# European Union Trade Agreement Update

## CT Harvester Meeting, April 8, 2022

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# EU Equivalence Background

- **Equivalence** is the process of determining whether a country's food safety controls achieve at least the same level of public health protection as measures required by U.S. law.
- This means that a foreign country is not required to develop and implement the same exact procedures and food safety controls that FDA requires, but rather the country must objectively demonstrate how its food safety controls meet at least the same level of public health protection achieved by U.S. measures.

# EU Equivalence Background

- 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 EU were stopped in 2010 due to findings by the EC that the US/EU programs had fundamental differences.
- FDA and EC technical experts finished their individual determinations in November 2015 and each authority recommended a finding of equivalence.

# EU Equivalence Background

- 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.

# Products Eligible for Shipment Under EU Equivalence

- Live, chilled, frozen, and processed shellfish
- Currently only Massachusetts and Washington have been accepted
- MA and WA acceptance delayed over a year due to COVID

THE HILL

**US, EU agree to resume oyster and mussel trade, ending 10-year dispute**

LOCAL

**Mass. shellfish farmers could see boost with new US-EU deal**

Support for GBH

Our record
breakthrou
Dana-Farbe
largest acad
recipient of

Dana-Farbe
Cancer Institute

**New agreement allows Washington shellfish producers to export to EU**

*By asmith February 7, 2022 6:53 am*

# Growing Area & Inspection Requirements for EU Importation

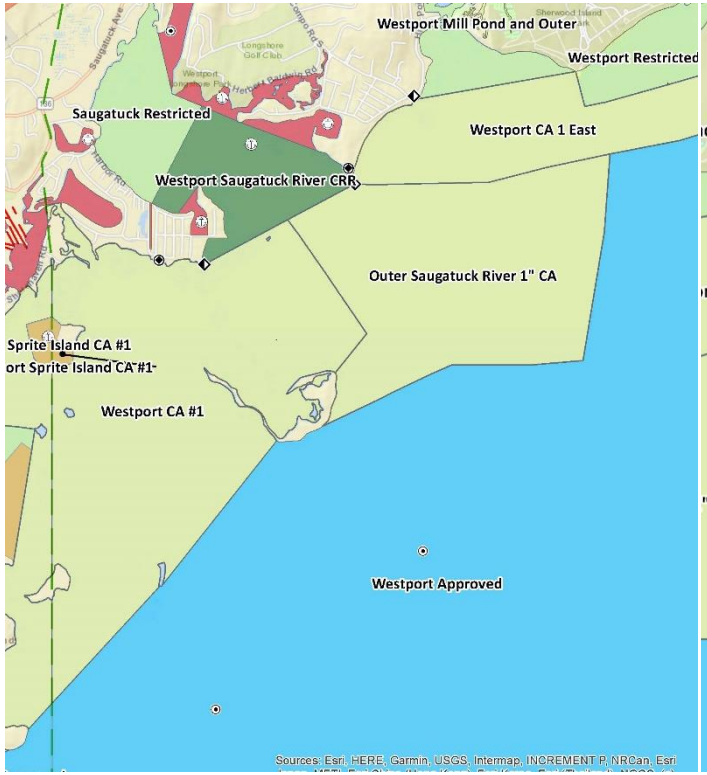
- The EU will only accept U.S. shellfish harvested and processed from **Approved** growing areas
- The EU will not accept shellfish products harvested from states with documented *Vibrio vulnificus* illnesses and operating under a required management plan
- Up-to-date Sanitary Survey Report required
- Submission of the most recent NSSP evaluation report(s) for certified state laboratories performing analysis of raw molluscan shellfish samples and any resulting corrective actions for each lab
- Firms must be listed on the Interstate Certified Shellfish Shippers List (ICSSL)
- Submission of the last inspection report for each firm and documentation of any corrective actions resulting from the inspection

# DABA Responsibilities

| ✓ | Document | Notes |
|---|---|---|
| ✓ | **List of Approved growing areas.** | |
| ✓ | State Shellfish Control Authority (SSCA) should provide all growing area information in the format of the Excel template provided. "Approval number" is a required field; growing area name is not mandatory. | |
| ✓ | **List of firms/processors harvesting product in those Approved growing areas.** | |
| ✓ | SSCA will determine which firms intend to ship to the EU and should include only those firms on the list they submit. | |
| ✓ | **Most recent sanitary survey(s) for those Approved growing areas.** | |
| ✓ | Relevant supporting growing area classification studies should be included. | |
| ✓ | **Most recent inspection reports for firms operating in those Approved growing areas and, in case of non-compliance, corrective actions taken by firms after the inspections.** | |
| ✓ | **List of laboratories performing official regulatory analysis of raw molluscan shellfish samples and the most recent NSSP evaluation report for each lab, including any resulting corrective actions.** | |
| ✓ | **Summary description of applicable U.S. mechanisms for implementing and enforcing FDA regulations, plus enforcement of additional controls, if any, applied to those growing areas/processors.** | |
| ✓ | **Most recent FDA audit of the NSSP participant's implementation of the NSSP and any corrective actions taken after the audit.** | |

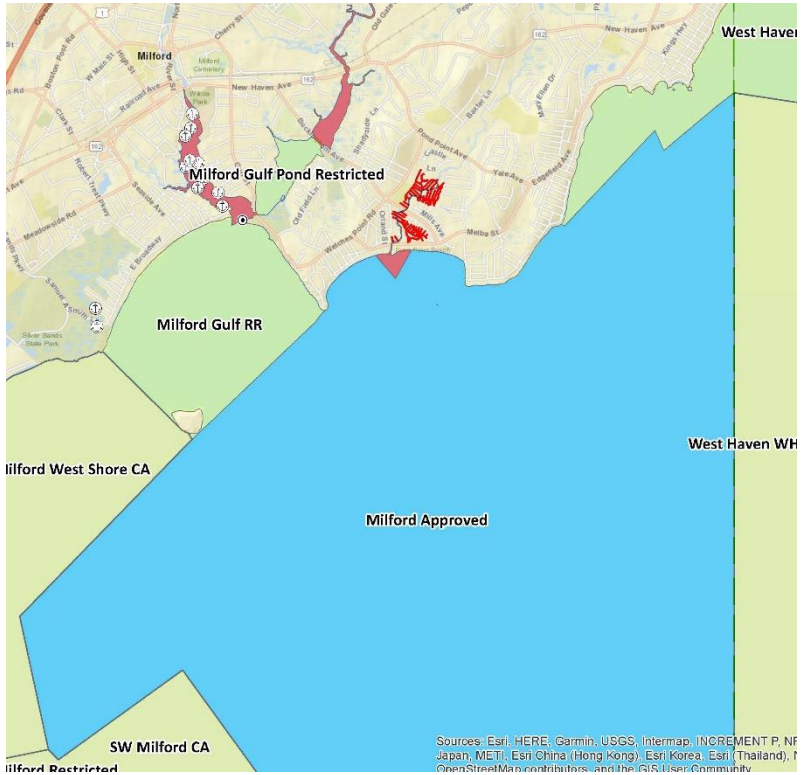
# Growing Areas Submitted for Equivalence

## Westport





## Milford



# DABA Timeline

## Step 1 Initial Submission Due December 31, 2020

- CT Packet Submitted to Shellfish Equivalence Team 12/21/2020

## Step 2 Supplemental Information Requested

- 12/22 & 12/23/20 Dealer Corrective Actions and CT Department of Public Health Laboratory Status Update Submitted
- 2/18/2021 CT Biotoxin Management and Contingency Plan Submitted

## Step 3 FDA Submits Package to the EC for Approval

- CT's Package has yet to be approved and submitted to the EC by the FDA Equivalence Team
- CFSAN is currently working with the EC on the logistics of how best to submit state packages to them. CFSAN anticipates that the information will be sent in the next couple of weeks. DABA will receive notification when the package is submitted

# Dealer Responsibilities Upon CT Acceptance

- Submit Electronic Listing Module (ELM) application
- The ELM will become available for industry use once the shellfish equivalence determination is approved
- Ensure that ELM issued EU approval numbers consistently appear on all documentation, tags, and packaging for trouble-free import review at EU ports of entry
- Listed firms must obtain an EU NOAA shellfish export certificate **for each shipment** of shellstock to the EU
- There is a fee for each NOAA export certificate issued

# Dealer Responsibilities Upon CT Acceptance

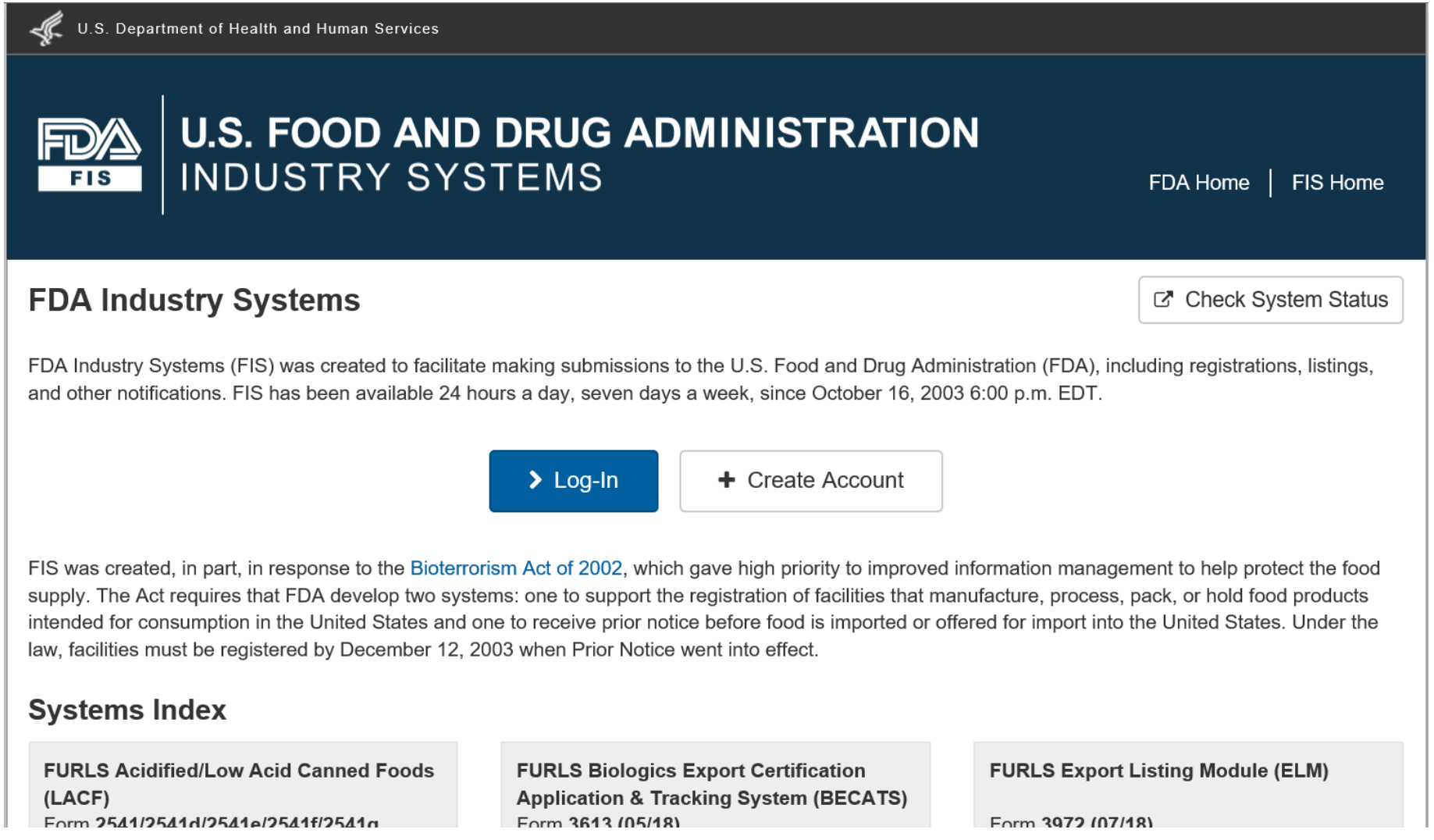
## Inspection Compliance

- There can be no outstanding corrective actions from your previous inspection
- Prompt submission of documentation of your firm's corrective actions (photos, forms, etc.) to DABA
- Accurate tags and associated shipping documentation

## EU Shipping Compliance

- All information must be listed ***exactly*** as it will appear on export documentation (bills of lading, tags, etc.) to avoid shipments being held for review of inconsistent information upon entry
- Dealers must ensure that growing area names, towns, and lot/lease information is ***exactly transcribed*** on ***each document*** that is submitted with ***each shipment***
- ***All documentation must also include your EU Approval Number***

# Dealer Responsibilities: Export Listing Module (ELM)



# Dealer Responsibilities: NOAA Export Certification

NOAA FISHERIES

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SEAFOOD COMMERCE & TRADE

## Export Certification to the European Union

Guidance on exporting to the European Union

**Update: Beginning February 27, 2022, the NOAA Seafood Inspection Program will require the new *Health Certificate for Imports of Live, Frozen, Chilled or Processed Bivalve Molluscs, Echinoderms, Tunicates, and Marine Gastropods Intended for Human Consumption from The United States of America* for eligible molluscan shellfish exports to the EU.**

Learn more >

The NOAA Seafood Inspection Program is the competent authority within the U.S. Government for issuance of certain certificates required for export of fish and fishery products to the European Union (EU). The program offers four documents required for export to the European Union. They are:

- EU export health certificate;
- Export Health - EU Bivalve Mollusc, Echinoderms, Tunicates, and Marine Gastropods

# Dealer Responsibilities: NOAA Export Certification

# Dealer Responsibilities: NOAA Export Certification

UNITED STATES OF AMERICA
U.S. DEPARTMENT OF COMMERCE

HEALTH CERTIFICATE FOR IMPORTS OF LIVE, FROZEN, CHILLED OR PROCESSED BIVALVE MOLLUSCS ECHINODERMS, TUNICATES AND MARINE GASTROPODS INTENDED FOR HUMAN CONSUMPTION FROM THE UNITED STATES OF AMERICA

United States (US) — Veterinary certificate to EU

*Part I: Details of dispatched consignment*

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| I.1. Consignor<br>Name<br>Address<br>Postal Code<br>Tel No. | | | | I.2. Certificate reference number | | | I.2.a. |
| | | | | I.3. Central Competent Authority<br>USDC NOAA NMFS Seafood Inspection Program | | | |
| | | | | I.4. Local Competent Authority | | | |
| I.5. Consignee<br>Name<br>Address<br>Postal code<br>Tel No. | | | | I.6. | | | |
| I.7. Country of origin<br>USA | ISO code<br>US | I.8. Region of origin<br>SEE BOX I.28 | Code<br>SEE BOX I.28 | I.9. Country of destination | ISO code | | I.10. |
| I.11. Place of origin<br>Name Approval number<br>Address | | | | I.12. | | | |
| I.13. Place of loading | | | | I.14. Date of departure | | | |
| I.15. Means of transport<br>Airplane☐ Ship☐ Railway wagon☐<br>Identification<br>Documentary references | | | | I.16. Entry BCP in EU<br>I.17. | | | |
| I.18. Description of commodity | | | | I.19. Commodity code (HS code) | | | |
| | | | | | I.20. Quantity | | |
| I.21. Temperature of product<br>Ambient ☐ Chilled ☐ Frozen ☐ | | | | | I.22. Number of packages | | |
| I.23. Identification of container/Seal number | | | | | I.24. Type of packaging | | |
| I.25. Commodities certified for<br>Human consumption☐ | | | | | | | |
| I.26. | | | | I.27. For import or admission into EU ☐ | | | |

# Next Steps

- Wait for FDA notification of submission of CT's package to the EC
- DABA will notify participating dealers when packet is submitted
- Firms should monitor EC decision and listing of submitted CT growing areas
- Once CT is listed, firms must submit ELM application
- The EC will issue each firm an EU Approval Number based on the current tag (e.g. CT-####-SS, AQ)

# Questions?

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https://portal.ct.gov/DOAG/Aquaculture1/Aquaculture/Aquaculture-Home-Page