

The background of the slide is a golden-yellow color with a repeating pattern of embossed currency symbols, including the dollar sign (\$), the euro symbol (€), the pound sterling symbol (£), and the yen symbol (¥).

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.

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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 GB-

Our record
breakthrough
Dana-Farber
largest acad
recipient of



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.	



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

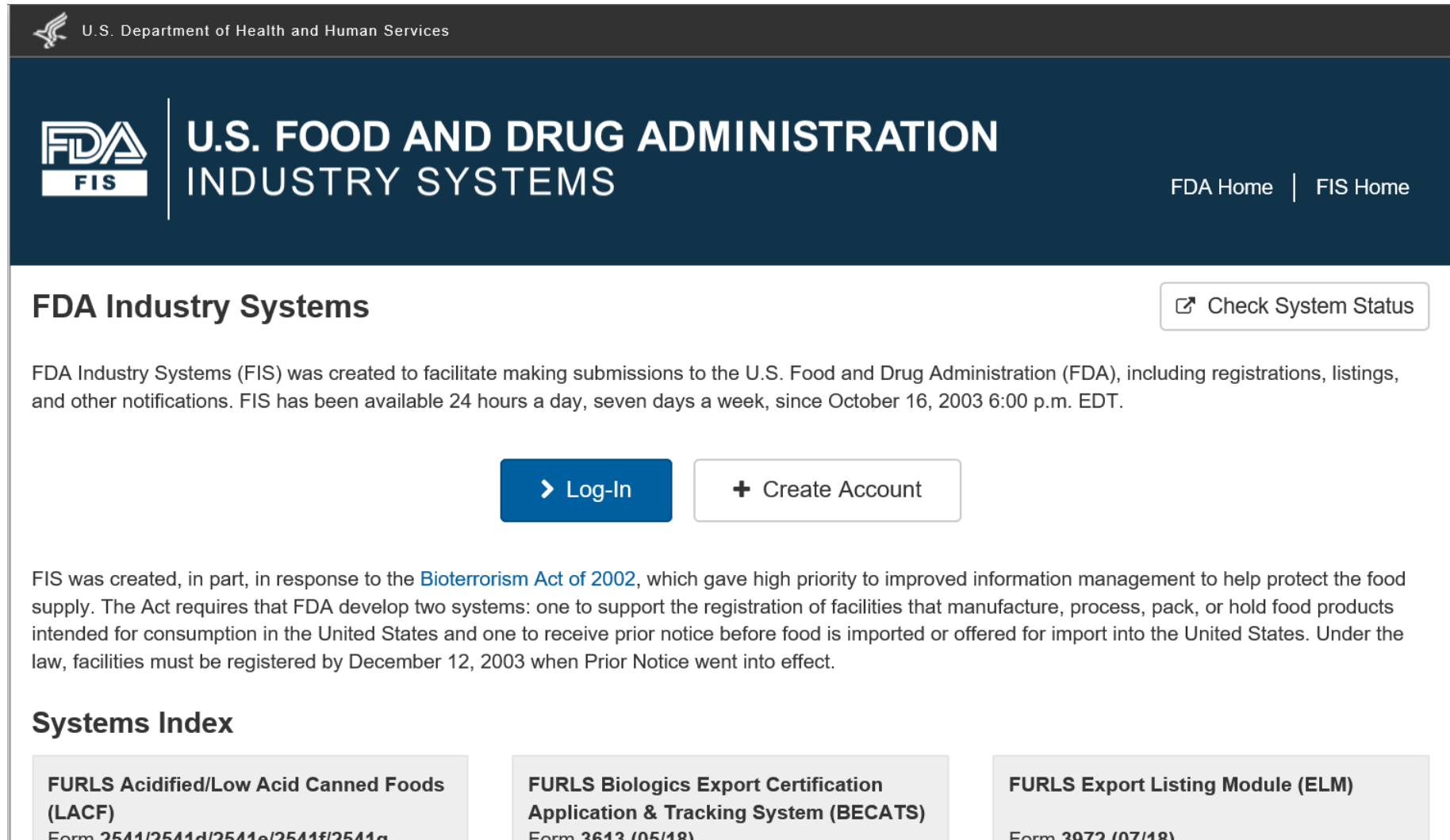
Inspection Compliance

- 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)



The screenshot shows the top portion of the FDA Industry Systems (FIS) website. At the top left is the U.S. Department of Health and Human Services logo. The main header features the FDA FIS logo and the text "U.S. FOOD AND DRUG ADMINISTRATION INDUSTRY SYSTEMS". Navigation links for "FDA Home" and "FIS Home" are on the right. Below the header, the page title "FDA Industry Systems" is followed by a "Check System Status" button. A paragraph explains that FIS was created to facilitate submissions to the FDA. Two buttons, "Log-In" and "Create Account", are prominently displayed. A paragraph below describes the system's origin in the Bioterrorism Act of 2002. At the bottom, a "Systems Index" section lists three modules: LACF, BECATS, and the Export Listing Module (ELM).

U.S. Department of Health and Human Services

FDA FIS | **U.S. FOOD AND DRUG ADMINISTRATION INDUSTRY SYSTEMS**

[FDA Home](#) | [FIS Home](#)

FDA Industry Systems

[Check System Status](#)

FDA Industry Systems (FIS) was created to facilitate making submissions to the U.S. Food and Drug Administration (FDA), including registrations, listings, and other notifications. FIS has been available 24 hours a day, seven days a week, since October 16, 2003 6:00 p.m. EDT.

[Log-In](#) [Create Account](#)

FIS was created, in part, in response to the [Bioterrorism Act of 2002](#), which gave high priority to improved information management to help protect the food supply. The Act requires that FDA develop two systems: one to support the registration of facilities that manufacture, process, pack, or hold food products intended for consumption in the United States and one to receive prior notice before food is imported or offered for import into the United States. Under the law, facilities must be registered by December 12, 2003 when Prior Notice went into effect.

Systems Index

FURLS Acidified/Low Acid Canned Foods (LACF) Form 2541/2541d/2541e/2541f/2541g	FURLS Biologics Export Certification Application & Tracking System (BECATS) Form 3613 (05/18)	FURLS Export Listing Module (ELM) Form 3972 (07/18)
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Dealer Responsibilities: NOAA Export Certification



Search NOAA Fisheries

Find A Species

Fishing & Seafood

Protecting Marine Life

Environment

Regions

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



The screenshot shows the NOAA Seafood Inspection Program website. At the top left is the NOAA logo and the text "NOAA SEAFOOD INSPECTION PROGRAM NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION". Below this is a release information string: "Release: 7.7.0.4 (#6750 | sha1:7dfea4f8)". On the right side, there are links for "SIP Home" and "Contact SIP". The main content area features a background image of several bright red lobsters. Overlaid on this is a white box with a blue header titled "Seafood Inspection Services Portal". Inside this box, there are two input fields: "User Name:" and "Password :". Below the password field is a blue "Sign In" button. To the right of the button, there is a link that says "New Customer Forgot Password?".

This site has been tested with Internet Explorer versions 9-11. We have identified several features that do not work with other browsers. If you encounter problems using other browsers, please use Internet Explorer.

Seafood Inspection Services Portal

User Name:

Password :

[Sign In](#)

[New Customer
Forgot Password?](#)

****WARNING**WARNING**WARNING****

You are accessing a U.S. Government information system, which includes: 1) this computer, 2) this computer network, 3) all Government-furnished computers connected to this network, and 4) all Government-furnished devices and storage media attached to this network or to a computer on this network. You understand and consent to the following: you may access this information system for authorized use only; unauthorized use of the system is prohibited and subject to criminal and civil penalties; you have no reasonable expectation of privacy regarding any communication or data transiting or stored on this information system at any time and for any lawful Government purpose, the Government may monitor, intercept, audit, and search and seize any communication or data transiting or stored on this information system; and any communications or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose. This information system may contain Controlled Unclassified Information (CUI) that is subject to safeguarding or dissemination controls in accordance with law, regulation, or Government-wide policy. Accessing and using this system indicate your understanding of this warning.

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	1.1. Consignor Name Address Postal Code Tel No.				1.2. Certificate reference number		1.2.a.		
	1.5. Consignee Name Address Postal code Tel No.				1.3. Central Competent Authority USDC NOAA NMFS Seafood Inspection Program				
					1.4. Local Competent Authority				
	1.7. Country of origin USA		ISO code US	1.8. Region of origin SEE BOX I.28	Code SEE BOX I.28	1.9. Country of destination		ISO code	1.10.
	1.11. Place of origin Name Address Approval number				1.12.				
	1.13. Place of loading				1.14. Date of departure				
	1.15. Means of transport Airplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/>				1.16. Entry BCP in EU				
	Identification				1.17.				
	Documentary references				1.19. Commodity code (HS code)				
	1.18. Description of commodity				1.20. Quantity				
	1.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				1.22. Number of packages				
	1.23. Identification of container/Seal number				1.24. Type of packaging				
	1.25. Commodities certified for Human consumption <input type="checkbox"/>				1.26.				
1.27. For import or admission into EU <input type="checkbox"/>									



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>

