

EU Shellfish Trade Embargo Update

Since 2010 the European Union has banned imports of molluscan shellfish from the U.S. This action was triggered by reciprocal reviews of each other's shellfish sanitation programs using the International Comparability Assessment Tool to evaluate the basic components of a good food safety program (e.g. regulatory foundation, inspection program, training program etc.) There is a fundamental difference between Europe and U.S. which has complicated the assessment. Europe uses a meat standard to ensure their shellfish is safe while the U.S. uses water quality standards for the growing areas coupled with shoreline sanitary surveys of potential pollution sources. We maintain that the U.S. National Shellfish Sanitation Program provides some of the safest shellfish in the world.

EU markets represent a significant and lucrative export opportunity for U.S. producers. Prior to the ban many shellfish growers from both the east and west coasts used to send tons of shellfish "across the pond."

Sanitation Program Equivalency: EU auditors inspected the U.S. program in 2009 alleging certain deficiencies in our program that were soundly refuted by the FDA. When FDA inspectors conducted their reciprocal audit in 2011 they found significant deficiencies in the EU program, initiating a protracted stalemate.

Finally, in 2015 after an additional round of reciprocal inspections, narrowing down initial trade to two states (Washington and Massachusetts) and two EU countries (Spain and the Netherlands) and limiting it to shellfish only from pristine harvest areas (Class "A" in Europe and "Approved" in the U.S.) it appeared agreement had been reached to allow trade to resume. Growers were assured that once the initial hurdles were cleared a process would be established to quickly allow other states and EU countries to join in trade.

Progress stalled in early 2016 when the EU announced it was changing the way it samples meats and defines Class "A" growing areas. Statisticians met in the U.S. for two days last spring, eventually concluding that the new program was still acceptable.

Before the FDA can finalize the equivalency agreement, a public process needs to be completed. The FDA General Council wants to ensure that the roll out of equivalence is done properly. This is the first such agreement FDA has done in many years, and it appears that other commodity groups (milk) are seeking similar approval and will expect to follow shortly. Peter Koufopoulos, Director of the FDA's Division of Seafood Safety told grower representatives while they were in Washington DC the week of March 6th that necessary documents should be ready to go from FDA's legal department to HHS in the next 4-6 weeks and then on to OMB for review and publishing in the Federal Register for public comment before the U.S. rulemaking process can be finalized. Grower representatives were told by FDA in December of 2015 that a similar complex process would be required in Europe, but at the time we were assured that trade could resume in Early 2017. It appears that we are still not close to achieving this goal.

Critically a streamlined process to evaluate and allow other states and EU countries to reopen trade also needs to be devised.

Request: Please consider sending a bicameral bipartisan Delegation letter to Dr. Nega Beru, Director of FDA's Office of Food Safety with a message along the lines of the attached draft.

Robert Rheault, Executive Director, East Coast Shellfish Growers Association
Margaret Barrette, Executive Director, Pacific Coast Shellfish Growers Association

March XX, 2017

Dr. Nega Beru
Director, Office of Foods and Veterinary Medicine
Center for Food Safety and Applied Nutrition
Office of Food Safety
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: European Ban on U.S. Shellfish Imports

Dear Dr. Beru,

Since July 1, 2010 the European Union has banned the importation of molluscan shellfish from the United States. We have been hearing from our shellfish growing constituents for the past six years about the impacts of this ban on their businesses. Many growers from both the east and west coast accessed the European markets prior to the ban. With farmed shellfish production increasing steadily around the country regaining access to these lucrative European markets is becoming more important by the day.

We understand the ban is related to reciprocal reviews of the equivalency of the E.U. and U.S. shellfish sanitation programs and that these are complicated reviews to complete. We also understand that the assessment has been made more challenging by different approaches in the U.S. and Europe to assessing the safety of shellfish for human consumption. Regardless, it is unacceptable that this matter has taken so long to resolve.

Please respond to this letter with an explanation of the steps necessary both in the U.S. and in Europe along with estimated timeframes for each of them to complete the process necessary to establish equivalency and to resume trade. We have been told by shellfish grower representatives that initially trade will be limited to Washington State, Massachusetts, Spain and the Netherlands. Please also explain what you expect the process to be and estimated timeframes for other states and European countries to be approved for trade.

We urge the FDA to do all that they can to expedite the process to allow the resumption of molluscan shellfish trade with Europe.

Sincerely,

Cc: William Jones, Deputy Director, Office of Food Safety
Peter N. Koufopoulos, Director, Division of Seafood Safety