

**Guidance and Protocol for Industry and
Food and Drug Administration Staff:
Certification of Fish and Fishery Products for Export to the
European Union and European Free Trade Association**

Draft Guidance

This guidance document is being distributed for comment purposes only.

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Comments and suggestions regarding this draft document should be submitted within 30 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket Number 2004D-0509. For questions regarding this draft document contact Tim Hansen, Center for Food Safety and Applied Nutrition (CFSAN), (301) 436-1405.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Seafood
November 2004

**Guidance and Protocol for Industry and
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This draft Level One guidance represents FDA's current thinking on Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of applicable statutes and regulations. The draft guidance is being distributed for comment purposes in accordance with FDA's Good Guidance Practices (21 CFR 10.115; September 19, 2000).

I. Purpose

The Food and Drug Administration (FDA or agency) is providing this draft guidance on how it is issuing health certificates that accompany shipments of fish and fishery products from the United States (U.S.) to the European Union (EU), EU Accession Partnership Countries (hereinafter referred to as EU Export Certificates), and members of the European Free Trade Association (EFTA). These certificates are required by the EU and these countries. The purpose of the draft guidance is to clarify the internal processes that FDA uses to issue these EU Export Certificates; the procedures that industry seeking these certificates should follow; the criteria that FDA generally intends to consider in determining whether to issue an EU Export Certificate; and related matters. This guidance, when finalized, is intended to supersede all previous protocols that were written by the various Districts Offices that provide EU certification for seafood products.

Since 1993, the EU has required that an EU Export Certificate accompany all shipments of fish and fishery products that are shipped to the EU. For fish and fishery products generally, the certificates that FDA signs essentially attest that the products have been produced in accordance with a Hazard Analysis Critical Control Point (HACCP)-based safety system that is at least equivalent to the EU system of control. The FDA HACCP regulations have been deemed by the European Commission to be equivalent, in principle, to the EU system of control. In 1996, the EU also began requiring a different certificate specifically for shipments of live molluscan shellfish (e.g., oysters, clams, mussels). These certificates are based partly on equivalence to, and partly on consistency with, EU requirements.

In 1993, to ensure the smooth flow of trade in fish and fishery products to the EU, FDA began signing certificates for shipments of fish and fishery products to the EU. The FDA also signs certificates for shipments of fish and fishery products to EU Accession Partnership Countries and EFTA Members. The certificates certify that the establishment¹ is in regulatory good standing, as defined in section III.B.

The Seafood Inspection Program of the National Oceanic and Atmospheric Administration (NOAA SIP) of the U.S. Department of Commerce also signs EU Export Certificates as one service that it offers U.S. seafood processors and other entities in its voluntary, fee-for-service seafood inspection program. The NOAA SIP typically issues these certificates on the basis of inspections conducted under its voluntary, fee-for-service program.

II. Agency Roles

The roles for the agency generally and for relevant agency components are described below.

A. FDA intends to:

1. Continue to serve as the lead competent authority in the U.S. for fish and fishery products.

¹ “Establishment” refers to any structure, or structures under one ownership at one general physical location, or, in the case of a mobile establishment, traveling to multiple locations, that manufactures/processes, packs, or holds food. Transport vehicles are not establishments if they hold food only in the usual course of business as carriers. An

2. Determine whether an establishment is eligible for EU Export Certificates based on whether the establishment is in regulatory good standing, as defined in section III.B.
3. Consider the results of inspections conducted by other governmental entities within the U.S. with which FDA has a contract, partnership arrangement, or MOU for a regulatory inspection when making the final determination as to whether or not an establishment is in regulatory good standing and, therefore eligible for an EU Export Certificate. Provide guidance and oversight to these governmental entities with regard to EU-related certificates.
4. Provide information regarding the regulatory standing of an establishment to facilitate the issuance of certificates by NOAA SIP under their authorities.
5. Maintain an updated database on the current regulatory status of U.S. entities that have applied to receive EU Export Certificates based upon the information provided by the District Offices pursuant to II.C. 2. FDA intends to maintain three EU Export Certificate Lists:
 - a. The EU Export Certificate List of Value-Added Processors (hereafter called the “Value-Added Processors List”);

establishment may consist of one or more contiguous structures, and a single building may house more than one distinct establishment if the establishments are under separate ownership.

b. The EU Export Certificate List – Value-Added Processing Vessels (hereafter called the “Value-Added Processing Vessels List”); and

c. The EU Export Certificate List - Other Than Value-Added Processors (hereafter called the “Other Than Value-Added Processors List”).²

B. FDA Office of Seafood intends to:

1. Serve as liaison with EU officials regarding fish and fishery products. Information will be provided to the District Offices, other agencies of government, and the industry as appropriate.
2. Issue guidance to industry, NOAA SIP, and FDA District Offices on the EU Export Certificate List program.
3. Maintain and provide to the EU on a quarterly basis the three current EU Export Certificate Lists. Make the updated EU Export Lists available on the web at: www.cfsan.fda.gov/~frf/sfeuexp.html.

C. FDA District Offices intend to:

² The terms “Value-Added Processor,” “Value-Added Processing Vessel,” and “Other Than Value-Added Processor” are defined in III.A.

1. Process requests submitted by establishments for inclusion on any of the three EU Export Certificate Lists, including deciding whether an applicant should be listed after considering the information described in section III of this document and providing written notification to applicants. FDA intends that the FDA District Offices will process all such requests for all establishments, even when the regulatory inspection is performed by another governmental entity in the U.S. with which FDA has a contract, partnership arrangement, or MOU for such an inspection, or when the EU Export Certificates for that establishment are issued by a certifying body authorized by FDA to issue those certificates.

2. Notify the Office of Seafood as soon as possible with changes to the EU Export Certificate Lists, including the addition of new establishments and changes in eligibility status of establishments already on the list. In addition, the District Offices may remove establishments from the list if they have not applied for an EU Export Certificate from FDA or NOAA SIP within two years or if FDA has reliable information indicating that the establishment is no longer exporting fish and fishery products.

3. Review each EU Export Certificate submitted by an establishment for FDA certification to determine whether all appropriate information has been included and entered in accordance with EU requirements, as noted in Section V.

4. Determine eligibility when the establishment requests the issuance of an EU Export Certificate. If the establishment is a Value-Added Processor or Value-Added Processing Vessel, eligibility should be based upon whether that establishment is in regulatory good standing as defined in section III.B. If the Value-Added Processor or Value-Added Processing Vessel has no inspectional history, a regulatory inspection should be performed as soon as work plan priorities permit. If the establishment is an Other Than Value-Added Processor or a Dispatcher as described in section III.A., eligibility should be based upon the regulatory good standing of the establishment's supplier(s). For the purposes of the EU Certificate Lists, regulatory inspections may be performed by FDA or by another governmental entity in the U.S. with which FDA has a contract, partnership arrangement, or MOU for such a regulatory inspection.
5. Respond to an establishment's request for certificates by signing the certificates, if appropriate, and providing them back to the establishment.
6. Provide written notification to the establishment of any change in its status on any of the lists that means it should no longer be considered in good standing. This notification may be included as part of a regulatory notice (e.g., warning letter) and need not be issued as a separate notification.
7. As necessary, where an establishment becomes eligible and requests certification before the Office of Seafood submits its quarterly listing of eligible establishments to the EU, provide to the establishment a letter to accompany the EU Export Certificates

explaining that the establishment has become eligible and should appear on the web, as described in section II.B.3, at: www.cfsan.fda.gov/~frf/sfeuexp.html. It should be understood, however, that such a letter may not be acceptable to some EU countries that may require that the firm appear on the official list.

III. Eligibility for inclusion on the EU Export Certificate Lists

A. Classification as a Value-Added Processor, a Value-Added Processing Vessel, an Other Than Value-Added Processor, or a Dispatcher

As indicated previously, FDA intends to maintain three EU Export Certificate Lists, two for Value-Added Processors (the Value-Added Processors List and the Value-Added Processing Vessels List) and one for exporters that do not engage in value-added processing, as defined below (the Other Than Value-Added Processors List).

1. Whether the establishment is a Value-Added Processor or a Value-Added Processing Vessel

EU Export Certificates should be available to U.S. establishments that engage in value-added processing of domestic and/or imported fishery products in the U.S.

a. Definition of Value-Added Processing:

For purposes of this document, “value-added processing” is defined as manipulating a product in a way that increases the value or usability of the products. Examples of value-added processing include preparing, heading, eviscerating, shucking, freezing, glazing, changing into different market forms, manufacturing, preserving, packing, repacking, labeling or relabeling of fish and fishery products. "Holding" or "storing," as conducted by a warehouse, should not alone constitute value-added processing. Only products that have been subject to value-added processing that has occurred in the U.S. should be eligible for EU Export Certificates, including such processing that occurs on a processing vessel such as a factory trawler. (For these purposes, when U.S. flag vessels engage in value-added processing on the high seas, this processing is deemed to have occurred in the U.S.) Harvesting vessels that engage in practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board that vessel should not be deemed to be engaged in value-added processing.

b. Examples:

- i. Frozen tuna loins that were processed in Indonesia are shipped to the U.S. where an establishment saws them into steaks, places them in vacuum packages and sells them to a customer in the United Kingdom. The U.S. establishment is a Value-Added Processor under this guidance.

ii. Farm raised Atlantic salmon is skinned and filleted in Chile and shipped to the U.S. chilled on gel ice via air freight. An establishment in the U.S. brines, dries, and smokes the fillets and packages them into reduced oxygen packages. The product is then shipped via air freight to a super market chain in The Netherlands. The U.S. establishment is a Value-Added Processor under this guidance.

iii. An imported product that enters the U.S. and proceeds directly to a warehouse for storage before it is shipped "as is" to the EU, should not be eligible for an EU Export Certificate under this guidance because no "value-added" processing occurred in the U.S. In such instances the establishment should request an EU Export Certificate from the country of origin. If an imported product has been warehoused in the U.S. for an extended period of time, however, there is a possibility that the EU will reject the entry in the absence of an EU certificate from the U.S. To preclude this from occurring, the shipper can ask for a specific lot certification from NOAA SIP.

iv. Live lobsters from Canada that are held in pounds, repacked in the U.S. and shipped to the EU may be eligible for EU Export Certificates. However, if the lobsters are just shipped as received from Canada, without repacking, they should not be eligible for EU Export Certificates under this guidance.

v. Tuna that was canned in Thailand is shipped to the U.S. in "bright stacks," which are plastic wrapped pallets of product with no label on the individual cans. In the U.S., a packing company labels and cases the product and stores it in a warehouse. The packer should be eligible for an EU Export Certificate as a Value-Added Processor because the addition of a label constitutes value-added processing in the U.S.

2. Whether an establishment is an Other Than a Value-Added Processor or a Dispatcher

EU Export Certificates should be available to certain types of establishments that do not themselves engage in processing so long as they provide appropriate information about the shipment, either to FDA or on the certificate itself.

a. Other Than Value-Added Processors: Establishments such as brokers that only ship products that have been processed by others in the U.S. may become eligible for inclusion on the Other Than Value-Added Processors List. Such establishments would obtain their own Central File Number (CFN) or FDA Establishment Identifier (FEI) number from FDA and include it on the certificate in lieu of the names and CFN or FEI numbers of their suppliers. It should be understood, however, that the absence of such identifying information about suppliers might cause the certificate to be rejected by some EU countries. Other Than Value-Added Processors ship at their own risk in that respect. In any event, the CFN or FEI numbers of all U.S. processors relevant to the shipment for which

a certificate is being sought should be provided to FDA along with the request for certification. All such processors should be in regulatory good standing.

b. Dispatchers: EU Export Certificates provide for shipments by "dispatchers," which are also establishments such as brokers that ship products that have been processed by others in the U.S. Unlike Other Than Value-Added Processors, dispatchers list on the EU Export Certificate the names and CFN or FEI numbers of their U.S. processors. Dispatchers do not need to be listed on any of the three EU Export Certificate Lists. Certificates should be issued when the listed processors are in current regulatory good standing.

c. Examples

i. A warehouse in the U.S. stores frozen cod fish from Alaska. A broker sells the product to a French company. At the time of sale, the product is still owned by the Alaska fishing company. The broker is a Dispatcher if it identifies the names and CFN or FEI numbers of the Alaska fishing company. If it does not identify the Alaska fishing company the broker would be an Other Than Value-Added Processor.

ii. Frozen shrimp from the Gulf of Mexico is shipped to Los Angeles where it is breaded and re-packaged. The value-added product is stored in a

warehouse which finds a buyer in Ireland. The warehouse is an Other Than Value-Added Processor.

iii. White shrimp from an aquaculture farm in Ecuador are transported on ice to a local Ecuadorian processor who washes, shells and cooks the products, individually quick freezes the shrimp, packages the lot into 2 kilo poly bags, and then has them cased. These cases are shipped to the U.S. and held in a cold storage freezer. The owner of the product eventually ships the product to France. Because no value-added processing occurred in the U.S., the owner of the cold storage freezer should not be eligible for an EU Export Certificate as an Other Than Value-Added Processor. The owner should request a certificate from Ecuador.

B. Determination of whether an establishment should be considered in regulatory good standing

An establishment should be considered in regulatory good standing and eligible to receive EU Export Certificates for its products when it is in adequate compliance with all applicable FDA laws and regulations. Regulatory good standing should be based primarily on the results of the most recent inspection of the establishment by either FDA or by another governmental entity in the U.S., such as a State regulatory authority, with which FDA has a contract, partnership arrangement, or other Memorandum of

Understanding (MOU), for the purpose of conducting inspections that count against the establishment's compliance status with FDA.

1. An establishment should not be considered in regulatory good standing and should not be issued an EU Export Certificate for any of its products after a Warning Letter has been issued or an FDA legal action has been filed in court, such as an injunction, seizure, or prosecution, under any of the laws or regulations administered by FDA. Nor shall an establishment be considered in good standing if it is being prosecuted for false statements to FDA. The establishment should be returned to regulatory good standing when the FDA District Office has concluded that the conditions that resulted in the Warning Letter or legal action have been resolved.
2. In addition to item 1, a Value-Added Processor of molluscan shellfish should be listed on the Interstate Certified Shellfish Shippers List (ICSSL) in order to be in regulatory good standing for shipments of molluscan shellfish.

IV. Guidance to Industry for inclusion on any of the three EU Export Certificate Lists

An applicant should apply for inclusion on the Value-Added Processors List, the Value-Added Processing Vessels List, or the Other Than Value-Added Processors List by sending a request to the EU coordinator in the FDA Office covering the geographical location of the

establishment seeking the certificate (see www.cfsan.fda.gov/~dms/eucert.html) for a list of EU coordinators and the area they cover) that includes the following:

- A. Identity of the list on which it is applying for inclusion and a list of the product(s) and packing types intended for export to the EU.
- B. The name, address and telephone number of the person(s) designated as the contact(s) for each applicant.
- C. For molluscan shellfish, assurance that the tag or other labeling includes the species name of the shellfish, the country of origin of the shellfish and, when in-shell oysters are being shipped, assurance that the oysters are being packaged with the concave side down, in accordance with EU non-safety requirements.
- D. A statement that the establishment and individual submitters of information are aware of, and know that, their EU Certificate submissions are subject to the provisions of Title 18, Chapter 47, Section 1001, United States Code (U.S.C.). Under 18 U.S.C. 1001, anyone who, among other things, makes a materially false, fictitious, or fraudulent statement to the U.S. government is subject to criminal penalties.
- E. For Other Than Value-Added Processors, in addition to items A-D, the name and address of each supplier that engages in value-added processing of the fish and

fishery product, as well as the name, address and telephone number of the person(s) designated as the contact(s) for each of these value-added suppliers.

- F. Submissions should be updated by the applicant whenever any information covered by item 1-5 changes, including notification to FDA if the applicant ceases shipment to the EU.

V. Guidance to Industry for Obtaining Completed EU Export Certificates

An establishment that has been placed on an EU Export Certificate List, or one that is acting solely as a dispatcher of product (as defined in II.A.2.b.) from establishments on any of the lists, and is now seeking EU Export Certificates should complete the appropriate EU Export Certificate(s) and submit it/them to the EU coordinator in the FDA Office covering the geographical location of the person issuing the certificate in accordance with this guidance. A list of EU coordinators and the area they cover is available at www.cfsan.fda.gov/~dms/eucert.html. If the establishment meets all the provisions in this guidance, the EU Export Certificate(s) should be signed and returned to the establishment.

A. General Guidance:

A completed EU Certificate should accompany each shipment of product to the EU and, in some cases, to non-EU countries. It is the establishment's responsibility to make

additional (legible) copies of EU Certificates required to meet their exporting needs, and to submit any additional information requested by the country.

1. The establishment should use the EU Health Certificate in the official language (or one of the official languages) of the country in which the product lands and clears customs, even if it is not the final destination EU country.

Copies of the EU Certificate in each of the official languages are available on FDA's Center for Food Safety and Applied Nutrition web site at:

www.cfsan.fda.gov/~dms/eucert.html. The website also provides additional information on how to handle certificate issues related to EU Accession Partnership Countries and EFTA Members.

2. In cases where a shipment is being trans-shipped to a non-EU country after landing in an EU country, two certificates may be required, the EU Certificate and a "Certificate of Export" for the non-EU country. See Compliance Policy Guide 110.100-Certification of Exports, (available at www.fda.gov/ora/compliance_ref/cpg/cpggenl/cpg110-100.html) for other types of export certificates available from FDA headquarters for shipments made to non-EU member countries. Further, information on these certificates can be obtained by calling FDA's Office of Seafood at 301- 436-1416.

3. The establishment should complete all entries on the EU Certificate in English. FDA will insert the reference number, sign as the "official signature," and apply the official seal.

4. Guidance for completing various sections of the EU Certificate is contained in section V.C.3 and 4.

B. Guidance on Whether a Single or Multiple Certificates Are Appropriate for a Shipment

1. A single EU Certificate is appropriate for a shipment of fishery products that underwent the same type of processing (e.g., all smoked, all canned, all fresh, etc.), is presented at the border in the same means of transportation as one shipment, and is being shipped to the same destination. As the following illustrates, variations on this scenario may exist:

a. A single EU Certificate is appropriate when the only difference is that the fishery products are shipped in several units, but by one means of transportation (for example, several container vans on a cargo vessel), provided the units are shipped together.

b. A single EU Certificate is appropriate when the only difference is that the fishery products come from more than one value-added processing establishment, provided the EU Certificate identifies the different value-added establishments.

c. A single EU Certificate is appropriate if a combination of a and/or b apply to a shipment.

2. A single EU certificate is generally not appropriate if:

a. The shipment is shipped to different destinations;

b. The shipment is conveyed in different means of transportation; or

c. The shipment is in multiple shipping containers that are entered at different times.

If an imported fishery product should not be eligible for EU certification because it was not subjected to value-added processing in the United States, as described in Section III of this document, the establishment may request a health certificate from the foreign source of the product. If an imported product has been warehoused in the U.S. for an extended period of time, there is a possibility that the EU will reject the entry in the absence of an EU certificate from the U.S. To preclude this from occurring, the shipper can ask for a specific lot certification from NOAA SIP.

The establishment shipping the product (i.e., the establishment listed as the dispatcher on the non-molluscan certificate or the consignor listed on the molluscan certificate), or its representative, should deliver the EU Certificate to the EU Monitor at the FDA office covering their geographical location for review and signature. The establishment, or its representative, should also arrange the return of the signed EU Certificate and prepay all postage, express package service, or courier fees. If the EU Certificate is to be returned by the U.S. Postal Service, the establishment should provide a self-addressed, stamped envelope. If the establishment wants the EU Certificate returned by express package service, it should provide a completed return air bill form under its account number.

C. Guidance to Industry for Completing the EU Non-Molluscan Health Certificate

The completed form (not including the sections to be completed by FDA, i.e., the reference number, the "official signature," and the official seal) should be delivered to the EU coordinator in the FDA Office covering the geographical location of the establishment seeking the certificate. The following provides guidance for completing various sections of the EU Certificate:

Reference Number – FDA will assign and enter a certificate number.

Country of Dispatch – Enter “United States of America.”

Competent Authority – Enter “United States Food and Drug Administration,” and the district name and address.

Description of fishery/aquaculture product – Enter an appropriate description of the product(s) being shipped, i.e., “Frozen, Dressed Head-off Coho Salmon.” Cross out either “fishery” or “aquaculture,” whichever does not apply.

Species (scientific name) – Enter the scientific name of the species being shipped, e.g., “Oncorhynchus kisutch” for Coho salmon. The FDA Seafood List is a listing of common and species fish names. It can be viewed on the FDA website at www.cfsan.fda.gov/~frf/seaintro.html.

Presentation of Product and Type of Treatment– Enter “frozen,” “canned,” “dried,” “smoked,” “preserved,” or other description as appropriate.

Code Number (where available) – Enter lot number if available. If none, leave blank.

Type of Packaging – Enter a description of the packaging, e.g., “Fiberboard Master Cartons with Plastic Liners.”

Number of Packages – Enter the exact number of packages in the shipment.

Net Weight – Enter the total net weight of the shipment.

Requisite Storage and Transport Temperature – Enter the manufacturer's recommendation for shipping temperature, e.g., "45° F or 6° C." General storage terms, such as "ambient," "refrigerated" "iced," or "frozen" are acceptable.

Name(s) and Official Approval/Registration number(s) of establishment(s), factory vessel(s), or Cold Store(s) Approved or Freezer Vessel(s) Registered by the Competent Authority to the EC – For Value-Added Processors: Enter the name of the last Value-Added Processor, city, state, and CFN or FEI number. If the processor is a vessel, enter the vessel name. If the shipment includes product from more than one establishment, the names and CFN or FEI numbers of all the establishments should be entered.

Example: Basalt Cove Seafood, Somewhere City, AK

CFN: 12645667

Fresh Fish Express, Inc., Astoria, OR

FEI: 9999999999

If the product has been value added by several different establishments, the EU Certificate should identify the last establishment that processed the product. For example, if salmon were eviscerated and frozen at establishment "A," portioned at

establishment "B," and breaded and placed in the final package at establishment "C," then the EU Certificate should identify establishment "C" as the processor.

For establishments acting solely as dispatchers: Enter the names, city, state, and CFN or FEI numbers of the last value added processor of the product being shipped.

For Other Than Value-Added Processors: Enter the name, city, state, and CFN or FEI numbers of the Other Than Value-Added Processor shipping the product. You should supply FDA with the names, cities, states, and CFN or FEI numbers of the Value-Added Processors of the product being shipped.

The Products are Dispatched: From – Enter the place the product left the country, e.g., Los Angeles, CA , USA.

The Products are Dispatched: To – Enter the port of debarkation, e.g., “Le Havre, France,” or if it is an air shipment, “Charles De Gaulle International Airport, Paris, France.”

By the Following Means of Transport – Enter the means of transport, e.g., "Air freight Northwest Airlines Flight 666." (Note: Flight information is optional but advisable, as there many need to be additional confirmation of this by some EU countries.)

Name and Address of Dispatcher – Enter the establishment name and address of the company or person that is making the shipment, e.g., "East West Seafood, P.O. Box 123 Nahcotta, WA, USA"

Name and Address of Consignee at Place of Destination – Enter the name and address of the final destination, e.g., "Pierre's Seafood, 508 Rue Lafayette, Paris, France."

Done at – Enter the place the certificate will be signed (not prepared), e.g., "Boston, MA, USA."

On – Enter the actual date of the voyage or flight.

Signature of Official Inspector – FDA official signs here in non-black ink.

Name in capitals, capacity and qualifications – FDA should enter in non-black ink the signatory's name, capacity, and qualifications, as appropriate in capitals.

Official Seal – FDA will apply the official seal (or stamp) to the circle as indicated.

D. Guidance to Industry for Completing EU Molluscan Shellfish Health Certificate

The completed form (not including the (reference) No. and the Signature of the Official Inspector, which are completed by FDA) should be delivered to the EU coordinator in the

FDA Office covering the geographical location of the establishment seeking the certificate. The following provides guidance for completing various sections of the EU Certificate:

No.— FDA will assign and enter a certificate number.

Dispatching country—Enter “United States of America.”

Competent authority—Enter “United States Food and Drug Administration,” and the district name and address.

Inspection service—Enter “United States Food and Drug Administration,” and the district name, and address.

Product wild/farmed—Check between the appropriate parentheses whether the product is wild or farmed.

Species—Enter the scientific name of the species being shipped, e.g., *Crassostrea gigas* for Pacific Oysters. The FDA Seafood List is a listing of common and species fish names. It can be viewed on the FDA website at www.cfsan.fda.gov/~frf/seaintro.html.

Nature of packaging—Describe the packaging material, e.g., “burlap bags with wire closures” or “wetlock boxes with individual molluscs in trays.”

Number of packages—Enter the exact number of packages in the shipment.

Net weight—Enter the total net weight for the shipment.

Necessary Storage and transport temperature—Enter the manufacturer's recommendation for shipping temperature that is needed to keep the product alive or in the case of processed products, safe for the consumer, e.g., "45° Fahrenheit or 6° Centigrade".

Reference number of analysis report—Enter the reference number of analytical reports required by the consignee, if known and available.

Approved production area—Enter the designation of the growing area provided by the shipper, e.g., "Willapa Bay, Washington, area 2A north." (Note: This applies to molluscan shellfish only. If the product is an echinoderm, tunicate, or marine gastropod, enter "not applicable.")

Name and Official Number of Approved Establishment—For Value-Added Processors covered under the National Shellfish Sanitation Program (live or shucked molluscan shellfish): Enter the name, city and state of the establishment that processed or handled the molluscan shellfish and the Interstate Shellfish Shippers List number. If the shipment

includes product from more than one establishment the names, cities and the Interstate Shellfish Shippers List numbers of all the establishments should be entered.

Examples: Scrimshaw Oyster Co.

South Bend, WA

WA 999

John's Mussel Farm Inc.

Bath, ME

ME 0000

Note : Shellfish that are further processed (e.g., cooked, breaded, or canned) are considered processed fishery products and should be certified using the Non-molluscan Shellfish certificate. For processed shellfish, whether you are shipping as a value added processor, dispatcher or Other than Value-Added Processor, follow instructions for the non-molluscan certificate under V. C. above.

For establishments acting solely as dispatchers: If the molluscan shellfish is live or shucked, enter the name, city and state, and Interstate Shellfish Shippers List number of the last value added processor under the National Shellfish Sanitation Program.

For Other Than Value-Added Processors: Enter the name city, state and CFN or FEI number of the Other Than Value Added Processor shipping the product. You should

supply FDA with the names, cities, states, and Interstate Shellfish Shipper list number of the value added processors of the product being shipped.

The products are to be sent from—Enter the place the product left the country, e.g., “Seattle, WA USA.”

The products are to be sent to— Enter the port of debarkation, e.g., “Le Havre, France,” or if it is an air shipment, “Charles De Gaulle International Airport, Paris, France.”

By the following means of transport—Enter the means of transport, e.g., “Air freight Northwest Airlines Flight 666.” (Note: Flight or voyage information is optional but advisable as there may need to be additional confirmation of this by some EU countries.)

Name and Address of Consignors—Enter the name and address of the company or person that is making the shipment, e.g., East-West Shellfish, P.O. Box 123 Nahcotta, WA U.S.A”

Name of Consignee and address of the place of destination—Enter the name and address of the consignee, e.g., “Pierre’s Seafood, 508 Rue Lafayette, Paris France”.

Done at—Enter the place the certificate will be signed (not prepared), i.e., “Boston, MA USA”

On-- Enter the actual date of the voyage or flight.

Signature of official inspector—FDA official signs here in non-black ink.

Name, title and designation of the signatory in capitals—FDA should enter in non-black ink the signatory's name, capacity, and qualifications, as appropriate, in capitals.

Official Seal—FDA should apply the official seal (or stamp) to the circle as indicated.

E. Additional Background Information

The following websites may be useful to firms that ship fish and fishery products to the EU, EU Accession Partnership Countries, and EFTA Members.

1. Sample EU Health Certificates

a. For non-molluscan fishery and aquaculture products:

<http://www.cfsan.fda.gov/~dms/eucert.html>

b. For molluscan fishery and aquaculture products:

<http://www.cfsan.fda.gov/~dms/eucert.html>

2. List of EU References

The following list of EU references can be found at

http://www.europa.eu.int/eur-lex/en/search/search_lif.html:

- a. Council Directive 91/493/EEC
- b. Council Directive 91/492/EEC
- c. Commission Decision 93/185/EEC
- d. Commission Decision 94/356/EC
- e. Council Decision 95/408/EC

3. FDA EU Coordinators

A list of EU coordinators can be found at:

<http://www.cfsan.fda.gov/~dms/eucert.html>

Interested persons may submit written comments on the draft guidance within 30 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Dockets Management Branch (HFA 305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of any comments are to be submitted, except that individuals may submit one copy. All comments are to be identified with the Docket Number 2004D-0509. Submit electronic comments on the draft guidance to www.fda.gov/dockets/ecomments. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 22, 2004