



SEAFOOD INSPECTION PROGRAM  
U.S. DEPARTMENT OF COMMERCE  
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April 22, 2009

Memorandum For: All USDC SIP Staff

From: Timothy Hansen 

Subject: SIP Procedures for EU Export Certification for Fishery Products

### SUMMARY

On January 15, 2009, the U.S. Food and Drug Administration (FDA) published a Federal Register Notice announcing that after February 17, 2009, FDA will no longer issue health certificates required by the European Union (EU) for export of fish or fishery products to the EU or the European Free Trade Association (EFTA). 74 FR 2600 (January 15, 2009). By subsequent notice in the Federal Register on February 11, 2009, FDA announced a 120-day delay in the effective date of the January 15, 2009 notice. FDA now intends to cease issuing EU Health Certificates on June 17, 2009. The U. S. Department of Commerce Seafood Inspection Program (SIP) will continue to issue these certificates upon request on a fee-for-service basis. Due to the large volume of demand for these certificates and the need for expedient service, SIP, through this memorandum, is announcing a change from current inspection practices, methods of certificate creation, including fee structure, for providing Export Health Certificates for the EU and EFTA, effective June 17, 2009.

### BACKGROUND

The Seafood Inspection Program of the National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce, operating under authority of the Agricultural Marketing Act and the Fish and Wildlife Act, is responsible for the development and advancement of commercial grade standards for fishery products and better health and sanitation standards in the industry and for furnishing inspection, evaluation, analytical, grading, and certification services to interested parties. Its major purpose is to encourage and assist the industry in improving the quality, wholesomeness, safety, proper labeling, and marketability of its products.

In 1993, the EU began requiring health certificates for fish and fishery products that entered the EU. Both the FDA and SIP were recognized by EU as competent U.S. Government authorities and acceptable sources for EU health certificates. The EU also required that shippers to EU be on a list of firms that demonstrated compliance with the U.S. food safety laws and regulations. Since 1993, FDA has issued health certificates for seafood processing firms appearing on the EU Export Certificate List free of charge. By contrast, SIP examined the product and labeling, confirmed all the shipping information and issued health certificates on a fee for service basis. FDA initially issued approximately 3000 certificates per year, but as European demand for U.S. fishery products increased over the years, the number of certificates issued annually by FDA has grown ten-fold to over 30,000. FDA currently issues about 80% of all EU health certificates.

The increased volume of certificates issued and concomitant decrease in agency resources has made FDA reassess its involvement in the issuance of EU health certificates.

### **Procedures for Receiving EU Certificates from SIP**

Effective June 17, 2009 SIP interim policy is as follows: SIP, upon request, will issue EU Health Certificates to SIP participants and rely on inspection results or an approved in process control system (e.g. HACCP QMP ) to issue the certificate. Seafood processors and other entities that are not SIP program participants may receive EU Health Certificates from SIP based on a periodic verification (frequency to be determined) of the information provided, compliance of the product labeling to EU requirements and the condition of the product.

All applicants for EU Health Certificates must be in regulatory good standing with the FDA and must be on the FDA's EU Export Certificate List. In addition, prior to the issuance of EU Health Certificates, all applicants will be required to sign a yearly agreement including, but not limited to, the following provisions:

- A statement that the applicant has read the terms and conditions of the agreement and understands that making false statements in connection with issuance of an EU Health Certificate would be a violation of 7 U.S.C.1622(h), punishable by a fine of not more than \$1,000 or imprisonment for not more than one year, or both.
- The applicant agrees to keep information about the origin of foreign raw material to ensure that it was produced in a firm and country that are approved by the EC, make this information available to SIP auditors upon request, and provide this information for each certificate request when foreign product is to be certified by SIP.
- Agree to allow SIP auditors or EC Food and Veterinary auditors entrance to the processing facility at reasonable times when periodic audits occur.

### **Fee Structure**

- ❖ The cost of individual shipments will remain constant. There will be no additional cost to the customer for random product inspections. The costs associated with random product inspection will be covered within the rates for inspection service provided by the SIP.

#### *Program Participants:*

For USDC Contract Inspection participants, certificates will be provided at a charge of 15 minutes to the firms contract, at no extra cost above the existing contract hours assuming that the work demands can be adequately addressed in the agreed upon contract hours. If additional time is needed for EU Health Certificate completion, it will be charged at the appropriate contract rate. EU Health Certificates for facilities operating under the HACCP QMP will be charged \$55 for each certificate. Participants may choose to contract specifically for EU Health Certificate services if there is a significant volume.

#### *Non-Program Participants:*

Seafood processors and other entities that are not SIP program participants will be charged at 30 minutes of the lot inspection rate or \$74 for each EU Health Certificate request.

## **INSTRUCTIONS FOR THE COMPLETION OF THE EU EXPORT CERTIFICATES**

- Requestors for EU Exports should be referred to the Seafood Inspection website. The EU Exports tab: will instruct requestors on the correct procedures for exporting fishery products, will have instructions for completing export requests and will have any updates and changes to the requirements for exports.
- Completion of the certificates should follow the current “Instructions for Completing EU Export Certificates for Fish and Fishery Products and Molluscan Shellfish Certificates.

### **❖ SPECIAL REQUIREMENTS TO BE NOTED**

- All certificates will be dated with Month and Year (Day to be filled in by customer)
- There is a maximum of 5 products per certificate accepted.
- Distribution of “Batch” certificates should follow these procedures:
  - All certificates will be prepaid or billed on DRC on date of issuance. (There is no limit to the number of certificates to be issued; there is NO refund for unused certificates.)
  - All certificates will be accounted for each month by the supervisors or designees. All batch certificates will be returned to the issuing office within 45 days of issuance for SIP accounting and review.
  - “Batch” certificates may be issued with the following text boxes empty (to be filled in by customer at time of shipment): Date (day number after month and year), Case Counts and Weights, Container Number and Seal Number.
  - Customers are responsible for the completion of all requested empty text boxes before certificate is considered valid.
  - All “Batch” certificates will be stamped with the Accepted per Specifications stamp with the Month and Year of certificate issuance.
  - All certificates will be printed on watermarked paper and signed on the date of issuance by an SIP inspector.
  - All foreign source products will require an EU certificate from the “origin country” referenced on the US Export Certificates under origin of products.