Aquaculture Drugs: Industry Concerns

Lisa Weddig
Vice President, Regulatory and Technical Affairs
National Fisheries Institute
Who is NFI?

• Leading advocacy organization in the U.S. for the seafood industry.

• NFI’s members represent every element of the industry
  • fishing vessels
  • processors
  • importers
  • restaurant and retail chains
  • suppliers to the industry

• NFI and members support and promote sound public policy based on science.
In other words ...

NFI members sell fish ...

and want to sell more!
### Top Ten Species - 2014

<table>
<thead>
<tr>
<th>Species</th>
<th>Price</th>
<th>Species</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shrimp</td>
<td>4.00</td>
<td>Pangasius</td>
<td>0.69</td>
</tr>
<tr>
<td>Canned Tuna</td>
<td>2.31</td>
<td>Cod</td>
<td>0.66</td>
</tr>
<tr>
<td>Salmon</td>
<td>2.30</td>
<td>Catfish</td>
<td>0.52</td>
</tr>
<tr>
<td>Tilapia</td>
<td>1.44</td>
<td>Crab</td>
<td>0.51</td>
</tr>
<tr>
<td>Pollock</td>
<td>0.98</td>
<td>Clams</td>
<td>0.34</td>
</tr>
</tbody>
</table>

U.S. Per capita consumption is 14.6 pounds (roughly 4.5 ounces per week)

*Source: National Fisheries Institute at www.aboutseafood.com*
2015-2020 Dietary Guidelines for Americans (www.dietaryguidelines.gov)

- ... variety of protein foods, including seafood, lean meats and poultry, eggs, legumes (beans and peas), and nuts, seeds, and soy products.

- ... incorporating seafood as the protein foods choice in meals twice per week in place of meat, poultry, or eggs, ... For example, choosing a salmon steak, a tuna sandwich, bean chili, or almonds on a main-dish salad could all increase protein variety.
2015-2020 Dietary Guidelines for Americans
100,000 reported illness from all food sources

2,348 illnesses reported from all imported food (2.4% of total)

141 illnesses reported from imported seafood (0.141% of total)

None of the fish identified as causing illnesses were from farmed sources.
Bipartisan Group Presses For Consumer Protections In Trade Negotiations

Trans-Pacific Partnership Could Open U.S. To Contaminated Seafood

WASHINGTON, DC—Congresswoman Rosa DeLauro (D-CT), Senator Mary Landrieu (D-LA) and Congressman Walter Jones (R-N.C.) pressed the Obama Administration today to ensure public health is protected as they continue to negotiate the Trans-Pacific Partnership (TPP) Free Trade Agreement. As a result of expanded trade with two particular TPP countries, Vietnam and Malaysia, the United States markets could see an influx of imported contaminated seafood. In a letter to US Trade Representative Ron Kirk, the members urged him to pursue agreements with these two countries to help ensure the American food supply is kept safe.

“In Fiscal Year 2012, Imported seafood products from Vietnam, the fifth largest exporter of shrimp to the United States, were refused entry 206 times because of concerns including filth, decomposition, drug residues, unapproved food additives and Salmonella. “Meanwhile... U.S. Customs and Border Protection (CBP) and Immigration and Customs Enforcement (ICE) officials determined that some exporters in Malaysia have acted as conduits to transship Chinese shrimp to the United States in order to circumvent both FDA Import Alerts and antidumping duties,” they wrote. “We strongly believe that these critical food safety issues should be resolved prior to the conclusion of the TPP FTA negotiations in order to best protect the public health from these known health risks.”
... imported seafood products from XXX ... were refused entry 206 times because of concerns including filth, decomposition, drug residues, unapproved food additives and Salmonella.

unapproved food additives and Salmonella. “Meanwhile... U.S. Customs and Border Protection (CBP) and Immigration and Customs Enforcement (ICE) officials determined that some exporters in Malaysia have acted as conduits to transship Chinese shrimp to the United States in order to circumvent both FDA Import Alerts and antidumping duties,” they wrote. “We strongly believe that these critical food safety issues should be resolved prior to the conclusion of the TPP FTA negotiations in order to best protect the public health from these known health risks.”
7 Foods Nutritionists Won’t Eat

by Toby Amidor in Healthy Tips, August 5, 2015

Imported Farm-Raised Shrimp

"I make a conscious effort to purchase and consume sustainable seafood, for both environmental and personal health. Imported shrimp are often unsustainably farmed and laden with chemicals and antibiotics. Sticking to this can certainly be a challenge, since 94 percent of the shrimp we consume in the U.S. is imported."

—Kristy Del Coro, M.S., R.D., CDN, senior culinary nutritionist at SPE Certified
“While US fisheries are very strictly managed, I am not confident that the same level of management is upheld for global fisheries.”

“While there are certainly standards in place as you pointed out, to my knowledge they are not necessarily enforced. For example, while not allowed in the US, shrimp in many foreign farms are given daily doses of antibiotics which we know can lead to antibiotic resistant disease.”

“... over 90% of the shrimp in the US is imported and less than 2% is inspected by the FDA is sufficient reason for me to personally avoid consuming this particular type of seafood ...”
“While US fisheries are very strictly managed, I am not confident that the same level of management is upheld for global fisheries.”

“While there are certainly standards in place as you pointed out, to my knowledge they are not necessarily enforced. For example, while not allowed in the US, shrimp in many foreign farms are given daily doses of antibiotics which we know can lead to antibiotic resistant disease.”

“… over 90% of the shrimp in the US is imported and less than 2% is inspected by the FDA is sufficient reason for me to personally avoid consuming this particular type of seafood ...”
Imported Catfish

Dangers of Unregulated, Imported Catfish

Imported catfish may be contaminated with antibiotic, pesticide or bacterial residues. Imported catfish often come from Southeast Asia, where use of chemicals and antibiotics is barely regulated. Because the U.S. Food and Drug Administration inspects less than 2% of imported seafood, imported catfish may be contaminated with antibiotic, pesticide or bacterial residues.
“... use of chemicals and antibiotics is barely regulated.”
2011 U.S. Government Accountability Office Study critiqued implementation of Seafood HACCP
SEAFOOD SAFETY

FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources

Why GAO Did This Study

About half of the seafood imported into the U.S. comes from farmed fish (aquaculture). Fish grown in confined aquacultured areas can have bacterial infections, which may require farmers to use drugs like antibiotics. The residues of some drugs can cause cancer and antibiotic resistance. The Department of Health and Human Services’ (HHS) Food and Drug Administration (FDA) is charged with ensuring the safety of seafood against residues from unapproved drugs, and the Department of Commerce’s National Marine Fisheries Service (NMFS) provides inspection services on request. In 2009, these agencies signed a memorandum of
Follow-Up GAO Study Underway

• At the request of Sen. Thad Cochran (R-Miss.) GAO will look at federal efforts to ensure imported seafood safety.

• Will include:
  • the degree that FDA tests imported seafood for unapproved drugs.
  • Compare the chemicals various government agencies (i.e., FDA vs. USDA) are testing for in imported seafood.

• Report expected Spring 2017
and most recently

Hearings

**Budget Hearing - Food and Drug Administration**

*Thursday, February 25, 2016 10:30 AM in 2362-A Rayburn*

*Agriculture, Rural Development, Food and Drug Administration, and Related Agencies*

**Witnesses**

Dr. Stephen Ostroff  
Acting Commissioner  
Food and Drug Administration  
Testimony
Budget Hearing - Food and Drug Administration

Thursday, February 25, 2016 10:30 AM in 2362-A Rayburn
Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2016

Witnesses
Dr. Stephen Ostroff
Acting Commissioner
Food and Drug Administration
Testimony
Stephen Ostroff, acting commissioner of FDA, was asked to comment about:

- more enforcement action against imported shrimp with illegal antibiotics.
- an “explosion” of seafood in light of TPP, and that FDA does not have the money to handle the threat of unsafe food from foreign food producers.
## FDA Approved Aquaculture Drugs

<table>
<thead>
<tr>
<th>Drug</th>
<th>Approved Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chorionic gonadotropin</td>
<td>Brood finfish</td>
</tr>
<tr>
<td>Formalin</td>
<td>Finfish</td>
</tr>
<tr>
<td></td>
<td>Finfish eggs</td>
</tr>
<tr>
<td></td>
<td>Penaeid shrimp</td>
</tr>
<tr>
<td></td>
<td>Salmon, trout, catfish, largemouth bass and bluegill</td>
</tr>
<tr>
<td>Florfenicol</td>
<td>Channel catfish</td>
</tr>
<tr>
<td></td>
<td>salmonids</td>
</tr>
<tr>
<td>Tricaine methanesulfonate</td>
<td>Families: Ictaluridae, Salmonidae, Esocidae and Percidae</td>
</tr>
<tr>
<td>Oxytetracycline dihydrate</td>
<td>Catfish, salmonids, lobster</td>
</tr>
<tr>
<td>Oxytetracycline hydrochloride</td>
<td>Finfish fry and fingerlings</td>
</tr>
<tr>
<td>Hydrogen peroxide</td>
<td>Fishfish eggs</td>
</tr>
<tr>
<td></td>
<td>Salmonids</td>
</tr>
<tr>
<td></td>
<td>Freshwater-reared coolwater finfish</td>
</tr>
<tr>
<td></td>
<td>Channel catfish</td>
</tr>
<tr>
<td>Sulfamerazine</td>
<td>Trout (rainbow, brook, brown)</td>
</tr>
<tr>
<td>Sulfadimethoxine/Trimethoprim</td>
<td>Catfish</td>
</tr>
<tr>
<td></td>
<td>Salmonids (trout and salmon)</td>
</tr>
<tr>
<td>Chloramine-T</td>
<td>freshwater-reared salmonids</td>
</tr>
<tr>
<td></td>
<td>walleye,</td>
</tr>
<tr>
<td></td>
<td>freshwater-reared warm water finfish</td>
</tr>
</tbody>
</table>
### FOOD AND DRUG ADMINISTRATION
**COMPLIANCE PROGRAM GUIDANCE MANUAL**

**PROGRAM** 7304.018

**CHAPTER 04 - PESTICIDES AND CHEMICAL CONTAMINANTS**

<table>
<thead>
<tr>
<th>SUBJECT</th>
<th>IMPLEMENTATION DATE</th>
<th>COMPLETION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemotherapeutics in Seafood Compliance Program <em>(FY 09/10/11)</em></td>
<td>10/01/08</td>
<td>09/30/11 or until revised</td>
</tr>
</tbody>
</table>

**DATA REPORTING**

**PRODUCT CODES**

<table>
<thead>
<tr>
<th>CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. PRC: 00010</td>
<td></td>
</tr>
<tr>
<td>2. PRF: 001</td>
<td></td>
</tr>
</tbody>
</table>

**PRODUCT/ASSIGNMENT CODES**

---

**DATE OF ISSUE:**

FORM FDA 2480 (10/21)
FDA has identified a number of drugs and families of drugs historically used in fish without FDA approval that are of high enforcement priority.

- Chloramphenicol
- Nitrofurans
- Fluoroquinolones and Quinolones
- Malachite Green
- Steroid Hormones
"Detention Without Physical Examination Of Aquaculture Seafood Products Due To Unapproved Drugs"

- Tilapia – malachite green, gentian violet, sulfadiazine
- Frog legs – ciprofloxacin, enrofloxacin, chloramphenicol
- Shrimp – chloramphenicol, nitrofurantoin, Fluoroquinolone
"Detention Without Physical Examination Of Aquaculture Seafood Products Due To Unapproved Drugs"

- 7 different countries
- Over 75 companies
"Detention Without Physical Examination of Crustaceans Due to Chloramphenicol"

- Crustaceans: Crab, Shrimp, Lobster, Crayfish, Langostino
"Detention Without Physical Examination of Crustaceans Due to Chloramphenicol"

- 6 countries
- Over 35 companies
"Detention Without Physical Examination of Seafood Products Due to Nitrofurans"

- Shrimp and prawns
"Detention Without Physical Examination of Seafood Products Due to Nitrofurans"

- 5 countries
- Over 40 companies
"Detention Without Physical Examination of Aquacultured Catfish, Basa, Shrimp, Dace, and Eel from China - Presence of New Animal Drugs and/or Unsafe Food Additives"

- Catfish, Basa, Other Pangasius – Fluoroquinolones, Malachite Green, Gentian Violet
- Shrimp – Malachite Green, Fluoroquinolones, Nitrofurans, Gentian Violet
- Dace – Malachite Green, Gentian Violet
- Eel – Malachite Green, Gentian Violet
"Detention Without Physical Examination of Aquacultured Catfish, Basa, Shrimp, Dace, and Eel from China - Presence of New Animal Drugs and/or Unsafe Food Additives"

- Only 21 companies on “Green List”
CHAPTER 11: Aquaculture Drugs

This guidance represents the Food and Drug Administration’s (FDA’s) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

Note: This document was corrected on August 3, 2011. The Agency corrected a typographical error appearing in the April 2011 version of this document. The Agency corrected "15%" to "1.5%" so that the sentence in "Chapter 11: Aquaculture Drugs" now reads "Sodium sulfite Used in a 1.5% solution for 5 to 8 minutes to treat eggs in order to improve their hatchability."

UNDERSTAND THE POTENTIAL HAZARD.

Use of unapproved drugs or misuse of approved drugs in aquacultured fish poses a potential human health hazard. These substances may be toxic, allergenic, or carcinogenic, and/or may cause antibiotic resistance in pathogens that affect humans.

general-purpose chemicals, or approved drugs in a manner that deviates from the labeled instructions.

When a drug is approved by CVM, the conditions of the approval are listed on its label or in the labeling (21 CFR 514.1). These conditions specify the species for which the drug is approved for use; indications (disease or other circumstances) for use; dosage regimen; and other limitations, such as route of administration and withdrawal time.
**TABLE 11-4
CONTROL STRATEGY EXAMPLE 4 - DRUG RESIDUE TESTING**

This table is an example of a portion of a HACCP plan using “Control Strategy Example 4 - Drug Residue Testing.” This example illustrates how a primary processor of farm-raised catfish can control aquaculture drugs. It is provided for illustrative purposes only.

Aquaculture drugs may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides).

<table>
<thead>
<tr>
<th>(1)</th>
<th>(2)</th>
<th>(3)</th>
<th>(4)</th>
<th>(5)</th>
<th>(6)</th>
<th>(7)</th>
<th>(8)</th>
<th>(9)</th>
<th>(10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRITICAL CONTROL POINT</td>
<td>SIGNIFICANT HAZARD(S)</td>
<td>CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE</td>
<td>WHAT</td>
<td>HOW</td>
<td>FREQUENCY</td>
<td>WHO</td>
<td>CORRECTIVE ACTION(S)</td>
<td>RECORDS</td>
<td>VERIFICATION</td>
</tr>
<tr>
<td>Receiving</td>
<td>Aquaculture drugs</td>
<td>No fish may contain residues of unapproved drugs (other than those used as an INAD subject to an investigational new animal drug exemption under 21 CFR Part 511 and according to requirements of the food use authorization or included on the list of low regulatory priority aquaculture drugs)*</td>
<td>Fish edible flesh for drug residues*</td>
<td>Obtain samples and analyze for drugs using rapid screening methods or other analytical methods*</td>
<td>Each lot received</td>
<td>Quality assurance personnel</td>
<td>Reject the lot</td>
<td>Analytical results</td>
<td>Periodically verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using an Association of Official Analytical Chemists (AOAC) or equivalent) Review monitoring, verification, and corrective action records within 1 week of preparation</td>
</tr>
</tbody>
</table>

* Note: This plan is for illustrative purposes only. An actual plan should specify: (1) in the Critical Limits column: the aquaculture drugs that are reasonably likely to be present and the critical limits to be applied to each drug; and (2) in the Verification column: the aquaculture drugs for which analysis will be conducted, the protocol for sample collection, and the analytical method to be used for each drug.
Primary Processor Controls

- On-farm visit
- Supplier’s certification
- Records of drug use
- Drug residue testing
- Quality assurance program
• From 2015 Warning Letter:
  • ... failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section ... renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of ... (the Act) ... 
  • Accordingly, your shrimp products are adulterated, in that they have been prepared, packed, or held under conditions whereby they may have been rendered injurious to health.
... your firm's revised HACCP plan for aquaculture farmed shrimp ... does not list the food safety hazard of aquaculture drugs that are not approved for use on shrimp destined for the U.S. marketplace.
Importer Controls

Develop and follow written Import Verification Procedures:

- to ensure product processed in accordance with requirements of 21 CFR 123
- Develop product specifications for all imported products that are designed to ensure product is not adulterated because it may be injurious to health or processed in unsanitary conditions
- Conduct affirmative steps
  - Regularly inspecting foreign supplier
  - Periodically test product and written guarantee
  - Obtain copies of HACCP and sanitation monitoring records
  - Other appropriate activities
  - Continuing or lot-by-lot certificate from foreign govt or 3rd party
  - Copy of HACCP plan along with written guarantee
• Only FDA approved drugs can be used for products going to the U.S.
• Drugs can only be used for the species as approved by FDA
  • Sulfamerazine for trout – ok
  • Sulfamerazine for tilapia – not ok
• If drug approved in one country but not by FDA, it is illegal to use for product going to the US
• It is not legal to –
  • Use an aquaculture drug not approved by FDA for periods of production and then stop using it just before harvest, in hopes the residue is below detectable limits
  • Use a common drug in a manner appropriate for other species and hope the residues do not show up in FDA testing.
Thank you!

Questions?
Aquaculture Drugs
Analysis of FDA Refusal Numbers

Mark Bowen, Regulatory Program Manager and Data Analyst
National Fisheries Institute, McLean, Virginia
Refusals for All Reasons Across Australia, Canada, the EU, Japan and the United States
2008 - 2015
Drug Refusals Across
Australia, Canada, the EU, Japan and the United
States
2008 - 2015
FDA Refusal Reasons
Seafood Products From All Countries
2008 - 2015

- Administrative
- Decomposition/ Filth/ Insanitary
- Labeling
- Pathogens
- All Others
- Drugs/ Residues
January - December 2015
FDA Refusals for Drugs/Residues Compared to All Other Reasons 2008 - 2015

[Bar chart showing monthly data for FDA refusals for drugs/residues compared to all other reasons from January to December 2015.]
FDA Refusals for Drugs/Residues From All Countries 2008 - 2015
January - December 2015
FDA Refusals for Drugs/ Residues

Jan 79
Feb 37
Mar 65
Apr 54
May 19
Jun 60
Jul 62
Aug 79
Sep 10
Oct 43
Nov 15
Dec 11
FDA Refusals for Drug Residues From Selected Countries 2008 - 2015

Country A | Country B | Country C | All Others
---|---|---|---
2008: 117 | 6 | 33 | 5
2009: 113 | 43 | 85 | 10
2010: 108 | 52 | 54 | 8
2011: 203 | 7 | 35 | 11
2012: 107 | 20 | 22 | 2
2013: 68 | 35 | 46 | 21
2014: 117 | 57 | 60 | 68
2015: 309 | 46 | 71 | 108

Graph showing the number of FDA refusals from selected countries from 2008 to 2015.