

Restore Exports of Molluscan Shellfish to the European Union

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. In 2009 FDA inspectors 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 alleged various concerns related to US products, however the FDA maintains that these concerns are not based on valid health concerns.

EU markets represent a significant export opportunity for US producers, however we have been unable to identify the dollar value of exports prior to the instatement of 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 our EU customers.**

Background

The US imports 91 percent of its seafood resulting in an annual \$10.4 billion trade deficit in seafood (FishWatch). Major oyster producer states in the EU have suffered 40-80 declines in production due to a viral disease (Perneti). Meanwhile, the US has enjoyed significant recent growth in the shellfish production, particularly on the East Coast (Murray, 2012). US shellfish producers view the EU market as potentially quite lucrative because EU consumers regularly pay a significant premium over what US consumers are willing to pay for similar shellfish products.

The FDA also acknowledges that they do not anticipate that EU producers would ship significant quantities of shellfish to US markets even if they were permitted to do so. EU shellfish prices are significantly higher than those in the US. (The exception would be for mussels that carry little health risk since they are typically cooked).

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 stated rationale for the decision was differences between the American and EU sanitary standards for live shellfish. Subsequently efforts to develop reciprocal equivalence between US and EU sanitary standards for bivalve mollusks have been frustrated.

The Request

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, as of January 2014 the FDA reported that they had not sent auditors and offered no timeline for action.

We welcome efforts to resolve this dispute so that our shellfish producers can once again access lucrative markets for shellfish in EU states. Should you have any questions or require additional information please do not hesitate to contact me.

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The Nitty Gritty Details

The FDA's regulates foreign shellfish 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 are judged to be equivalent with our program (New Zealand, Canada, Mexico and Korea, but not the EU).

In 2009 the FDA audited several EU growing areas to assess their sanitation program for equivalency. Our sanitation 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 essentially equivalent to the US "Approved" harvest area classification. The FDA's problem with the EU meat standard arises in growing areas near population centers, where depuration (purging of contaminants) is required. In these areas the FDA maintains that the EU standard does not provide an adequate level of protection from enteric viruses.

The FDA rightly believes that **there should be no equivalency requirement** (eg. 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 instance, preventing honest negotiations to resolve the issue.

FDA officials meet once or twice a year with EU counterparts, however little progress is 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. 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.

While *Vibrio vulnificus* bacteria are a management challenge, they are primarily associated 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 while millions of servings are safely consumed.

References

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FishWatch. http://www.fishwatch.gov/farmed_seafood/outside_the_us.htm.

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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.

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