

## SEAFOOD EXPORTERS TO THE EUROPEAN UNION (EU)

The EU is requiring that all seafood products produced for export to the EU on or after January 1, 1996, must be processed using HACCP controls.

This applies to product made on January 1, 1996 and thereafter.

The Food and Drug Administration will send a letter soon to notify you of any change in procedures to be included on FDA's EU List of Accepted Establishments or to obtain EU Health Certificates.

MEANWHILE, YOU ARE ADVISED TO IMPLEMENT HACCP CONTROLS IF YOU OR YOUR CUSTOMER PLAN TO SHIP TO THE EU PRODUCT MANUFACTURED ON OR AFTER JANUARY 1, 1996.

Attached is more information about the EU export requirements.

Questions regarding EU certificates may be directed to the FDA Office of Seafood (202) 418-3160 or your local FDA District Office. Also, questions can be directed to the National Marine Fisheries Service in Silver Spring, Maryland (301) 713-2355.

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(ON FDA LETTERHEAD) August 16, 1995

### I N D U S T R Y A D V I S O R Y EUROPEAN UNION(EU) REQUIREMENTS FOR UNITED STATES(US) FISH AND FISHERY PRODUCT EXPORTS

This is an important notice for all US firms that ship, or plan to ship, fish or fishery products to the EU.

#### H A C C P

The EU will require that by January 1, 1996, all seafood companies in EU member states and those making product to ship to the EU have in place an effective food processing control program. This program must be based on the principles of HACCP (Hazard Analysis Critical Control Point).\*

This means that processing plants shipping to the EU will need to institute preventive controls, such as HACCP as soon as possible.

Consequently, firms that ship to the EU are being advised to implement HACCP before HACCP is required in the US. The January 1, 1996 effective date of the EU requirement is before the anticipated effective date of FDA's Seafood HACCP regulation.

FDA advises that any US fish or fishery product processor exporting to the EU consider using two FDA publications to prepare to meet the EU requirements. They are: the FDA HACCP proposal of January 28, 1994, "Proposed Rule to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products," and the February 16, 1994, draft Fish and Fishery Products Hazards and Controls Guide. The proposal of January 28 includes an explanation of the internationally recognized principles of HACCP and how they can be applied by a processor. While the final version of the document may be revised from the proposal, the principles of HACCP remain the same.

No change is anticipated in the health certificate. The certificates and list of accepted firms will continue to be required by the EU until July, 1997.

\* The EU term for HACCP in their documents is "own checks," as in, "...persons responsible must carry out their own checks..."

### FDA'S ROLE

FDA will continue the program to list acceptable firms and sign certificates for exports to the EU. Effective January 1, 1996, the product must be processed under a HACCP system. US competent authority assurance by FDA of the acceptability of US fish and fishery product exports will continue to be used to minimize resistance to US exports in the EU.

The FDA list of US processors and signature on certificates will relate to the use of HACCP by the industry. Companies seeking EU health certification for shipment to the EU need to have a HACCP program in place by January 1, 1996.

FDA recognizes that the changes in EU requirements\*\* described above may require the Agency to revise the procedures for obtaining a certificate after January 1, 1996. FDA is refining the implementation procedures for any necessary changes for the Agency and industry. A second advisory will issue once this procedure is complete.

### FRAMEWORK OR GLOBAL AGREEMENT

The "Global Agreement" will be an agreement between the EU and the US. The goal of the "Global" or "Framework" agreement is to establish procedures for equivalency agreements on specific products such as seafood. Equivalent controls have the same public health goals (or animal health goals), although the methods for achieving the goals may differ. The US delegates intend to reach such an agreement for seafood, recognizing that the US system of controls provides the same or a higher level of protection as the EU system of controls. These discussions are on-going.

### THIRD COUNTRY VISITS

US firms that export to the EU may be the subject of audits by EU inspectors to check that our control systems are equivalent starting in 1996. The US Congress passed a bill and the President signed it into law stating the United States has accepted the World Trade Organization (WTO) agreement. Under

\*\* FDA believes this advisory, plus the proposed rule and "Hazard Guide" mentioned above, (and contained on the enclosed disk in WordPerfect format) provide the HACCP information manufacturers need to design an appropriate control program. However, for those who want the applicable EU documents, "COMMISSION DECISION of 20 May 1994" and "COUNCIL DIRECTIVE of 22 July 1991," copies are available from the FDA Office of Seafood. (See telephone number on page 1.)

That agreement, members of WTO, who are importer countries can make visits to verify the controls implemented by exporting countries. Therefore, under the WTO agreement, the US shall facilitate such visits. FDA may accompany EU inspectors during these audits to observe their activities.

The EU has been conducting audits of third country firms and regulatory control systems. The audits by EU inspectors have focused on major EU requirements. For US processors this means having a HACCP plan in operation, sanitation and GMP's (good manufacturing practices).

In a meeting between the US and EU officials in Brussels, Belgium on June 14, 1995, EU officials favorably received FDA's invitation to make several presentations in October 1995 directly to the US

fish and fishery products industry. The US locations, dates, and times will be announced when the arrangements are worked out and confirmed. The presentations would review and clarify EU directive requirements and interpretations by EU officials. This will also provide an opportunity for face-to-face dialogue between EU officials and US industry representatives.

#### NMFS' ROLE

NMFS is a recognized authority to issue EU health certificates for firms on the list of US processors. At a meeting between EU and US representatives in June 1995, the EU stated that it considers the NMFS "voluntary HACCP-based program" as providing equivalent assurances to the EU requirements. NMFS inspectors may accompany EU inspectors on visits to plants under that program.

#### MOVEMENT DOCUMENTS

In addition to the human health certificates required by the EU as a condition of entry into the EU market, animal movement documents (certificates) pertaining to animal health are also required by the EU for certain animals and products.

These movement documents (certificates) may be obtained from the US Fish and Wildlife Service (FWS) of the US Department of the Interior, or the National Marine Fisheries Service (NMFS) of the US Department of Commerce. The Animal and Plant Health Inspection Service (APHIS) of the US Department of Agriculture issues certificates for live animals or uneviscerated fish including farm-grown fish such as salmonids, ornamentals and fresh water aquaculture fish. FDA does not issue such documents. For further information, contact Otis Miller, DVM, APHIS, USDA at (301) 734-7679.



[Go to the International Meat & Poultry HACCP Alliance Home Page](http://www.haccpalliance.org/alliance/seafood.html)