Safety in Seafood

Regulatory Interplay Combines Testing, Enforcement

Summary

Testing in the United States and elsewhere has found chloramphenicol and other banned chemical substances in seafood. Subsequent increased testing frequency and improved industry practices have led to fewer instances of violative imports. Breaking down large shipments into test populations based on distinct processing events could save unnecessary product destruction.

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The U.S. Food and Drug Administration (FDA) food safety inspection, detection, and monitoring capabilities have expanded dramatically since the events of September 11, 2001. Common screening procedures for seafood include pathogen detection and tests for microscopic insect debris, decomposition, parasites, toxins, methyl mercury, chloramphenicol, nitrofurans, malachite green, fluorquinolones, and quinolones.

Seafood Testing

The U.S. Public Health Security and Bioterrorism Preparedness and Response Act of 2002 increased funding and research projects for the development of new testing methodologies to increase the nation's ability to rapidly detect adulteration of food.

Pursuant to this objective, in 2003, the FDA Compliance Branch issued an advisory titled "Chemotherapeutics in Seafood," which focused resources on the development of residue testing for malachite green, multiple quinolone drug residues, ivermectin, oxytetracycline, fluoroquinolones, nitrofurans, and chloramphenicol. The seafood products to be investigated included both imported and domestic products, which involved both aquaculture-raised and wild-caught species.

In August 2003, Canadian health officials found traces of prohibited nitrofuran antibiotics in imported catfish and shrimp. By June of 2004, the FDA hired 800 new employees, of which 600 were hired to be trained as new inspectors, with the balance dedicated to support research and detection efforts within FDA's laboratory infrastructure.

Fast forward to 2006, during which FDA plans to collect at least 750 samples of catfish, basa, and crab to test for fluoroquinolones, quinolones (oxolinic acid and flumequine), malachite green, and chloramphenicol. Additionally, the agency will test 345 samples of shrimp from various countries for chloramphenicol and nitrofurans.

During 2005, more-sensitive tests were developed to test for chloramphenicol in crabmeat and certain metabolites of nitrofurans and malachite green. Metabolites are often found in fish tissues long after the antibiotic or fungicide has dissipated from the tissue.

The increased harmonization and sophistication of regulatory agencies could change importers' exposure to food detention, refusal, and/or seizure actions.

Evolution of Food Regulatory Enforcement

Global food regulatory enforcement has grown by design, as well as ad hoc sampling events. It is important to understand the evolution of food regulatory enforcement and how the increased harmonization and sophistication of food regulatory agencies could change importers' exposure to food detention, refusal, and/or seizure actions.

Chloramphenicol Testing

As most know, the first findings for chloramphenicol occurred in September 2001 in shrimp consignments exported from Southeast Asia to the European Union. This discovery triggered the enhanced surveillance of farm-raised shrimp and later included residue testing for nitrofurans. Canada was the next country to test shrimp for chloramphenicol and nitrofurans.

While the U.S. has tested farm-raised shrimp for chloramphenicol since 1994, once the violation records of the E.U. and Canada became known, FDA developed more-sensitive testing methodology and moved its levels of detection for chloramphenicol from 5.0 ppb to 1.0 ppb and finally its current detection level of 0.3 ppb.

Increased sampling, testing, and follow-up led to essentially eliminating chloramphenicol from U.S. imports of crabmeat.

In July 2002, when the chloramphenicol level was 1.0 ppb, FDA found the first violative chloramphenicol in farm-raised shrimp from Vietnam. At that time, FDA would pull 12 samples, composite them, and run one test for chloramphenicol. However, later analysis revealed that the findings of chloramphenicol were sporadic, as opposed to uniform, so the agency changed its sampling protocol to require testing in each of 12 samples for each imported parcel sampled.

Once FDA reduced the level of detection to 0.3 ppb and required 12 tests for each import entry, the frequency of chloramphenicol findings increased dramatically. This testing focused on farm-raised shrimp, but Canadian authorities also decided to subject crabmeat to chloramphenicol testing. They found chloramphenicol in a 27-kg shipment of Indonesian crabmeat imported into the U.S. and then exported out of Detroit, Michigan into nearby Canada.

This revelation was brought to the immediate attention of the FDA, which then commenced frequent testing of imported consignments of crabmeat. The testing gave rise to a separate import alert that subjected foreign processors whose shipments were found contaminated with chloramphenicol to detention without physical examination (DWPE). Of course, an earlier alert for chloramphenicol in shrimp had applied DWPE practices to foreign processors that also subjected all future shipments to 100% sampling until compliance could be proven to the FDA.

Malachite Green

In another ad hoc sampling event, malachite green showed up as a contaminant in farm-raised salmon in the United Kingdom. However, an exhaustive investigation showed it did not come from the farm, but a hand towel used by workers at the retail level. Apparently the malachite green, which is also used as an industrial dye, moved via a wet towel to the hands of an employee onto the salmon when placed into the retail display case.

Mercury in Swordfish

Years ago, swordfish were imported from many countries into the U.S., and refusal actions were few and far between. FDA had tested swordfish products intermittently for mercury, but the more rapid, precise Hite Test for methyl mercury led to hundreds of new detention events for foreign processors of swordfish. Subsequently, an import alert created for methyl mercury in swordfish grew to contain over 100 foreign processors and changed the swordfish trade forever.

Sampling Effective

The findings of new adulterations and the research under way to create more-sensitive tests underscore the great uncertainty which lies ahead for the global seafood sector. Obviously, the finding of chloramphenicol in crabmeat suggested an external contamination mechanism apart from the harvesting practices for wild-caught crab, which may trigger more widespread testing for chloramphenicol in other wild-caught species.

One theory suggested that antibiotic creams or lotions used by workers to protect against infections may include trace elements of chloramphenicol. Crabmeat harvesting is labor-intensive, and removing meat from sharp-shelled edges or protrusions would create a greater need to protect against cuts and infections. In fact, intensive sampling and corrective practices implemented in the HACCP plans of foreign processors known to have previously shipped contaminated parcels of crabmeat succeeded in eliminating chloramphenicol from future consignments.

Stepped-Up Sampling

FDA's stepped-up 2006 sampling assignments dedicated to multiple species and drug residues underscore its concerns and understanding that a number of drugs are used in different seafood products from countries that are major exporters to the U.S. market. This announced plan represents only the tip of the iceberg.

Submerged icebergs and other unseen dangers could alter the risk of global seafood trading overnight. The changes under way in detection, testing methodology, sampling protocols, and the knowledge gained through ad hoc sampling events will result in more-focused audits of seafood products.

Increased Seafood Awareness, Demand

Articles on food safety issues are plentiful in mainstream media. Fortunately, as a result of recently published long-term scientific studies that demonstrate the huge health benefits of increased weekly consumption of seafood, the public has responded by increasing demand, and those delivering seafood to consumers have promptly and responsibly responded by mandating supply chain certification.

The Global Aquaculture Alliance, for example, developed Best Aquaculture Practices standards that address food safety, seafood sustainability, and social and environmental concerns. Implemented through certification inspections by Aquaculture Certification Council, Inc., the standards has been embraced by leading buyers in the U.S. market as these companies seek to respond proactively to consumer concerns.

In the area of food safety, impressive new technology acts as a pathogen-killing step in the processing of many species of seafood. The adoption of patented equipment from companies like Global Food Technologies is being considered by leading seafood-producing nations that are key suppliers to the world's consuming markets.

Pathogens, Decomposition

Beyond the interplay among food regulators and changes in testing for unapproved drugs that could increase exposure to food regulatory interventions, one should not overlook common violations for pathogens and sensory evaluations. In fact, the most frequent violations at time of entry into the U.S. are pathogen detection first and, secondly, decomposition. Both of these areas relate to the management of the cold chain.

The types of microorganisms found in refrigerated seafood are diverse. To further complicate matters, each type of microorganism has its own preferred growth temperature range. Under ideal conditions, some bacteria can grow and divide every 20 minutes. Consequently, one bacterial cell can increase to 16 million cells in eight hours.

The growth of foodborne pathogens in seafood can be indigenous, such as with certain *Vibrios, Salmonella,* and *Shigella* species. Nonindigenous pathogens such as *Listeria monocytogenes* and *Staphylococcus aureus* can be present in cooked products as a result of processing, handling, or postprocessing environments.

Fluctuations of temperatures during harvesting, distribution of product to foreign processors, and processing up to the point of freezing present great potential for microorganisms to grow. Guarding against hazards emanating from pathogen contamination events and insufficient time and temperature controls may require the implementation of certification systems and new kill-step technologies.

Segregated Sampling

Current FDA policy encourages foreign processors to consistently produce product free of all known adulterants. However, one must recognize that no industry can produce product that is always free of defects. FDA should acknowledge that intermittent adulterations can slip through statistically sound and rigorously constructed "in process" and "finished" product testing protocols.

When product is found violative at time of entry, FDA should permit the importer to break down a large shipment into recognized testing populations based on harvesting, daily production, separate handling, or other distinct processing events that could give rise to isolated contamination.

This intensified sampling could demonstrate that a portion of a shipment is in compliance and allow the foreign processor to forensically determine where his process broke down. Moreover, intensified sampling could assist processors in strengthening corrective actions within plants' HACCP plans.

New cooperation between regulators and foreign processors can only lead to building stronger HACCP teams and plans, and would result in minimizing the potential for future food safety violations. Experience has shown that this collaboration, if properly executed, will reduce the frequency of future food safety violations.