

Shellfish Equivalence

Opening Markets Between the United States and the European Union Webinar for States and Industry October 1, 2020

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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 EU 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 determinations 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.
- The EC's equivalence determination applies to shellfish harvested from U.S. Approved growing areas, initially in Massachusetts and Washington.
- We anticipate a resumption of this shellfish trade with the EU this winter.
- FDA and the EC signed an arrangement for a streamlined evaluation process and letters of understanding.

What is Equivalence?

- Equivalence is the tool defined in trade law (the WTO-SPS Agreement) that can be used to assess foreign food safety controls to ensure that they provide at least the same level of public health protection as domestic controls.
- The WTO agreement requires FDA to evaluate a foreign system for equivalence to ours when requested to do so by a foreign government.

The Shellfish Evaluation Process used by FDA and the Directorate General for Health and Food Safety of the European Commission (DG SANTE)

- Document reviews of food safety laws, regulations, and controls by technical experts.
- In-country audits/evaluations covering state/member state implementation, laboratories, and oversight of growing areas and processing plants.

In-depth Review

- The following areas were identified for in-depth evaluations:
 - Procedures and enforcement for growing area controls (including water quality testing vs. shellfish meat testing)
 - Marine pathogens (*Vibrios*)
 - Marine biotoxins (different approaches posed a concern for DG SANTE)

Classification of Shellfish Growing Areas

- Safety and the Classification of Growing Waters Through Water Testing (U.S.) vs. Shellfish Meat Testing (EU)
 - Statistical analysis of 7,300 water and meat samples concluded that “no statistically significant level of disagreement can be established between failure and approval outcomes using U.S. Approved and EU Class A criteria.”
 - Technical experts on each side concluded that the other classification system provides the same level of public health protection.

Resolution of Growing Areas Management Issues

- Growing area controls: the United States use sanitary surveys; the EU tests for bacteria in the meat:
 - DG SANTE agreed to adopt additional EU controls (U.S. standards) for pollution sources and buffer zones.
 - FDA assessed the new controls in specified growing areas in the Netherlands and Spain and found them effective.
 - DG SANTE agreed that only growing areas applying the additional controls could ship to the United States.

Restriction on Certain U.S. Shellfish

- At this time, the EU will only accept U.S. shellfish harvested and processed from Approved growing areas in the states of MA and WA.
- The EU at this time will not accept shellfish products harvested from states with documented illnesses linked to the pathogen *Vibrio vulnificus* and operating under a required management plan.
- The states that fall under this restriction currently are those that border the Gulf Coast (Florida, Alabama, Louisiana, Mississippi, Texas), New Jersey, and Virginia.



Additional Steps to Address *Vibrios*

- Both the U.S. and the EU recognized *Vibrio parahaemolyticus* as a public health concern.
- FDA and DG SANTE agreed to pursue technical consultations to improve understanding and control of *Vibrio parahaemolyticus* under the administrative arrangement.
- The European Food Safety Authority has agreed to consider an FDA proposal regarding the efficacy of post-harvest processing options for *Vibrio vulnificus*. A positive evaluation is necessary to allow export from Vv states.

Biotoxin Monitoring and Testing

- Differences in surveillance and laboratory methods for control of biotoxins in shellfish were fully evaluated.
- FDA documented that the monitoring and controls in use in Spain and the Netherlands were effectively managing the hazards, based on the absence of biotoxin illnesses/outbreaks linked to shellfish.
- In Nov. 2015, DG SANTE accepted FDA assurances, an important step to reaching an equivalence recommendation.

On-site Evaluations

- FDA and DG SANTE conducted on site evaluations and each identified deficiencies in the other system.
- These deficiencies were discussed and both sides committed to taking the necessary corrective actions.



The Equivalence Determinations

- The determinations open trade for shellfish harvested from U.S. Approved growing areas, initially in Massachusetts and Washington State, and for raw shellfish harvested from Class A production areas in Spain and the Netherlands.
- It covers only the growing waters classified as U.S. Approved and EU Class A.
- U.S. shippers must be on the EU's list and obtain an EU export certificate from the National Oceanic and Atmospheric Administration (NOAA).
- The determinations do not cover requirements for food labeling, food additives, drug residues, and pesticide limits. Compliance required.

What products are covered by the EU's equivalence determination?

Live, chilled, frozen, and processed shellfish harvested from U.S. growing areas with Approved classification, initially in Massachusetts and Washington.

Export Eligibility

Three steps for becoming eligible to export to the EU:

1. U.S. States must be listed on EU List of Third Countries Eligible to Export Shellfish, Tunicates and Marine Gastropods to the EU.
 - States must submit required documentation through FDA to be considered by the EU for listing.
2. Shellfish growing areas and firms in officially listed States must be listed on the EU's List of Approved Third Country Establishments.
 - Shellfish firms must be listed on the Interstate Certified Shellfish Shippers List (ICSSL) and requires application through FDA's Export Listing Module (ELM).
3. Listed firms must obtain an EU shellfish export certificate from NOAA for each consignment shipped to the EU.

EU Lists

List of Third Countries Eligible to Export Live, Chilled, Frozen or Processed Bivalve Molluscs, Echinoderms, Tunicates and Marine Gastropods to the EU for Human Consumption (Amendment to Annex I of EU Decision 2006/766/EC)

<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02019R0626-20191214&from=EN#tocId10>

EU's Third Country Establishments List

https://webgate.ec.europa.eu/sanco/traces/output/non_eu_listsPerActivity_en.htm#

(5) Decision 2006/766/EC should therefore be amended accordingly.

(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 139, 30.4.2004, p. 206.

⁽²⁾ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

⁽³⁾ Commission Decision 2006/766/EC of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted (OJ L 320, 18.11.2006, p. 53).

8.11.2018

EN

Official Journal of the European Union

L 278/27

HAS ADOPTED THIS DECISION:

Article 1

In Annex I to Decision 2006/766/EC, the entry for the United States of America is replaced by the following:

'US	United States of America	States of Massachusetts and Washington'
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Article 2

This Decision is addressed to the Member States.

Done at Brussels, 6 November 2018.

Snipping Tool

File Edit Tools Help

New Delay [Icons]

Establishments List per Section x +

webgate.ec.europa.eu/sanco/traces/output/non_eu_listsPerActivity_en.htm#

Third Country Establishments List per Section

Food

- [Section I : Meat of domestic ungulates](#)
- [Section II : Meat from poultry and lagomorphs](#)
- [Section III : Meat of farmed game](#)
- [Section IV : Wild game meat](#)
- [Section V : Minced meat, meat preparations and mechanically separated meat \(MSM\)](#)
- [Section VI : Meat products](#)
- [Section VII : Live bivalve molluscs](#)
- [Section VIII : Fishery products](#)
- [Section IX : raw milk, dairy products, colostrum and colostrum-based products](#)
- [Section X : Eggs and egg products](#)
- [Section XI : Frogs' legs and snails](#)
- [Section XII : Rendered animal fats and greaves](#)
- [Section XIII : Treated stomachs, bladders and intestines: casing only](#)
- [Section XIV : Gelatine](#)
- [Section XIV/XV : Treated raw material for the production of gelatine and collagen \(TCG\)](#)
- [Section XV : Collagen](#)
- [Section XIV/XVbis : Raw materials for the production of gelatine and collagen](#)

Semen and Embryo

- [Section I : Semen centers](#)
- [Section II : Embryo team](#)

Section VII : Live bivalve molluscs

PDF Documents (last change date)

- [Australia \(03/12/2019\)](#)
- [Canada \(14/01/2020\)](#)
- [Chile \(13/10/2019\)](#)
- [Jamaica \(02/04/2008\)](#)
- [Japan \(26/02/2020\)](#)
- [Korea, Republic Of \(29/07/2015\)](#)
- [Morocco \(21/03/2020\)](#)
- [New Zealand \(29/01/2020\)](#)
- [Peru \(19/02/2020\)](#)
- [Thailand \(17/01/2018\)](#)
- [Tunisia \(28/05/2019\)](#)
- [Turkey \(14/01/2020\)](#)
- [Viet Nam \(26/02/2020\)](#)

COUNTRY
SECTION

Canada
Live bivalve molluscs

Validity date from
14/01/2020
Date of publication
04/03/2011

00295

List in force

Approval number	Name	City	Regions	Activities	Remark	Date of request
0020	Clearwater Seafoods Limited Partnership "Arctic Endurance"	Argentia	Newfoundland & Labrador	FV		23/11/2009
0036	Couche Seafoods Limited	Couche	Newfoundland & Labrador	IP, PP		02/06/2017
0047	Allen's Fisheries Limited	Benoit's Cove	Newfoundland & Labrador	IP, PP		02/06/2017
0050	Dorman Roberts Limited	Tritou	Newfoundland & Labrador	IP, PP		02/06/2017
0055	Atlantic Cold Sea Foods Ltd.	Saint Joseph'S	Newfoundland & Labrador	IP, PP		02/06/2017
0076F	Clearwater Seafoods Limited Partnership	Harbour Grace	Newfoundland & Labrador	FV		01/09/2015
0079	Green Seafoods Ltd	Winterton	Newfoundland & Labrador	IP, PP		02/06/2017
0083	Norlantic Processors Limited	Pleasantview	Newfoundland & Labrador	IP, PP		02/06/2017
0084	Icewater Seafoods Inc.	Arnold'S Cove	Newfoundland & Labrador	IP, PP		02/06/2017
0111	Deep Atlantic International Inc.	New Ferolle	Newfoundland & Labrador	IP, PP		02/06/2017
0130	Quinlan Brothers, Ltd	Bay De Verde	Newfoundland & Labrador	IP, PP		02/06/2017
0156	Clearwater Seafoods Limited Partnership	Grand Bank	Newfoundland & Labrador	IP, PP		02/06/2017
0157	Labrador Gem Seafood Incorporated	Ramea	Newfoundland & Labrador	PP		14/07/2015
0157F	Labrador Gem Seafood Incorporated	Ramea	Newfoundland & Labrador	IP		02/06/2017
0171	Quin-Sea Fisheries Limited	Old Pelican	Newfoundland & Labrador	IP, PP		02/06/2017

List in force

Approval number	Name	City	Regions	Activities	Remark	Date of request
PQ-N-14.4.2E	,	QUEBEC	Quebec	Z	ZA	23/11/2009
PQ-N-20.3.1.1E	,	QUEBEC	Quebec	Z	ZA	23/11/2009
PQ-N-28.1E	,	QUEBEC	Quebec	Z	ZA	23/11/2009
PQ-N-28.2E	,	QUEBEC	Quebec	Z	ZA	23/11/2009
PQ-N-30.1E	,	QUEBEC	Quebec	Z	ZA	23/11/2009
PQ-N-31.1.1E	,	QUEBEC	Quebec	Z	ZA	23/11/2009
PQ-N-32.1E	,	QUEBEC	Quebec	Z	ZA	23/11/2009
PQ-P-01.1	,	QUEBEC	Quebec	Z	ZA	23/11/2009
PQ-P-01.2	,	QUEBEC	Quebec	Z	ZA	23/11/2009

Activities Legend :
 FV Factory Vessel
 IP Dispatch centre
 PP Processing Plant
 Z Production Areas

Remarks Legend :
 ZA Production zones in compliance with provision laid down in Annex II, Heading II A3, of the Regulation (EC) 2004/854

NOAA Certificates

<https://www.fisheries.noaa.gov/national/seafood-commerce-certification/export-certification-european-union>



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Export Certification to the European Union

National

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 three documents required for export to the European Union. They are:

- EU export health certificate;
- EU IUU catch document for fisheries products harvested in the United States, to prevent, deter, and eliminate illegal, unregulated and unreported (IUU) fishing; and,
- The EU “Annex IV” catch document for products harvested in a country other than the United States but being exported through the United States to the EU, to prevent, deter, and eliminate illegal, unregulated and unreported (IUU) fishing.

Under EU regulations, an export health certificate is required as well as one of the two catch documents.

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Listing Additional States

- FDA and DG SANTE established a process for considering additional U.S. states or EU Member States seeking to export under equivalence that meet the requirements for growing water classification and other criteria.

Listing Additional States

3. In the context of handling the requests by National Shellfish Sanitation Program (NSSP) participants to be added to the EU List:

3.1. FDA intends to submit to DG SANTE requests from NSSP participants seeking to be added to the EU List.

3.2. FDA intends to review the information referred to in points 3.3 and 3.4 and inform DG SANTE that, based on the information provided, NSSP participants seeking to be added to the EU List have applied relevant U.S. measures.

Listing Additional States

- 3.3. FDA normally intends to submit the following documents and information with the requests referred to in points 3.1 and 3.2, unless a NSSP participant is seeking to be listed using point 3.4:
- a) List of Approved growing areas;
 - b) List of firms/processors harvesting product in those Approved growing areas;
 - c) Most recent FDA audit of the NSSP participant's implementation of the NSSP and any corrective action taken after the audit;
 - d) Most recent sanitary survey(s) for those Approved growing areas;

Listing Additional States

- e) 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;
- f) 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; and
- g) Summary description of applicable U.S. mechanisms for implementing and enforcing FDA regulations, plus enforcement of additional measures, if any, applied to those growing areas/processors.

Listing Additional States

- 3.4. For NSSP participants seeking to ship raw shellfish harvested from an Approved growing area in another NSSP participant that is already on the EU List, documentation normally consists of:
- a) The most recent Plant and Shipping Element Program Evaluation Report; and
 - b) The most recent inspection report for each shellfish processing firm seeking to be listed for export to the EU.

Listing Additional States

- 3.5. Without limiting the number of NSSP participants to be considered, DG SANTE intends to evaluate promptly the documents referred to in point 3.3 or 3.4 and notify FDA of the results of its evaluation.
- 3.6. Following a positive evaluation, DG SANTE intends to promptly initiate its administrative procedures relevant to the context of handling the requests by NSSP participants to be added to the EU List, without prejudging the final outcome of such procedures.

Listing Additional States – State Responsibilities

- States should notify their FDA Shellfish Specialist of their interest in exporting shellfish to the EU.
- FDA Shellfish Specialist will assist the State in putting together the information needed to submit to the EC for consideration.

Required Documents - Checklist



✓	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.	



Maintenance of Growing Area List - State Responsibilities

- States will provide an initial list of Approved growing areas based on the template and instructions provided by FDA.
- States will notify their FDA Shellfish Specialist of classification changes as required under the NSSP.

EU Shellfish Export List



	A	B	C	D	E	F	G	H
1	Approval Number	Name	Street Address	City	State	Activities	Remark	
2						Z	ZA	
3						Z	ZA	
4								
5								
6								
7								
8	Date: 8/1/2018							
9								
10	Activities Legend:							
11	FV – Factory Vessel							
12	IP – Dispatch Centre							
13	PP – Processing Plant							
14	Z – Production Areas							
15								
16	Remarks Legend:							
17	ZA – Production zones in compliance with provision laid down in Annex II, Heading II A3, of the Regulation (EC) 2004/854							
18								
19	Instructions							
20	Approval Number	Enter a unique identifier for each growing area.						
21	Establishment Name	Enter the name or description of the growing area.						
22	Street Address	Leave this field blank.						
23	City	Enter the city (if applicable) or state name.						
24	State	Enter the state name.						
25	Activities	Enter "Z" (without quotation marks).						
26	Remark	Enter "ZA" (without quotation marks).						
27	Date	Enter the date.						

Summary

State Responsibilities

- Determine interest in listing and notify FDA Shellfish Specialist.
- Work with FDA Shellfish Specialist to prepare and submit complete package of documents.
- Use template to populate list of **Approved** growing areas.
- Submit updates to growing area listing as needed.

EU Shellfish Export List

Establishments/Dealers/Shippers

- Any establishment that intends to harvest, process, or dispatch shellfish products to the EU must apply to be included on the EU's list of approved establishments via the **FDA's Export Listing Module**.
- The ELM is an online portal that FDA uses to receive and process requests from industry to be included on export lists. Available at <https://www.access.fda.gov/>
 - Certified shellfish shippers will identify themselves for listing using the certificate number on the ICSSL.
 - Processing establishments will identify themselves for listing using their Food Facility Registration information or the FDA Establishment Identifier (FEI number).



Export Listing Module



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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)

EU Approval Numbers

- The approval number will appear on the EU list.
 - The same approval number must appear on all product labels.
 - The same approval number must be used for the NOAA certificates that accompany each shipment.
- Strict consistency in the identification of approval numbers on the EU Shellfish Shippers List, shellfish tags, and the EU shellfish certificate is critical to ensuring trouble-free import review at EU ports of entry.

EU Approval Numbers

- FDA's standard procedure will be to assign approval numbers as follows:
 - For firms on the ICSSL, FDA will use the following format for a shellfish shipper's certification number as the approval number for the EU List: DC-0001-SS-PHP.
 - For processing plants not on the ICSSL, FDA will use FDA Establishment Identification (FEI) numbers as approval numbers for the EU list.
- If any firm wishes to be listed using a different approval number or format, it can upload a letter to its ELM application and request to be listed with a different approval number format.

EU Approval Numbers

- Firms may request a different approval number format based on their current shellfish tag (e.g., DC0001SS-PHP or DC.0001.SS.PHP) or they can request to be listed with their FEI number as the approval number.
- Some shellfish firms may already be listed on the EU seafood export list using their FEI number and for purposes of consistency may wish to continue this practice.

NOAA Certificate

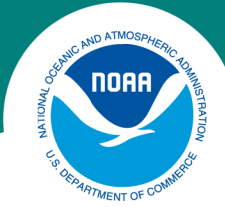


UNITED STATES OF AMERICA
U.S. DEPARTMENT OF COMMERCE



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



NOAA Seafood Inspection Program

The Seafood Commerce and Certification website offers information and guidance on export requirements.

<https://www.fisheries.noaa.gov/topic/seafood-commerce-certification#overview>

The Seafood Inspection Services Portal (SISP) is the NOAA SIP online certification request system.

<https://seafoodinspection.nmfs.noaa.gov/customer/customerlogin.html>

The NOAA Handbook Part 7: Certification provides guidance on the specific requirements of the export certificate for EU Shellfish.

<https://www.fisheries.noaa.gov/national/seafood-commerce-certification/seafood-inspection-manual>

Summary

Industry Responsibilities

- Notify Shellfish Control Authority of interest in exporting to the EU.
- Monitor EC decision and listing for addition of State name.
- Submit ELM application.
- Ensure that approval numbers consistently appear on all documentation and packaging and match EU list for ease of entry review.



Recognizing Additional EU Member States

For EU Member States seeking to be recognized by FDA, DG SANTE normally intends to submit the following for FDA review:

1. List of eligible Class A production areas;
2. List of firms/processors harvesting product in those Class A production areas;
3. Most recent EC audit of the EU Member State's implementation of EU measures, additional measures, and the corrective actions taken, if any, after the audit;
4. Most recent sanitary survey(s) for those eligible Class A production areas;

Recognizing Additional EU Member States

5. Most recent inspection reports for firms operating in those Class A production areas and, in case of non-compliance, the corrective actions taken, if any, after the inspection,
6. List of laboratories performing official regulatory analysis of raw molluscan shellfish samples, and the most recent ISO 17025:2017 (or equivalent) audit report for each laboratory, including any resulting corrective actions, and
7. Summary description of EU Member State's mechanisms for implementing and enforcing: EU measures applied to raw bivalve molluscan shellfish; any additional national measures adopted by the EU Member State; and application of additional agreed measures.



CFSAN / Office of Food Safety
Updated: September 18, 2020

Interstate Certified Shellfish* Shippers List

(* Fresh and Frozen Oysters, Clams, Mussels, Whole or Roe-on Scallops)

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- [Country Officers Responsible for Interstate Shellfish Sanitation Certificates](#)



Interstate Certified Shellfish Shippers List

Interstate Shellfish Shippers

- Tennessee**
- Texas**
- Utah**
- Virginia**
- Virgin Island
- Vermont**
- Washington**
- Wisconsin**
- West Virginia**
- Wyoming

Foreign Certified Shippers

- British Columbia**
- New Brunswick**
- Newfoundland**
- Nova Scotia**
- Ontario**
- Prince Edward Island**
- Quebec**
- Chile
- Spain
- Korea**
- Mexico**
- Netherlands
- New Zealand**

Timelines

Massachusetts and Washington

- Industry: Firms should apply now to the ELM in order to be included in initial listing – Due October 24.
- States: Work with FDA Shellfish Specialist to confirm listing of Approved growing areas is accurate – Due October 24.

All Other Interested States and Industry

- In order to be included in the first group of requests, complete packages need to be submitted to FDA within 3 months of FRN publication; by December 24.

Federal Register Notice:

<https://www.federalregister.gov/documents/2020/09/24/2020-20755/food-and-drug-administration-equivalence-determination-regarding-implementation-by-spain-and-the>



Questions?

ShellfishEquivalence@fda.hhs.gov

<https://www.fda.gov/food/international-interagency-coordination/international-cooperation-food-safety#equivalence>

