

Reduce Our Trade Deficit with Europe - Restore Exports of Molluscan Shellfish

Since 2009 the European Union has banned the imports of molluscan shellfish from the United States. While EU regulators claim that the ban is a result of health risks associated with US shellfish, we suspect that the ban is retaliatory and punitive and not based on actual human health issues. FDA inspectors have audited certain EU member states and found significant deficiencies in their shellfish sanitation program that preclude their imports into the US. In apparent retaliation, EU regulators have alluded to various concerns related to US products, however FDA officials feel these concerns are not justified and are not based on valid significant health concerns.

EU markets represent a significant export opportunity for US producers, however we are unable to identify the dollar value of exports prior to the 2009 trade restrictions. The shellfish producers in the US have been working diligently for several years in an effort to resolve the impasse without success. We are hopeful that high-level efforts to resolve non-tariff trade barriers with the EU will allow us to restore trade in shellfish with EU customers.

Background

In 2009 the EU Directorate General for Health and Consumers removed the US from the list of countries permitted to export bivalve mollusks and other fishery products to the EU. The decision was based on indicated differences between the American and EU sanitary standards for live bivalve mollusks. The report highlighted issues with *Vibrio* bacteria associated with oysters from the Gulf of Mexico. Subsequently the United States and the European Union agreed to examine the reciprocal equivalence between US and EU sanitary standards for bivalve mollusks, however to date there has been no agreement of equivalence.

The FDA molluscan shellfish safety program regulates foreign imports under the Import Seafood Products Compliance Program 7303-844 (FDA) in cooperation with the NOAA Seafood Inspection Program. The FDA has negotiated agreements (MOUs) with those countries that have shellfish sanitation programs that have been evaluated and are judged to be equivalent with our program (New Zealand, Canada, Mexico and Korea, but not the EU). FDA audits of EU growing grounds and shellfish sanitation practices had determined that the EU program has deficiencies that make their products unsuitable for import to US markets.

The US imports 91 percent of its seafood resulting in an annual \$10.4 billion seafood trade deficit (FishWatch). Meanwhile major oyster producers in the EU have suffered 40-80 declines in production due to diseases (Perneti). Meanwhile, the US has enjoyed significant growth in the shellfish farming industry, particularly on the East Coast (Murray, 2012).

For several years shellfish industry representatives have travelled to Washington DC to meet with members of Congress and top officials from the FDA in an effort to resolve this issue. In January 2012 the FDA offered to send auditors over to inspect three clean water sites in EU states in the hopes that they could allow specific harvest areas to import into the US (as they do for other MOU nations). It was our hope that this would break the impasse and bring negotiators back to the table. However, in January 2013 the FDA reported that they had not sent auditors and that they now saw no way to resolve the impasse. The FDA offered no timeline for action and provided little hope for resolution. The FDA also acknowledged that while they believe EU shellfish sanitation standards are inadequate, they did not anticipate that EU producers would ship much product to US markets if they were permitted to do so. EU shellfish prices are significantly higher than those in the US so there is a financial disincentive to send shellfish to the US. (The exception would be for mussels that carry little health risk since they are typically cooked).

The FDA rightly believes that there should be no equivalency requirement (our ability to export should not be contingent on their ability to export to us). Each nation should make these decisions based solely on independent assessments of public health considerations. Unfortunately, it appears that contingency and retaliation are dominant concerns in this case, preventing honest negotiations to resolve the issue.

FDA officials met with EU counterparts in December of 2012, however little progress was made. The EU negotiator continues to highlight two issues with US product: 1) US regulators do not require monitoring for all marine biotoxins (PSP, Red Tide etc) - and 2) we cannot seem to eliminate or control for the naturally-occurring bacterium *Vibrio vulnificus*. In the US rigorous biotoxin monitoring is conducted by state shellfish control authorities and is required in states that have experienced problems. (NSSP 2009 Section II Chapter IV - Shellstock Growing Areas, 2009, p. 04 Marine Biotoxin Control). The FDA notes that we have not had a biotoxin-related illness from commercially harvested product in decades. While *Vibrio vulnificus* bacteria are a management challenge, they are primarily associated with warm water production with the vast majority of cases associated with Gulf Coast oysters harvested during warm-weather months. *V. vulnificus* associated with shellfish consumption causes only about 35 illnesses a year

Several years ago the FDA visited some of the growing areas in the EU to assess their sanitation program for equivalency. Our standard is based on water quality measurements while the EU monitors bacteria levels in shellfish meats (CODEX). Studies comparing our water standard with the CODEX meat standard indicate that clean EU Class "A" areas are equivalent to the US "approved areas." The FDA's problem with the EU meat standard arises in growing areas near population centers, where depuration or purging of contaminants is required. In these areas the FDA believes that the EU standard does not provide an adequate level of protection from enteric viruses.

It is notable that Canada has Shellfish Sanitation Program that is essentially identical to ours, however Canada and the EU do have an active MOU based on equivalency. Canada complies with the EU requirements by testing for marine biotoxins and performing additional meat testing for exports. Because of recent budget cuts the FDA is considering equivalency under a HACCP approach where the monitoring and reporting are the responsibility of the exporting country.

ECSGA is contacting the legislative offices that indicted they might help on trade about this meeting and hoping that maybe one of them will have an idea how to move this issue forward. The Senate HELP committee has jurisdiction (Mikulski-MD, Whitehouse-RI, Murphy-CT, Warren-MA). (n.d.). FDA. (n.d.). Food Guidance Compliance Regulatory Information. online. FishWatch. (n.d.). http://www.fishwatch.gov/farmed_seafood/outside_the_us.htm. Murray, T. J. (2012). Situation and Outlook Report. VIMS, Virginia Sea Grant Marine Extension Program. Gloucester: Virginia Institute of Marine Science. Perneti, F. B.-F. (2012). Mass mortalities of Pacific oysters *Crassostrea gigas* reflect infectious diseases and vary with farming practices in the Mediterranean Thau Lagoon, France. *Aquaculture Environment Interactions*, Vol.2: 215-237. USFDA. (2009). NSSP 2009 Section II Chapter IV - Shellstock Growing Areas. National Shellfish Sanitation Program.