A Message from the Editors:

Welcome to another issue of our newsletter! We hope these periodic updates are helpful in keeping you apprised of seafood safety issues. If this is your first issue, back issues can be found on the internet at <www.seagrant.uconn.edu/seafood.html>. The focus of this issue is once again new developments in biosecurity.

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Biosecurity is Here

We've been sending you updates on the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002". The food and drug provisions of the Act represents an expansion of FDA's enforcement authorities. The part of the Act that affects the seafood industry is Title III, Subtitle A, Protection of the Food Supply.

TWO of the four drafted regulations are now Interim Final Rules that are scheduled to go into effect on DECEMBER 12, 2003.

1. Registering Food Facilities

The FDA is requiring all domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. to register with the FDA. A foreign facility must designate a U.S. agent that lives or maintains a place of business in the U.S. and be physically present in the U.S.

Domestic facilities will be required to register whether or not food from the facility enters interstate commerce. There is no registration fee and each facility will be assigned its own registration number. Exemptions include, for example, retail operations, restaurants, and fishing vessels not engaged in processing, as defined in the HACCP regulation.

How do I Register my Facility?

The U.S. Food and Drug Administration (FDA) FDA strongly encourages registration on-line at www.fda.gov/furls. The website is accessible now. If a facility does not have reasonable access to the internet, a paper copy of the form may be obtained by calling 1-800-216-7331.

The registration form is about 5 pages in length, but is not difficult to fill out. FDA estimates it will take about 1 hour to register on-line. We recommend you download the forms, look them over and fill them out for reference. That way, on-line registering will take less time.
If you need help registering, call the on-line registration help desk (1-800-216-7331) or you can FAX (301-210-0247) or email questions to furls@fda.gov.

Registration is required only once, but should be updated within 60 days if the business location or contact information changes. Once registered, you will receive a registration number that indicates you have complied with the rule. Neither the list of registered facilities, any registration documents, or any information derived from the list or documents that reveals the identity or location of the facility is subject to disclosure under the Freedom of Information Act.

**What happens if a facility does not register as required?**

Failure to register initially and provide any updates in accordance with the regulation is prohibited under the Federal Food, Drug, and Cosmetic Act.

2. **Prior Notice of Imported Food Shipments**

   Beginning **December 12, 2003**, the FDA is requiring prior notice of imported food shipments. The regulation requires that information that had been required from importers or brokers when the foods arrive in the U.S., are now required prior to the foods' arrival. The FDA will review, evaluate, and assess the information and determine whether to inspect the shipment. Prior notice can be submitted through the Bureau of Customs and Border Protection (CBC) Automated Broker Interface of the Automated Commercial System (ABI/ACS) or FDA's Prior Notice (PN) System Interface.

**What are the key elements of this rule?**

Prior notice must be received and confirmed electronically by FDA no more than five days before arrival, and as specified by the mode of transportation, no fewer than:

- 2 hours before arrival by land by road
- 4 hours before arrival by air or by land by rail
- 8 hours before arrival by water

We encourage you to learn as much as possible about these new rules. For more information, including copies of fact sheets and both these interim final rules, please visit the following website:

http://www.cfsan.fda.gov/~dms/fsterr.html