Shellfish Equivalence

EU Update

FDA/ISSC Information Meeting
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Reopening Trade for Safe Shellfish

- FDA stopped accepting raw bivalve molluscan shellfish imported from Europe in the 1980s due to public health concerns.
- The European Commission (EC) requested an equivalence assessment in 2008, which FDA initiated in 2010.
- Shellfish exports to the European Union were stopped in 2010 due to findings by the EC that the United States/European Union (EU) programs had fundamental differences.
- FDA and EC technical experts finished their individual assessments in November 2015 and each authority recommended a finding of equivalence.

Reopening Trade for Safe Shellfish

- FDA published a proposed equivalence determination for public comment on March 9, 2018 in the Federal Register.
- FDA addressed public comments and published its final equivalence determination in the Federal Register on September 24, 2020.
- FDA's equivalence determination applies to raw shellfish harvested from Class A production areas in Spain and the Netherlands.
- DG SANTE's equivalence determination applies to shellfish harvested from U.S. Approved growing areas, initially in Massachusetts and Washington.
- FDA and DG SANTE signed an arrangement containing a streamlined evaluation process for additional states.

Why the delay?

- Shellfish export certificates and animal health attestations
- Ongoing communications between USTR and DG SANTE

Status of FDA Actions

- Updating the EU export list quarterly for WA and MA
- Prepped ICSSL to accommodate Spain and the Netherlands
- Reviewed packages for additional states

Notes

- Bilateral technical working group
- Equivalence evaluation for processed shellfish

Resources

- Webinar – October 2020
- Electronic Listing Module Demo – aired Sept 22
  https://www.youtube.com/watch?v=lLqIFuWUDew

Questions?

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