

PROPOSED
“CUSTODIAL PROGRAM”
FOR
FDA EU EXPORT CERTIFICATE GUIDANCE AND PROTOCOL FOR
FISH AND FISHERY PRODUCTS
by
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Exporters of live and fresh fish and fishery products must be able to obtain EU Export Certificates in advance of shipments in order to compete in the global marketplace. The ability to respond to constant changes in price, product availability and order demands by EU customers, is critical to the success of the U.S. fish export industry.

The New England District Office of the FDA has successfully implemented an EU certificate program that prescribes a specific process for exporters on the FDA’s official EU export list to obtain certificates in advance of shipments. This successful program has spurred an ever increasing export industry, particularly in live lobsters, valued in the hundreds of millions of dollars. The lifeblood of the industry is dependent upon the continuance of this type of program, particularly with the expansion of the EU and the resultant increased demand for certificates.

The recently issued “Guidance and Protocol for Industry and Food and Drug Administration Staff for Certification of Fish and Fishery Products for Export to the European Union and European Free Trade Association” (November 22, 2004) does not specifically authorize nor prohibit advanced issuance of EU certificates. To ensure the survival of the export industry the Guidance must incorporate a program that provides for advanced issuance. If such a program is not incorporated into the Guidance, New England exporters of live lobster and fresh fish will not be able to compete in the EU and Canada will be the beneficiary of these failed businesses. The “Custodial Program” described below provides a recipe for the type of program FDA should adopt.

Proposed
EU Export Certificates
Voluntary Custodial Program
For
Low Risk Fish and Fishery Products

- Establishments wishing to participate in the voluntary Custodial Program must agree to certain safeguards and requirements to ensure accountability above and beyond the existing eligibility requirements for receiving EU export certificates.
- The program would be limited to shipments of low health and safety risk fish and fishery products (such as live lobsters, fresh scallop meat, monk tails, dogfish, whiting) as determined by FDA.
- Establishments or shippers could apply for and receive up to 75 blank certificates in advance. These certificates would be assigned to a specific establishment using its unique CFN number and could only be used by (or for) that facility. FDA would prescribe the days and/or times when requests for multiple certificates under this program should be submitted and provide guidance on processing of requests.
- Establishments or shippers would be expected to use all of their certificates prior to receiving new ones which would eliminate the existing problem of unused certificates being returned to FDA. Currently returned certificates create a substantial amount of unnecessary work for the FDA.
- Establishments and shippers must “hold” certificates in custody in a locked and secure cabinet and must make them available to FDA/NMFS for verification upon request.
- Establishments and shippers must maintain a separate and comprehensive log of certificate use to enable FDA/NMFS to verify which certificates have been used (and for which specific shipment) and which certificates are being held in custody.
- Establishments and shippers must immediately notify FDA/NMFS when assigning a certificate to a specific shipment by faxing (e-mail or other appropriate method) a copy of the completed certificate before the shipment leaves the facility. This will provide FDA/NMFS with real time information on the specific shipment to which a certificate is assigned. It will also provide FDA/NMFS with the ability to notify a participating establishment or shipper that it wants to meet and inspect the shipment (for good cause) prior to it being transferred to the airlines.
- FDA would, to the extent possible, increase inspections of participating establishments to at least twice a year.
- If the proposed referral program is enacted, participating establishments and shippers would pay a fee (\$15-\$20 per certificate) to NMFS to help offset the cost of issuing a certificate. For some companies this will create a new cost of more than \$50,000 annually.
- Failure of an establishment or shipper to adhere to the rules of the voluntary custodial program may disqualify it from participating in the program for at least one year.

For FDA/NMFS purposes, a certificate issued under this voluntary program would not be considered “valid” until the assignment and usage of the certificate is reported to FDA/NMFS. For purposes of the Custodial Program, fish and fishery products destined for export that are accompanied by an invalid certificate will be considered adulterated under the Federal Food, Drug and Cosmetic Act. If a participating establishment or shipper uses a certificate without first recording and reporting it to FDA/NMFS, it would forfeit the shipment and the ability to participate in the program.

The current EU export certificate program in the FDA’s New England District Office that provides EU export certificates in advance of shipment evolved out of the realities and the necessities of the seafood export business. The program outlined above is designed to meet those same industry needs, while providing the Federal agencies with an even greater ability to monitor and control EU export certificate usage. The voluntary Custodial Program allows export companies to hold export certificates for the government until such time as those certificates are activated and validated through the reporting system. And, the Program imposes severe penalties (forfeiture of shipment and expulsion from program) on participating establishments and shippers that do not follow the rules. We ask the FDA to incorporate this Program in its Guidance and Protocol before moving forward with the proposed referral program otherwise the industry will be forced to oppose the referral project.