SUMMARY POSITION ON THE PROPOSED RULE (Docket #2004D-0509 & 0510)

It has been quite clear for some time that FDA feels unduly burdened by its role in issuing Health Certificates to facilitate the export of fishery products to the EU. Though the need for such certification is clear, the process itself is onerous for all involved. Assumption by the FDA of its current role in 1993, providing an alternative to the NMFS lot inspection, fee for service, certification program, represented a major improvement in circumstances for the industry. Returning to a lot inspection based, fee for service program, administered by NMFS, would be truly catastrophic for the industry.

If the intention of the proposed rule is the transfer of current operating procedures from FDA to NMFS personnel, it would not constitute a problem. Current operating procedures involve the shipper submitting, in advance, blank certificates, identifying: product(s) in terms of physical state, packaging used, and temperature required during storage and transport; origin of product(s); destination of shipment; and, the month during which the certificate is proposed to be used. FDA routinely has executed such requested certificates, in advance, requiring that copies of used certificates be submitted with documentation indicating their proper use (an Air Waybill indicating that the specified number of pieces and weight was shipped to the specified importer), and unused certificates be returned. While it is certainly possible to improve upon these procedures, increasing flexibility and reducing paperwork, without compromising adherence to EU standards, the current procedures have constituted an economic and logistical environment in which the industry can function.

If the intention of the proposed rule is to return the industry to on-site, lot inspection, fee for service procedures, which has characterized the NMFS option in the past, it would change that environment, making this export industry less competitive and less accessible to the logistics realities of moving these products from the source to the market.

BACKGROUND

Legislators and regulators must be certain that they understand how the U.S. Fisheries export industry functions, before they change the circumstances under which it currently operates. While there may still be some EU fresh and live

seafood buyers who tender orders even 24 hours in advance of shipment, the majority of such customers are either placing these orders or adjusting the quantities and items on the same day as the consignment is scheduled to be exported (the EU is 6 hours ahead of New England, so orders are often placed by 05:00 U.S. Eastern Time for consignments they expect to receive the next day). The "cut-off" time for delivery of finished goods to the various airports which are transporting these consignments to the EU is typically 13:00, and the transport time to the airport from the hundreds of "establishments" can be as much as 2-6 hours. This results in a very short time available to "establishments" to pack the consignment and transfer them into the logistics pipeline.

Practically speaking, if on-site inspection by NMFS were required, for all shipments, before issuance of an Health Certificate to travel with the consignment, it would be necessary to station an Inspector at each of the establishments in order to be available, in the event that establishment receives an order for export on any given day. The cost of such a program would be monumental. If the direct cost of each inspector were charged to each establishment to which that inspector was "available," it would reduce the export trade to a few large exporters, putting many of the smaller "establishments" out of business.

If an attempt was made to "share" NMFS personnel (scheduled inspections, where one inspector would travel from one "establishment" to another in close proximity, to try and service more than one consignment within the daily window), the logistics system of trucks to airports would be seriously jeopardized. Any failure to get consignments from the "establishment" to the airport on time would result in lost sales, lost investments in labor and packaging, and a shameful waste of valuable marine resources.

## CONCLUSION

The industry doesn't much care which bureaucracy issues the certificates. It is the procedure under which they are issued which is important. If NMFS were to issue the certificates tomorrow, under the same circumstances as does FDA today, it should not constitute a major problem. This industry employs thousands of people and contributes positively to our balance of payments. Conditions under which it must operate should be made easier, not more difficult.