



East Coast Seafood

Dockets Management Branch (HFA-305)
Attn: Docket No. 2004D-0510
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Comments on Draft Guidance entitled “ Proposed Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Live and Perishable Fish and Fishery Products for Export to the European Union and the European Free Trade Association”.

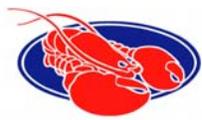
Dear Sir or Madam:

Since 1981 East Coast Seafood, Inc. has grown to become the largest North American exporter of live lobsters (*Homarus americanus*), procuring and distributing over 20 million pounds annually. Our global sales strength, supplying live lobster and fresh and frozen seafood products from North American, has made us a vital part of the New England economy. Recently the company has expanded to a family of companies managed by American Holdco Inc. (AHI). As a member company of AHI, East Coast Seafood Inc. (ECSI) maintains a vast presence throughout the Northeast. In addition, our Worldwide Perishables (WWP) freight forwarding company manages domestic and international logistics and transportation not only for the AHI family of companies but also seafood exporters in the region. For over 10 years, WWP has secured agreements with all the major airlines carrying freight from Northeast to Europe and other destinations across the globe.

Due to the imperative global nature of the industry and our company, Export Health Certificates are an integral part of our operation. To ensure that our customers receive a consistent high level of service and product quality, we have spent the last 24 years securing relationships with fisherman and seafood suppliers through the northeast region of the US. In addition, ECSI has built the customer base abroad necessary for the continuous livelihood of the live lobster industry. It is important to note the live lobster industry spans the northeast Atlantic coast of North America including the Canadian Maritimes where it is a key industry for the region. The vast scale of the industry positions US companies in direct competition with Canadian companies. Therefore, the pending decision to move the FDA Health Certificate program to “fee for service” National Marine Fishery Service (NMFS) EU Certificate program will significantly hinder our ability to compete with Canadian companies, which receive Health Certificates from their government at no charge. This will also have much broader effect on all businesses directly or indirectly associated with the seafood industry.

With over 20 years of experience exporting live lobsters, we are familiar with services offered by the NMFS and the Department of Commerce Seafood Inspection Program (DOC SIP). Prior to

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the FDA program we operated under the voluntary fee-for-service program managed by authorities of the Agricultural Marketing Act of 1946 (USC 1621-27).

FDA's seafood safety HACCP program varies greatly from the services offered by the DOC SIP. DOC SIP program is designed specifically to emphasize standards of quality and to inspect, certify and identify class, grade and quantities of agricultural products. These services surpass the existing FDA's "safety" program that has proven effective and efficient for many years. While the services offered by the DOC SIP program are important to seafood industry, they are quite extensive and not necessary for exporters of live lobsters. Simply, the nature of live lobster places it as a "low risk" product and is therefore less likely to cause food borne illnesses. Additionally, DOC SIP program is offered at a price. Having operated under the DOC SIP from 1996 - 2000, ECSI incurred \$ 130,000 - \$ 150,000 in additional costs annually solely for the issuance of Health Certificates for the European Union. This does not take into consideration the cost of the issuance of Health Certificates to countries outside the EU in which we do business regularly. Furthermore, it is important to note that the fees have increased significantly over the past four years.

We understand that the main goal of the FDA's Guidance is to expedite the exportation of live and perishable fish and fishery products, however we do not believe that the Proposed Referral Program will help the FDA to reach this goal. Instead, it will impose hundreds of thousands of dollars of new costs onto industry already operating on slim profit margins and will put US companies at a significant disadvantage competing with Canadian companies. Indirectly it will also have a large impact on businesses associated with the export of seafood from the US such as airlines, fisherman, transportation companies and other seafood exporters.

We urge the FDA not to go forward with the Proposed Referral Program and to seek alternate ways of resolving the diversion of resources to lower priority, discretionary activities, which diminishes the agency's ability to carry out public health activities and regulatory oversight that are intended to protect the U.S. consuming public. I am available for further questions or comments that may assist in the creation of a solution that will not hinder the industry or economy of the Northeast and will resolve the pending resource issues facing the FDA.

Sincerely,

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