About Food & Water Watch

Food & Water Watch is a nonprofit consumer rights organization, based in Washington, DC, that challenges the corporate control and abuse of our food supply and water resources.

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# Laboratory Error

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Executive Summary

Over the past few years, food safety alerts about dangerous tomatoes, canned chili, peanut butter and beef have made Americans uneasy at the grocery store. Even before this summer’s warning about salmonella-tainted tomatoes and jalapenos, three-quarters of Americans were more concerned about food safety than they were five years ago.

The growing volume of nearly uninspected imported food only exacerbates these consumer concerns. A key import that should concern consumers is seafood. Fish and seafood cause one fifth of reported foodborne illness outbreaks. More than four out of five pounds of fish that Americans eat come from overseas. And our reliance on imported seafood is growing — seafood imports grew 11 percent between 2003 and 2006, to 5.4 billion pounds of fish. A 2007 Food & Water Watch study, Import Alert, found that U.S. Food and Drug Administration inspectors examined less than 2 percent of imported fish and seafood shipments.

To follow up the 2007 study, Food & Water Watch examined all laboratory-testing records on imported fisheries products between 2003 and 2006. This data was obtained through a Freedom of Information Act request to the Food and Drug Administration. During this period, FDA took 26,369 samples and performed 34,683 laboratory tests.

<table>
<thead>
<tr>
<th>Fish Type</th>
<th>Failure Percent</th>
<th>Failure Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eel</td>
<td>18.2%</td>
<td>1 in 5</td>
</tr>
<tr>
<td>Lobster</td>
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<tr>
<td>Salmon</td>
<td>5.2%</td>
<td>1 in 20</td>
</tr>
</tbody>
</table>
Key Findings

- The number of imported fish samples FDA sent for laboratory testing fell by 25 percent between 2003 and 2006. Since the volume of fisheries imports grew as FDA’s laboratory testing fell, the percentage of imported fish shipments that receive scientific scrutiny is miniscule — and declining. This low rate of testing is not justified by the test results — about one in eleven laboratory tests (8.7 percent) exceeded FDA’s standards during this time period.

- Although FDA has issued consumer advisories about the dangers of mercury in fish, the number of laboratory tests for elemental metals on imported fish fell by 30 percent between 2003 and 2006.

- In 2007, FDA issued a countrywide “import alert” on shrimp, eel, catfish, basa (a kind of catfish) and dace (a carp) from China that directed portside inspectors to seize all shipments of these fish. FDA found high levels of illegal antibiotics, veterinary drugs and chemicals on Chinese aquaculture products for several years before issuing this alert.

- Many of FDA’s tests on Chinese aquaculture products found very high levels of antibiotics and chemical residues, yet when FDA finally issued the ban in 2007, it reported “very low” levels. The import alert reported malachite green chemical residues no higher than 122 parts-per-billion, but FDA test results examined by Food & Water Watch included test results as high as 3,200 parts-per-billion — 25 times higher than FDA announced to the public.

Key Recommendations Include

- FDA should only allow seafood imports from countries with food safety regulations that are at least as strong as U.S. standards.
- FDA must propose in its budget and Congress must provide adequate funding for FDA to conduct at least annual inspections of domestic food establishments and annual visits to countries that export to the United States.
- FDA should increase its laboratory testing rates for imported seafood to the levels conducted in the European Union and Japan.
- FDA should not close any of its regional laboratories and should direct laboratory testing of imported seafood to be done at these regional laboratories.
- FDA should publish quarterly food safety enforcement reports that include port of entry laboratory testing results broken down by country and type of seafood.
Introduction

Over the past few years, food safety alerts about dangerous tomatoes, canned chili, peanut butter and beef, have made Americans uneasy at the grocery store. Even before this summer’s warning about salmonella-tainted tomatoes and jalapenos, three-quarters of Americans were more concerned about food safety than they were five years ago. These concerns are not unwarranted. More than 5,000 consumers die from foodborne illnesses each year and 325,000 consumers require hospitalization. Fish and seafood cause one fifth of reported foodborne illness outbreaks.

The growing volume of nearly uninspected imported food only exacerbates these consumer concerns. Since 2007, imported food, consumer products and pharmaceuticals from China alone have prompted a cascade of product recalls and import bans attempting to keep unsafe imports off store shelves. Tainted pet food, toxic toothpaste, lead-painted toys, antibiotic-laden fish and allergen-laced blood products all undermine American confidence in the safety of imported products. According to a 2008 Wall Street Journal-Harris Interactive poll, nearly two-thirds (65 percent) of American consumers doubted the safety of imported food from developing countries.

A key import that should concern consumers is seafood. More than four out of five pounds of fish that Americans eat come from overseas. And our reliance on imported seafood is growing — seafood imports grew 11 percent between 2003 and 2006 to 5.4 billion pounds of fish. A 2007 Food & Water Watch study found that U.S. Food and Drug Administration inspectors examined less than 2 percent of imported fish and seafood shipments.

Unsafe Chinese fish imports have highlighted America’s broken food import inspection system. Chinese fish exports to the United States rose by 60 percent between 2003 and 2006 to 1.2 billion pounds. Many of these exports are raised in industrial aquaculture facilities that use illegal antibiotics, veterinary medicines and chemicals to maximize their output. In the summer of 2007,
Laboratory Error

FDA confirmed that five types of aquacultured fish from China were so likely to be tainted with illegal chemical and drug residues that they were banned from entering the United States. European, Japanese and several state regulators in the United States had raised the alarm about illegal drug contaminants in Chinese aquaculture for years, but FDA waited to ban these imports. FDA’s low level of import inspection and even lower level of laboratory testing — the only way to confirm the presence of these chemicals and medicines — made it difficult for food safety regulators to prevent these hazards. By the end of 2007, fewer than half of American consumers (48 percent) were confident that fish and seafood products were adequately regulated.8

Certainly the capacity of America’s fish import inspection system has not grown to meet the demand rising imports have placed upon the food safety infrastructure and personnel. There is a dire need to increase the number of inspectors and inspections at the port of entry, especially for seafood. But many health risks cannot be assessed by physical inspections alone. Foodborne bacteria, mercury contamination, and illegal veterinary drug or chemical residues cannot be found by physical and sensory inspection, only through laboratory tests.

Food & Water Watch has found that the current laboratory-testing regime for imported seafood is inadequate. The number of imported fish samples FDA sent for laboratory testing fell sharply between 2003 and 2006. Since the volume of fisheries imports grew as FDA’s laboratory testing fell, the percentage of imported fish shipments that receive scientific scrutiny is miniscule and declining. This low rate of testing is not justified by the test results — even though FDA performed only 34,000 laboratory tests on 20 billion pounds of imported fish between 2003 and 2006, about one in eleven laboratory tests (8.7 percent) exceeded FDA’s standards.

Laboratory Testing: A Vital Tool

FDA is responsible for ensuring the safety of all the fish and seafood products on supermarket shelves. FDA border inspectors and laboratories monitor imported fish shipments and examine selected seafood cargo for food safety hazards. As the first step in the import surveillance program, inspectors at ports of entry screen import shipment information from the U.S. Customs Bureau and the importing companies to determine which shipments are low-risk or high-risk.9 The highest risk

Histamine

Certain kinds of fish — in the tuna, mackerel and mahi mahi families — are likely to develop histamine toxicity if they are not properly refrigerated. Histamines are formed when naturally occurring proteins interact with bacteria during decomposition at room temperature. At high enough concentrations, histamine toxicity can mimic allergic reactions with symptoms including facial flushing, headache, sweating, rashes, abdominal cramping, nausea and vomiting. Severe reactions can require medical attention. Laboratory testing is the only reliable method to determine dangerous histamine levels. Cooking does not reduce histamine levels, although decomposed fish may appear less appetizing and taste strangely peppery.

Methodology

Food & Water Watch examined all laboratory-testing records on imported fisheries products between 2003 and 2006. This data was obtained through a Freedom of Information Act request to the Food and Drug Administration. During this period, FDA took 26,369 samples and performed 34,683 laboratory tests.

Food & Water Watch’s analysis eliminated five types of laboratory test findings that each made up less than 1.5 percent of the total tests (three food safety tests for “color additives,” “dioxin” and “food additives” compromised 0.3 percent of all tests combined and a “food economics” test for labeling requirements accounted for 1.2 percent of tests). Any “additional analysis” test findings were recoded where appropriate as unapproved antibiotic test findings during 2003 when there was no specific coding for antibiotic testing; the remaining additional analysis tests accounted for 0.2 percent of tests. All testing data was coded on a fiscal year basis (October through September), the same way FDA reports testing.

Import data was downloaded from the U.S. Department of Agriculture for fresh, chilled, frozen and processed fishery and crustacean products on a calendar year basis.

FDA confirmed that five types of aquacultured fish from China were so likely to be tainted with illegal chemical and drug residues that they were banned from entering the United States. European, Japanese and several state regulators in the United States had raised the alarm about illegal drug contaminants in Chinese aquaculture for years, but FDA waited to ban these imports. FDA’s low level of import inspection and even lower level of laboratory testing — the only way to confirm the presence of these chemicals and medicines — made it difficult for food safety regulators to prevent these hazards. By the end of 2007, fewer than half of American consumers (48 percent) were confident that fish and seafood products were adequately regulated.8

Certainly the capacity of America’s fish import inspection system has not grown to meet the demand rising imports have placed upon the food safety infrastructure and personnel. There is a dire need to increase the number of inspectors and inspections at the port of entry,
seafood products include ready-to-eat seafood, histamine-forming fish, aquacultured seafood products and fish packed in reduced oxygen packages. Imported fish shipments that are prone to food safety problems (for example, shellfish) or imports from companies with a history of previous food safety problems might be designated higher-risk. FDA considers the majority of imports low risk and these imports enter the U.S. food supply without any FDA field inspection or laboratory testing.

The basic weakness in FDA’s surveillance system is that the volume of imports swamps the ability of border inspectors to monitor and assess the risk of imported fish. The total number of shipments of imported seafood has increased by 15 percent, from nearly 750,000 shipments in 2003 to more than 850,000 shipments in 2006. This flood of imported fish along with all the other food and medicine FDA regulates gives import inspectors only about 45 seconds to examine the electronic record of each imported shipment. A 2007 House Energy and Commerce Committee investigation found that FDA’s computer surveillance system removed 80 percent of the food imports from even cursory electronic scrutiny because they were deemed low-risk.

Some imports that receive a high-risk designation are examined by FDA inspectors at the port. Others, especially those from companies with a history of problems, might go directly to FDA laboratories for testing. A tiny fraction of imported fish shipments receive any scrutiny beyond FDA’s electronic surveillance. In 2007, Food & Water Watch found that FDA import inspectors performed physical examinations of only 1.25 percent of imported fish shipments between 2003 and 2006. Physical inspection can include document reviews, sensory evaluations or label examinations. These physical examinations help import inspectors decide which imported fish shipments are sent to the laboratory for further examination. The low level of physical examination from the outset limits the volume of fish samples that are transferred to FDA laboratories for further examination.

FDA physical examinations provide the first physical contact with imported fish shipments, but these examinations alone are insufficient to keep dangerous imported fish products out of the food supply. Many foodborne hazards are invisible, odorless and cannot be detected by sensory examination. Portside physical inspections cannot detect bacteria that cause food borne illnesses like salmonella or illegal veterinary drugs and chemicals often used in aquaculture. Laboratory analysis can measure spoilage as well as mercury and mercury compounds in imported seafood that cannot be determined by visual portside examination.

But a 2008 review of FDA’s scientific capacity found that field laboratory resources and staffing have been stagnant, even in the face of growing imports. FDA does not provide detailed information on its field laboratory capacity, but laboratory staffing has declined at three FDA field operations that disclose their resource allocations. The total FDA field laboratory staff in Arkansas, Massachusetts and Ohio declined by 6 percent, from 184 laboratory staff in 2006 to 172 laboratory staff in 2008.
Laboratory Sampling: One in a Million

Between 2003 and 2006, the number of imported fish samples subjected to laboratory analysis fell by 25 percent, from 7,330 in 2003 to 5,493 in 2006. This decline coincided with steady growth in the number of shipments and volume of imported seafood. (Shipments can be of any size, from a crate of salted herring to a shipping container full of canned tunafish; import volume is measured in shipping weight.) Imported seafood shipments grew by 15 percent between 2003 and 2006, and the volume grew by 11 percent to 5.4 billion pounds. If FDA performed the same level of testing in 2006 as it performed in 2003 when it tested 1.3 percent of the shipments, an additional 4,000 laboratory tests should have been performed in 2006.

As laboratory sampling declined and imports rose, the percentage of imports subjected to laboratory analyses fell by a third. In 2003, FDA collected laboratory samples from only 0.98 percent of imported shipments, but even that low sampling rate fell by a third to 0.64 percent by 2006. The low sampling rate is even starker when measured by the tonnage of imports. In 2003, FDA took a single laboratory sample for every 665,000 pounds of imported fish, but by 2006, FDA took one sample for every 982,000 pounds of imported seafood — basically a one in a million sampling rate.

Other Countries Do More Testing

Most industrial countries perform more laboratory tests on imported seafood than the United States. FDA targets high-risk seafood imports for physical inspection, laboratory testing or both. This system is supposed to provide closer scrutiny for designated high-risk imports but ignores the allegedly low-risk shipments. As a result, some known risks are more likely to get inspected but unknown risks receive no further examination before they enter the food supply. As illustrated by melamine-laced pet food or antifreeze-tainted toothpaste, seemingly low risk products can contain significant hazards. A system that does not randomly sample seemingly lower-risk imports will never find these hazards.

The European Union and Canada both target risky seafood imports and randomly test samples from all imported seafood. Japan tests a much higher percentage of targeted imports than FDA does. These countries also perform more portside inspections than the United States, so they are able to refer more dubious seafood...
shipments for further laboratory analysis. The additional random sampling programs in the EU and Canada provide a first line of defense against unknown or little known risks.

The European Union physically examines between one fifth and one half of seafood at the border and sends samples for further laboratory testing if the inspection raises concerns. But the EU also subjects between 1 and 5 percent of imported fish shipments to random laboratory testing in addition to samples referred by border inspectors. \(^1\) Even at the lowest random testing level, Europe sends at least 40 percent more samples for laboratory analysis than the United States. Canada samples between 5 and 15 percent of imported seafood shipments for laboratory testing, depending on risk of the fish product (for example, oysters and clams might be sampled more frequently than haddock). This is at least 8 times higher than the U.S. import sampling rate. \(^2\) In 2006, Japan physically examined just under a fifth (19.3 percent) of fish shipments and performed laboratory test sampling on 6.1 percent of fish shipments — about 10 times higher than the U.S. rate. \(^3\)

### FDA Laboratories

Once the laboratory samples are collected by FDA port inspectors, they are sent to one of FDA field laboratories for scientific analysis. While the testing of imported seafood for key food safety problems has declined between 2003 and 2006, one out of 11 tests found seafood hazards that exceeded FDA standards. Some of the largest seafood exporters and most commonly imported fish had even higher failure rates.

The majority of seafood imports come from a handful of countries and consists predominantly of a few types of fish and seafood products. Food & Water Watch analyzed the testing rates of these key exporters and fish products based on volume of imports. Between 2003 and 2006, the top 10 seafood-exporting countries shipped 15.8 billion pounds of fish and seafood products to the United States, accounting for 77 percent of all seafood imports. Slightly more than half of the imports came from just three countries: Canada (19.4 percent), China (18.0 percent) and Thailand (13.2 percent). The top 10 exporting countries or companies from these countries have been heavily represented on FDA’s list of banned fish imports (those contained in FDA’s monthly import alerts). Since 1990, there were 78 bans on specific firms or exporting countries from the ten largest seafood exporters, often multiple countries or firms were subject to a single regulatory alert. \(^4\) The top 10 exporters are included in almost all of FDA Import Alerts.

### Top Imported Types of Seafood, 2003-2006

<table>
<thead>
<tr>
<th>Fish Type</th>
<th>Millions of Pounds</th>
<th>Percent of Total Imports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shrimp/Prawns</td>
<td>4,736.6</td>
<td>23.2%</td>
</tr>
<tr>
<td>Tuna</td>
<td>2,519.7</td>
<td>12.3%</td>
</tr>
<tr>
<td>Eel</td>
<td>1,276.9</td>
<td>6.2%</td>
</tr>
<tr>
<td>Crab</td>
<td>1,016.6</td>
<td>5.0%</td>
</tr>
<tr>
<td>Salmon</td>
<td>789.8</td>
<td>3.9%</td>
</tr>
<tr>
<td>Octopus/Squid</td>
<td>708.9</td>
<td>3.5%</td>
</tr>
<tr>
<td>Lobster</td>
<td>318.3</td>
<td>1.6%</td>
</tr>
<tr>
<td>Scallops</td>
<td>210.4</td>
<td>1.0%</td>
</tr>
<tr>
<td>Mussels</td>
<td>196.6</td>
<td>1.0%</td>
</tr>
<tr>
<td><strong>Top 10</strong></td>
<td><strong>11,773.7</strong></td>
<td><strong>57.6%</strong></td>
</tr>
</tbody>
</table>
Since 1990, more than four out of five (82 percent) of FDA import alerts have specifically applied to the top 10 exporting countries or firms, an additional 6 percent applied to all countries. Only four (12 percent) FDA import alerts did not include the top 10 exporters.

A small list of fish products also make up the majority of all imports. The top 10 imported types of fish make up nearly three-fifths (58 percent) of all fish imports, accounting for 11.8 billion pounds of imports between 2003 and 2006. Most of the leading types of imported fish are high-value seafood products like lobster, shrimp, crab, salmon, tuna and scallops. Shrimp imports alone constituted 4.7 billion pounds of imports and nearly a quarter (23.2 percent) of all imported seafood products from 2003 to 2006. Several of these fishery products are also common aquaculture products, including shrimp, eels, salmon and scallops.

**Few Fish Imports Receive Laboratory Testing**

Food & Water Watch examined FDA’s laboratory testing of imported seafood for seven important food safety laboratory tests, the number of tests FDA performed and whether the imported fish failed these tests. The seven tests Food & Water Watch analyzed include tests for microbial contamination (foodborne illnesses like *Salmonella* or *Listeria*), decomposition testing for histamines, testing for chemical and veterinary drug residues, testing for metals like mercury and lead, testing for pesticides, microscopic testing for filth and testing the integrity of low-acid canned products like canned tuna for possible botulism risk.

FDA has been performing an average of 8,500 of these tests each year on about 5 billion pounds of imported fish, but the number of tests has declined significantly in recent years. The number of laboratory tests declined by 27 percent from 9,552 laboratory tests in 2003 to 6,995 tests in 2006. The decline in testing was especially steep for many of the top 10 fish exporters and the most commonly imported types of fish. Laboratory testing declined for nine of the top 10 exporting countries and nine of the top 10 types of imported fish. The number of laboratory tests performed on fish imports from Mexico and India fell by more than half and the number of tests on fish from Vietnam and Chile dropped by more than a third.

The laboratory testing rate — by both number of shipments and weight — is alarmingly low and has been falling. In 2003, only 1.3 percent of imported fish shipments were subject to laboratory testing but by 2006 only 0.8 percent of shipments were tested — a 36 percent decline. On a volume basis, the low testing rate means that a larger number of imported tons of fish enter the United States food supply without a laboratory test. In 2003, FDA performed one laboratory test for every half a million pounds of imported fish. However, by 2006, FDA performed one laboratory test for every three quarters of a million pounds of fish — a 50 percent increase.
For some of the largest seafood exporters and most commonly imported types of fish, the laboratory testing rate is even lower. In 2006, only one out of 2.5 million pounds of imported fish from Canada was subject to laboratory tests. FDA performed one lab test on every million pounds of imported fish from Chile and Thailand and one laboratory test per 950,000 pounds of imported fish from Ecuador in 2006. Although scallops, salmon and crab were tested more than average, six of the top 10 imported fish types were tested less than average — some considerably less. FDA performed only one laboratory test for every 3.7 million imported pounds of eels. And the agency performed only one laboratory test on every 1.2 million pounds of imported lobster and one test on every 923,000 pounds of imported tuna.

Despite the tiny proportion of fish that are tested, a fairly large proportion of laboratory tests reveal food safety hazards in imported fish. FDA found foodborne diseases, unclean products, decomposing fish, high levels of illegal chemical and veterinary medicine residues, pesticides, high levels of elemental metals like mercury, and fish that were improperly canned. Between 2003 and 2006, about one in 11 (8.7 percent) of FDA laboratory tests on imported seafood turned up unacceptably high levels of disease, decomposition or adulteration.

Fish from some of the largest exporting countries and some commonly imported fish were more likely to fail laboratory tests than the overall failure rate. Nearly one-fifth (18.3 percent) of tests on fish from Vietnam failed
Laboratory Test Failure Rate for 10 Biggest Exporters, 2003-2006

<table>
<thead>
<tr>
<th>Country</th>
<th>Failure Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vietnam</td>
<td>18.3%</td>
</tr>
<tr>
<td>Indonesia</td>
<td>13.2%</td>
</tr>
<tr>
<td>Philippines</td>
<td>12.0%</td>
</tr>
<tr>
<td>Mexico</td>
<td>6.2%</td>
</tr>
<tr>
<td>India</td>
<td>4.7%</td>
</tr>
<tr>
<td>China</td>
<td>4.2%</td>
</tr>
<tr>
<td>Ecuador</td>
<td>3.9%</td>
</tr>
<tr>
<td>Thailand</td>
<td>2.9%</td>
</tr>
<tr>
<td>Chile</td>
<td>2.4%</td>
</tr>
<tr>
<td>Canada</td>
<td>2.3%</td>
</tr>
</tbody>
</table>

Laboratory Test Failure Rate for Most Commonly Imported Fish

<table>
<thead>
<tr>
<th>Fish Type</th>
<th>Failure Percent</th>
<th>Failure Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eel</td>
<td>18.2%</td>
<td>1 in 5</td>
</tr>
<tr>
<td>Lobster</td>
<td>16.4%</td>
<td>1 in 6</td>
</tr>
<tr>
<td>Crab</td>
<td>11.1%</td>
<td>1 in 9</td>
</tr>
<tr>
<td>Octopus/Squid</td>
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<td>Tuna</td>
<td>8.2%</td>
<td>1 in 12</td>
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<tr>
<td>Shrimp/Prawns</td>
<td>7.5%</td>
<td>1 in 14</td>
</tr>
<tr>
<td>Salmon</td>
<td>5.2%</td>
<td>1 in 20</td>
</tr>
<tr>
<td>Scallops</td>
<td>3.7%</td>
<td>1 in 27</td>
</tr>
<tr>
<td>Mussels</td>
<td>3.0%</td>
<td>1 in 33</td>
</tr>
<tr>
<td>Haddock</td>
<td>2.7%</td>
<td>1 in 37</td>
</tr>
</tbody>
</table>

the laboratory tests — more than double the overall failure rate. Fish samples from Indonesia, Mexico and the Philippines failed about one eighth (13.2 percent, 12.9 percent and 12.0 percent, respectively) of laboratory tests — nearly 50 percent more frequently than the overall failure rate. Eel, lobster and crab were also more likely to fail FDA laboratory tests. Nearly a fifth (18.2 percent) of eel samples and a sixth (16.4 percent) of lobster samples failed FDA laboratory tests — about double the overall failure rate of 8.7 percent. One ninth (11.1 percent) of crab samples failed FDA laboratory tests — 28 percent higher than the overall failure rate.

Between 2003 and 2006, the total laboratory test failure rate declined from 9.4 percent to 7.5 percent, but laboratory testing fell by 27 percent over the same period. If FDA performed the same level of testing in 2006 as it performed in 2003 when it tested 1.3 percent of the shipments, an additional 4,000 laboratory tests would have been performed in 2006.

As testing levels have dropped, the failure rate for imported seafood laboratory tests has also declined. This does not necessarily demonstrate that imported seafood is safer today than in prior years, but rather that the number of tests performed combined with a larger pool of imported product made it harder for FDA to find tainted seafood samples. Given such a small sample, it is not surprising that any modest increase in the number of tests yields a higher failure rate. FDA increased the number of laboratory tests for illegal chemicals and veterinary medicine residues from 368 in 2003 to 595 in 2006 — a 62 percent increase — and the failure rate increased from 10.6 percent to 15.1 percent — a 43 percent increase. Over the same period, the number of tests for foodborne illnesses decreased by 24 percent and the failure rate for these microbiological hazards decreased by 40 percent. These figures suggest that when FDA looks for violations, it can find them, but when testing declines, the number of violations also declines.

Failure Rates of Key FDA Laboratory Tests

Some key laboratory tests had much higher failure rates than the overall failure rate. The highest failure rates were for antibiotics and chemicals used in aquaculture and decomposition. One eighth (12.2 percent) of samples tested for illegal antibiotics and one ninth (10.8 percent) of samples tested for decomposition exceeded FDA standards.

Illegal Antibiotics and Chemicals Used in Aquaculture

The widespread use of illegal antibiotics, veterinary medicines and chemicals in aquaculture production received increased public attention when FDA banned the importation of several Chinese aquaculture products in 2007. Aquaculture produces about half the fish consum-
ers eat worldwide, and 40 percent of U.S. imports come from fish farms, many of which are in Asia.

Aquaculture production facilities are essentially just underwater feedlots. Thousands of fish — often high-value shrimp, shellfish or catfish — are raised in densely packed ponds. The high concentration of fish can make them susceptible to disease and parasites, especially if the fish are not raised in clean water. Some aquaculture facilities raise fish in water that is polluted with sewage, farm runoff containing pesticides and industrial chemical discharges.

Aquaculture producers combat bacterial infections, disease and parasites by applying antibiotics, fungicides and other pesticides. Some of the antibiotics (notably nitrofurans, fluoroquinolones and chloramphenical) may contribute to increased antibiotic resistance. The application of these veterinary medicines affects not only the fish they aim to treat but also the surrounding environment and non-target species, which can cause anti-microbial resistance and impact human health. Since there are no systems in place to monitor antibiotic resistant foodborne pathogens in fish products, FDA has prohibited fluoroquinolones for use in aquaculture production. Several other chemicals used in aquaculture production (nitrofurans, malachite green and gentian violet) have been associated with increased human cancer risks.
Testing for residues of antibiotics, fungicides and other veterinary drug residues is a new and growing area of FDA laboratory testing in seafood products, but these laboratory tests had the highest failure rate by 2005. In 2003, about one in nine (10.6 percent) of the tests found high levels of illegal antibiotics or veterinary medicines. By 2006, the failure rate had risen by 43 percent to 15.1 percent. Some top aquaculture producers had higher failure rates for antibiotic laboratory testing. Between 2003 and 2006, Vietnamese fish failed 29.3 percent of antibiotic laboratory tests — more than double the overall laboratory testing failure rate. Chinese fish failed 17.2 percent of antibiotic tests, nearly a third higher than the overall rate.

**FDA Slow to Issue China’s Import Alert**

In 2007, FDA issued a countrywide Import Alert on shrimp, eel, catfish, basa (a kind of catfish) and dace (a carp) from China that directed portside inspectors to seize all shipments of these fish. FDA issued the ban after finding high levels of illegal antibiotics, veterinary drugs and chemicals on Chinese aquaculture products for several years.

China’s fish exports, especially aquaculture-produced fish, have faced increased regulatory oversight worldwide as more authorities have found banned chemical residues on imported fish. Although FDA’s own lab testing found similar problems, FDA did not impose a total ban for six years after FDA first acted to slow some tainted aquaculture products in 2001 because of veterinary drug residues. In 2003 the EU banned Chinese shrimp and in 2005 Japan stopped Chinese eel imports. Taiwan banned the import of certain crab types in 2006 after finding cancer-causing veterinary drug residues that were 16 times higher than allowed.

The 2001 FDA action against some Chinese aquaculture producers did not motivate the agency to step up testing for antibiotics or drug residues. In 2003, FDA found that nearly one fifth (18.5 percent) of the 92 laboratory tests on Chinese shrimp contained drug residues exceeding FDA standards. The agency’s import rules call for an automatic countrywide ban on fish products once the specific import fails 25 percent of at least 48 tests in any six-month period from key exporting firms. This policy, in addition to the fact that Europe banned Chinese shrimp altogether that year, should have encouraged FDA to at least increase its monitoring of Chinese shrimp, if not ban Chinese shrimp. Instead, FDA tested fewer shrimp samples.

In 2004, the number of laboratory tests for illegal veterinary drug residues on Chinese shrimp fell by about half, to 47 tests. Only 4.3 percent of the tests found high levels of antibiotic residues, but that could be the result of a steep decline in laboratory testing. In 2005, FDA only performed 10 tests on Chinese shrimp for banned veterinary drugs, but it expanded its laboratory testing on Chinese aquaculture products beyond shrimp to eel, basa and catfish. Nearly two out of five (38.6 percent) of the tests on these four aquaculture products found residue levels above FDA standards. Despite the high failure rate, FDA did not ban Chinese aquaculture imports in 2005.

In 2006, FDA more than doubled the number of antibiotic laboratory tests on the five types of aquaculture
products from 44 in 2005 to 116. More than a third (34.5 percent) of the samples failed the tests. FDA found antibiotic drug residues on 53.3 percent of eel samples, 40.0 percent of catfish samples, 25.0 percent of Dace samples and 8.1 percent of shrimp samples in 2006. In November 2006, FDA issued an import alert on eel from China due to the high failure rates for chemical residues. In November 2006, FDA issued an import alert on eel from China due to the high failure rates for chemical residues.

Many of FDA’s tests on Chinese aquaculture products found very high levels of antibiotics and chemical residues, yet when FDA finally issued the ban in 2007 it reported that the antibiotics were found at “very low” levels. The import alert reported malachite green chemical residues no higher than 122 parts-per-billion, but FDA test results examined by Food & Water Watch found test results as high as 3,200 parts-per-billion — 25 times higher than FDA announced to the public. FDA also claimed that the highest level of fungicide gentian violet was 30 parts-per-billion, but the highest FDA laboratory result was four times higher at 133 parts-per-billion.

**Microbial Testing**

One of the most common food safety hazards in seafood is caused by microbial contamination with bacteria such as *Salmonella*, *E. coli* and *Listeria*. Foodborne bacteria can spread rapidly throughout the food supply and can cross-contaminate other food during any processing or preparation in kitchens or restaurants. Many of these illnesses can make consumers quite sick, and patients with weak or compromised immune systems — especially seniors and children — are most at risk.

Laboratory tests are an essential tool to identify the presence of bacteria in food products. FDA’s laboratory testing for microbial contamination on imported fish declined by 24 percent between 2003 and 2006. During this period, more than one out of 20 (7.2 percent) of laboratory tests found bacteria that cause foodborne illnesses. Fish from some key exporters and some commonly imported types of fish had much higher failure rate. Between 2003 and 2006, one sixth (16.4 percent) of Vietnamese and one seventh (14.3 percent) of Indian fish samples failed FDA’s microbial laboratory tests — double the overall failure rate. Imported lobster failed 10.6 percent of microbial tests and one in twelve samples of salmon, eel and shrimp (8.2 percent, 8.2 percent and 8.0 percent, respectively) samples contained foodborne illness-causing bacteria.

**Decomposing Imports**

FDA performs laboratory tests for decomposition that cannot be determined by physical and sensory examinations alone. Decomposition and its associated dangerous histamine levels can develop without detectable odors or physical signs and some seafood producers use chemicals to mask the signs and smells of decomposition. Imported fish that are stored for long periods and shipped long distances are very susceptible to decomposition. Higher temperatures during transit can promote bacterial growth that produces histamines, which can cause serious allergic reactions. Histamines cannot be eliminated by cooking but can be prevented with proper refrigeration and handling.
Between 2004 and 2006, one in nine laboratory tests on imported fish revealed high levels of decomposition. The decomposition failure rate was the second highest of the examined tests with 10.8 percent of the samples testing positive for decomposition or high levels of histamines. Even though the failure rate for decomposition tests was among the highest, the number of FDA laboratory tests for decomposition fell by 37 percent between 2003 and 2006.

More than a quarter (28.3 percent) of lobster samples failed decomposition tests from 2003 to 2006 — more than double the average failure rate. About one in seven (15.2 percent) crab samples and more than an eighth of eel and octopus samples (13.3 percent and 12.9 percent, respectively) failed decomposition tests. Some countries also had much higher decomposition failure rates; about one-fifth of samples from Vietnam and Indonesia (21.0 percent and 18.6 percent, respectively) failed decomposition tests between 2003 and 2006.

**FDA Warns Consumers About Mercury but Performs Few Tests**

FDA tests fish for contamination by lead, mercury, cadmium and arsenic compounds resulting from industrial pollution. Large, long-lived predatory fish have the highest accumulation of these contaminants. These compounds can be risky for consumers who regularly eat certain kinds of contaminated fish — especially children, nursing mothers and pregnant women. Although FDA has issued consumer advisories about the dangers of mercury in fish, the number of laboratory tests for elemental metals on imported fish fell by 30 percent between 2003 and 2006.

Many of these warnings focus on tuna. Yet tests on imported tuna for elemental metals declined by a quarter from 133 tests in 2004 to 105 tests in 2005. By 2006, FDA performed only 54 tests for elemental metals on imported tuna.
Conclusion

In 2007 and 2008, a cascade of recalls for unsafe toothpaste, toys, pet food, medicine and fish shook American confidence in imported food and consumer products. The repeated import inspection failures prompted the Bush administration to re-evaluate their oversight of imports. The Administration’s proposed approach de-emphasizes inspection efforts, dismissively arguing that we cannot inspect our way to food safety.

Instead, FDA and other agencies are proposing two new approaches to monitor and ensure the safety of imported products. The first is to replace the current import inspection approach with a more risk-based inspection system that would focus resources on the imported products that FDA deems the most dangerous. The second is to use private laboratories hired by the exporters to certify which exporters and products are safe.

Both of these approaches fail to address the fundamental disconnect between growing imports and declining import safety oversight.

Risk-Based Inspection Is Not a Hit

FDA does not have the capacity to implement a risk-based inspection system in the foreseeable future. An effective risk-based inspection program needs reliable information and powerful analytical tools to calculate and assess risk. Currently, FDA’s information systems cannot effectively evaluate risks and properly target resources to address higher-risk food imports. In 2008, import inspectors do not have sufficient or timely access to the necessary laboratory testing and import refusal data to make informed decisions about which incoming shipments need heightened scrutiny. And historical data is poorly maintained and not analyzed by the agency.

According to FDA’s Science Board, the agency’s crumbling information infrastructure cannot even perform today’s surveillance responsibilities, let alone a more advanced risk-based inspection system. A 2007 report by FDA’s Science Board found that FDA’s “inadequate sensing technology to augment surveillance and investigational activities, inadequate scientific capability to effectively model food supply risks, and inadequate staff to inspect an adequate sample of domestic and internationally produced food products all limit the effectiveness of the Agency.”

FDA itself testified to Congress in 2008 that revamping its fragmented and incomplete information technology systems could cost hundreds of millions of dollars. Although the structure of the information system upgrade will determine the effectiveness of any future risk-based inspection efforts, FDA is keeping its data improvement plans under wraps. The Government Accountability Office has reported that FDA does “not intend to make these plans public.”

Currently, FDA is failing to dedicate resources to known risks. Although Brazil is a significant seafood exporter to the United States, ranking in the top 20 exporters by shipping 219 million pounds of fish between 2003 and 2006, FDA reduced the number of laboratory tests on Brazilian fish even as the percentage of samples from Brazil that failed the tests increased. Between 2003 and 2004, the failure rate for laboratory tests on Brazilian fish increased by 70 percent from 8.2 percent of tests in 2003 to 13.9 percent in 2004. After the steep increase in the Brazilian failure rate, the number of laboratory tests declined by nearly half (46 percent), from 267 tests in 2004 to 143 laboratory tests in 2005 — but the failure rate remained steady at 13.3 percent in 2005. Even
Laboratory Error

though the failure rate remained considerably higher in 2005 than in 2003, the number of laboratory tests on Brazilian fish declined by more than half (52 percent) to 68 lab tests in 2006 when the failure rate for Brazilian fish rose to 17.6 percent. If FDA were focusing import scrutiny on the riskiest imports, it should perform more laboratory tests on fish from countries that have rising failure rates.

Certification for Sale

Replacing or supplementing inspectors with third party certification is no solution either. Food inspection is a basic government function. Relying on third party certifiers would essentially privatize food inspection. Third party certification for seafood would require FDA to shift its limited resources to oversee private laboratories instead of overseeing seafood imports.

A July 2007 Energy and Commerce Committee Subcommittee on Oversight and Investigations staff report found that the third party laboratories that currently certify import safety force FDA to rely on unverified laboratory findings to monitor the food supply and that quality of third party testing operations varies widely. One FDA laboratory deputy director deemed some of the third party lab work as “scary,” “not good” and “spooky.” An unnamed FDA deputy lab inspector told the investigative counsel to the House Energy and Commerce Committee that “none of the test results [from private labs] are completely accurate.”

The lack of oversight of third-party laboratories and the conflict of interest inherent when the certifier is working for the importing company undermine the credibility and independence of third party certifiers. FDA does not require that private third party laboratories be accredited or inspected by FDA. These private labs are not required to report negative test results to FDA, but rather only to the importing company that hires them. One FDA laboratory supervisor told congressional investigators that third party laboratory work is “shoddy” because the private companies had a financial interest in clearing the imports.

Currently, some imported fish that is certified as safe receive very few laboratory inspections, but the few certified imports that are tested have very high failure rates. In 1996, FDA issued an import alert banning all imported swordfish because laboratory testing found unacceptably high levels of mercury contamination. Exporters were allowed to resume shipping swordfish to the United States if they presented certification that their swordfish did not contain high mercury levels. Since 1996, nearly 400 companies from 40 countries have provided this certification and are exempt from the import ban. The third party certification of swordfish has helped exporters enter the U.S. market, but it has not ensured that the imported swordfish is free of high levels of mercury. Between 2003 and 2006, the United States imported 97.8 million pounds of swordfish but only performed 17 laboratory tests for mercury. Twelve of the certified swordfish samples — 71 percent — had mercury levels that exceeded FDA standards.
Recommendations

- FDA should allow seafood imports only from countries with food safety regulations that are at least as strong as U.S. standards. Only approved companies from these countries should be allowed to export to the United States.

- FDA must propose in its budget and Congress must provide adequate funding for FDA to conduct at least annual inspections of domestic food establishments and annual visits to countries that export to the United States. These visits should include audits by FDA employees of the exporting countries’ food safety regulations and enforcement system as well as visits to eligible exporting establishments.

- FDA should increase its laboratory testing rates for imported seafood to the levels conducted in the European Union and Japan. Some portion of this testing must be random testing, in addition to the testing devoted to high-risk products.

- FDA should cease efforts to implement Risk-Based Inspection until the Government Accountability Office can confirm that FDA’s information systems can handle the task of accurately assessing the risk posed by different types of imported seafood.

- FDA should not close any of its regional laboratories and should direct laboratory testing of imported seafood to be done at these regional laboratories. If FDA’s laboratories cannot perform all of the testing necessary and the agency needs to use private laboratories, these private laboratories must be certified by FDA. All testing results from these private laboratories must be provided simultaneously to the agency and the importing company.

- FDA should not divert any portion of its budget for port of entry inspection to pay for oversight of third party certifiers or private laboratories. Funding for this oversight should be separate, and in addition to, funding for port of entry inspections.

- FDA should publish quarterly food safety enforcement reports that include port of entry laboratory testing results broken down by country and type of seafood.

- FDA should establish a separate Imports Regulatory Division to coordinate all import food safety issues, including laboratory testing.
Endnotes

6. See Food & Water Watch, “Import Alert,”
17. Ibid.
20. FAO 2005 at 22.
23. FDA issued 33 import alerts or updates since 1990, 27 included top ten exporters, 2 applied to all countries and 4 did not apply to any of the top ten exporters.
25. Food & Water Watch did not analyze every type of FDA test. Three types of tests (for color additives, dioxin and food additives) each constituted 1 percent or less than all FDA tests on imported seafood and were excluded as being too infrequent to analyze; laboratory examination of the FDA “food economics” test relates to label accuracy and also accounts for very few FDA tests; and a catch-all FDA test for “additional analysis” was re-coded as a test for antibiotics/veterinary drug residues prior to the specific delineation of antibiotic testing in 2004.
26. The number of tests exceeds the number of samples because the FDA can perform more than one type of test on each sample, for example testing the same sample for both mercury and salmonella.
27. UN Food and Agriculture Organization, State of World Fisheries and Aquaculture 2006, 2007 at 3; FDA, Import Alert No. 16-131, August 3, 2007, “Detention without Physical Examination of Aquacultured Catfish, Basa (Pangasiidae), Dace, and Eel Products from the People’s Republic of China Due to the Presence of New Animal Drugs and/or Unsafe Food Additives,” attachment September 18, 2007.
33. Ellis, Linden J. and Jennifer L. Turner, Western Kentucky University, China Environment Health Project Research Brief, “Aquaculture and Environmental Health in China,” May 7, 2007 at 1.
36. No Basa were tested in 2006.
37. Statement of Dr. David Acheson, Associate Commissioner on Foods, FDA, before the Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, September 25, 2007.
Food & Water Watch


44 Ibid.


47 Ibid.


