillets, steaks, nuggets, and any other flesh from a farm-raised fish or shellfish
Method of Production (fish and shellfish)

Wild-Caught

- Naturally born or hatchery originated fish and shellfish released in the wild and caught, taken, or harvested from non-controlled waters or beds

- Includes fillets, steaks, nuggets, and any other flesh from wild fish and shellfish
Country of Origin and Method of Production Labeling

Wild Caught Label

Farm-Raised Label
Additional Information

Visit: www.ams.usda.gov/COOL

Submit questions to: cool@ams.usda.gov

or

(202) 720-4486
Office of International Affairs & Seafood Inspection

Steven Wilson
Deputy Director

March 7, 2016
Seafood Expo N. America, Boston, MA
NOAA Seafood Inspection ensures that fish and fishery processors and products meet:

- **Regulatory requirements**
- **Quality specifications**

So international and domestic buyers and consumers can have confidence in the seafood products they purchase.
NOAA Seafood Inspection

FDA is the mandatory authority for seafood inspection in the United States.

- FD&C Act, PHS Act, FP&L Act
  - 21CFR Part 110 (GMPs)
  - 21 CFR Part 123 (SHR)
  - 21 CFR Part 101 (Labeling)
- Periodic audits of processors of fish and fishery products for compliance:
  - Food Safety
  - Wholesomeness
  - Proper Labeling
NOAA Seafood Inspection Program

Fee for Service Program

Mission: to provide inspection service for fish and fishery products and processors to:

• Ensure safety and quality
• Enhance marketability
• Support sustainability
NOAA Seafood Inspection Program

Stakeholders and Beneficiaries:
- Harvesters
- Farmers (aquaculture)
- Processors
- Distributors
- Retailers
- Food Service Operators
- Importers and Exporters
- Foreign Processors
- Foreign Governments
- Consumers
NOAA Seafood Inspection Program – Industry Services

• Inspection, Grading and Auditing
• Export Certification

• Consultative Services
• Training and Education
NOAA Seafood Inspection Program – Conclusion

Thank you!

For more information, please see:

http://www.seafood.nmfs.noaa.gov/