Sections included in this document

1. Purpose

Establish a uniform procedure, and assign responsibility, for processing requests for inclusion on a Food and Drug Administration (FDA) Fish and Fishery Products Export Health Certificate List (a List).

2. Scope

This procedure applies to all districts and all requests for inclusion on a List.

3. Responsibility

District Director:

a. Ensures a coordinator for the FDA Fish and Fishery Products Export Health Certificate List (the Lists) is assigned and the duties fulfilled.

b. Ensures that Compliance Branch notifies the coordinator about regulatory actions against seafood firm's on the list.

District Coordinator for the Lists:

a. Review all requests for inclusion on the Lists.

b. Determine eligibility for inclusion on the Lists.

c. Determine regulatory standing of establishment by working with district investigations and compliance branches.

d. Request an inspection of the establishment, when needed.

e. Send a response to the requestor.

f. Notify Center for Food Safety and Applied Nutrition (CFSAN) of any changes to a List.

4. Background

Certain countries have specific requirements for companies seeking to export food from the United States. Information on these requirements may be found on FDA's web site at: http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/default.htm. FDA maintains lists of establishments in the United States that seek to export fish and fishery products to certain countries, including the European Union and China. These Lists contain firms in good regulatory standing who wish to export their products to those countries requiring the US to maintain such lists. These lists are being used by other agencies to determine whether or not to certify fish and fishery products that are being exported to these countries, and by foreign governments, or institutions to develop official lists of approved establishments. Establishments may contact the district office with inquiries about the Lists and ask to be included on the Lists. The District Coordinator will handle these inquiries as described in the Procedures section below.

5. References

A. European Union (EU) Export Certificate List

http://www.accessdata.fda.gov/scripts/fdcc/?set=EUCert

6. Procedure

6.1 Reviewing Requests

Review the request to ensure that it contains the following information:

6.1.1 Name and Address - the official company name and physical address of the requesting establishment and any other DBAs or alias names the firm may use.

6.1.2 Establishment Food Establishment Identifier (FEI), Food Facility Registration (FFR) numbers and establishment type (e.g., M, R,).

6.1.3 What operations are performed by the establishment and a list of Products/Other Establishment(s) - a list of products, including the type of packaging, the establishment intends to export. If any of the products are not processed by the requesting establishment, the List of Products must identify the official company name and physical address of the establishments that process the product(s).

6.1.4 Contact Information - the name, mailing address, email, telephone number, and FAX number (if available) of the designated contact person for the requesting establishment.

6.1.5 Assurance that the firm or individual(s) representing the firm and submitting EU health certificate(s) to the FDA or other government certifying agencies realize that they are subject to the provisions of Title 18, Chapter 47, Section 1001 of the United States Code of Federal Regulations. Title 18 states that it is a criminal offense to willfully make false statements to a United States official in the performance of their duties, or alter or counterfeit official documents. The written request shall include a statement acknowledging this fact

6.2 Determine Eligibility

Determine whether the requesting establishment is eligible for inclusion on one of the Lists, using the following criteria:

6.2.1 If the establishment is a domestic processor (as defined in 21 CFR 123.3(l)), the establishment must have been inspected within the last two years by FDA, or a Federal, state, or local government regulatory agency under contract with FDA, and be in regulatory good standing with FDA.

AND,

6.2.2 If the establishment intends to export fish and fishery products that are not processed by that establishment (e.g., an Exporter Other Than Processor), the establishment that processes the product must be listed on the list of establishments to which the request pertains. The other processor must meet eligibility requirements as well.

6.3 Requesting an Inspection

If the requesting establishment is a domestic processor (as defined in 21 CFR 123.3(l)) and it has not been inspected within the last two years, request an inspection of the establishment. [Note: The inspection should be performed in accordance with the instructions in the seafood HACCP compliance program (CP 7303.842), except that the inspection should include a technical review of the HACCP plan(s) for all of the products listed in the request, when a plan is required.] Inspections will be scheduled in accordance with district resources and normally conducted within the next quarter.

6.4 Sending a Response

Send a written response (an email is acceptable) to the requesting establishment indicating whether the establishment meets, or does not meet, the criteria for inclusion on a List. The response should include an explanation of the process that follows or the reason why the establishment does not meet the criteria (*See* Appendix I and II, respectively).

6.5 Notifying CFSAN

6.5.1 Notify (email is acceptable) the Information Specialist (Data Management) in the Division of Seafood Safety in CFSAN's Office of Food Safety of any changes to a List. [Note: Establishments cannot be removed from a List without "due process of law," unless the establishment is no longer in business or no longer intends to export fish or fishery products to the country, or countries, to which the list pertains.] Changes to the list would include the eligibility of the establishment, names of responsible individuals, changes in products or processes, etc.

6.5.2 In addition, District Director should be copied on the email.

7. Glossary/ Definitions

District Coordinator for the Lists- also known as Food Registration Monitors

Regulatory good standing – An establishment should not be considered in "regulatory good standing" if:

a. The most recent establishment inspection is classified OAI.

OR

b. A regulatory action (advisory, administrative, or judicial action) is being considered against the establishment or any product(s) processed by the establishment.

8. Records

Establishment Inspection Reports

Official Establishment Inventory memoranda

Communications related to establishment eligibility including memoranda and email

Notification Letters to establishments

Archived copies of the Lists maintained by CFSAN

9. Supporting Documents

N/A

10. Document History

Version #	Status* (D,I, R, C)	Date	Author Name and Title	Approving Official Name and Title
1	I	11/28/2014	GLENN BASS DIRECTOR,OFFO	GLENN BASS, DIRECTOR,OFFO

* - D: Draft, I: Initial, R: Revision, C: Cancel

11. Change History

12. Attachments

12.1 Attachment A: Model Notification Letter- Acceptance

(**Appropriate Letterhead**)

FOR OFFICIAL USE ONLY

DATE

NAME
TITLE
COMPANY
STREET
CITY, STATE ZIP

Dear NAME:

This is in reply to your [letter/email/facsimile], dated [DATE], requesting that your establishment, [COMPANY, STREET, CITY, STATE ZIP], be included in the Food and Drug Administration (FDA) [Country or Institution] Fish and Fishery Products Export Certificate List (the List).

In order to be included on the List, your establishment should meet the following criteria:

- If you are a domestic processor (as defined in 21 CFR 123.3(l)), your establishment must have been inspected within the last two years by FDA, or a Federal, state, or local government regulatory agency under contract with FDA and be in regulatory good standing with FDA.

NOTE: If your establishment intends to export fish and fishery products that are not processed by your establishment, the establishment(s) that process(es) the product(s) you intend to export must be included on the List.

We are pleased to inform you that FDA has determined that your establishment meets the criteria for inclusion on the List.

Although your establishment has been, or will soon be, added to the FDA [Country or Institution] Fish and Fishery Products Export Certificate List, it may not appear on the [Country or Institution]'s Official List of approved establishments for some time. We highly recommend that you verify that your establishment is on the [Country or Institution]'s Official List of approved establishments prior to making a shipment.

If your establishment does not appear on the [Country or Institution]'s Official List of approved establishments, the shipment may be rejected.

For additional information about the FDA [Country or Institution] Fish and Fishery Products Export Certificate List, please contact [NAME], the Coordinator for the FDA's [NAME] District Office, at [PHONE NUMBER].

Sincerely,

[NAME, TITLE]
[NAME] District Office

12.2 Attachment B: Model Notification Letter- Denial

(**Appropriate Letterhead**)

FOR OFFICIAL USE ONLY

DATE

NAME
TITLE
COMPANY
STREET
CITY, STATE ZIP

Dear NAME:

This is in reply to your [letter/email/facsimile], dated [DATE], requesting that your establishment, [COMPANY, STREET, CITY, STATE ZIP], be included in the Food and Drug Administration (FDA) [Country or Institution] Fish and Fishery Products Export Certificate List (the List).

In order to be included on the List, your establishment should meet the following criteria:

- If you are a domestic processor [as defined in 21 CFR 123.3(l)], your establishment must have been inspected within the last two years by FDA, or a Federal, state or local government regulatory agency under contract with FDA, and be in regulatory good standing with FDA.

NOTE: If your establishment intends to export fish and fishery products that are not processed by your establishment, the establishment(s) that process(es) the product(s) you intend to export must be included on the List.

We regret to inform you that FDA has determined that your establishment does not meet the criteria for inclusion on the FDA [Country or Institution] Fish and Fishery Products Export Certification List.

Based on our investigation, [your establishment is not in regulatory good standing with FDA. [EXPLAIN]] [the following establishment(s), that process(es) product(s) that you intend to export, [is][are] not listed on the FDA [Country or Institution]Fish and Fishery Products Export Certificate List: [LIST ESTABLISHMENT(S)]].

For additional information about the FDA [Country or Institution] Fish and Fishery Products Export Certificate List, please contact [NAME], the Coordinator for the FDA's [NAME] District Office, at [PHONE NUMBER].

Sincerely,

[NAME, TITLE]
[NAME District Office]