

# SEAFOOD SAFETY SAVVY: A HACCP UPDATE

from the Cooperative Extension & Sea Grant Programs, University of Rhode Island,  
and the Connecticut Sea Grant College Program, University of Connecticut

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## ***A Message from the Editors:***

By now, you have taken one or more of the FDA-mandated seafood processing HACCP training courses and have implemented your HACCP plan and sanitation standard operating procedures. We hope things are going smoothly and that the implementation process has not been too difficult. Since your course was held, some of the information regarding food safety hazards, sanitation, and the interpretation of the regulation may have been changed or clarified. As we noted during your course, HACCP is an evolving process and we encourage you to keep current of any changes. To help you stay updated, we will periodically send you this newsletter detailing important changes.

*Lori F. Pivarnik*

Cooperative Extension and Sea Grant Programs  
University of Rhode Island  
401-874-2972

*Nancy Balcom*

Connecticut Sea Grant College Program  
University of Connecticut  
860-405-9127

## ***FDA Hazard Guide and New Curriculum***



The second version of the FDA *Fish and Fisheries Products Hazards and Controls Guide* is available. This contains the most current information on potential seafood hazards. If you do not have a copy (red cover), you may purchase one for \$15.00 directly from: North Carolina Sea Grant, NC State University, Box 8605, Raleigh NC 27695. There are some significant changes in the guide of which you should be aware. If you want to be on "the same page" as the FDA inspector, you should obtain a copy if you do not already have one. Revisions will continue and a third edition is expected to be released next year.

We are now using the third edition of the training curriculum. While many chapters are the same, several new generic HACCP models are included that may be very helpful i.e., parasites, histamine and wholesale/distribution. If you wish to purchase this manual you can do so at the same address for North Carolina Sea Grant cited above for \$20.00. An alternative is to go on-line to the Seafood HACCP Alliance Website: <http://www-seafood.ucdavis.edu/>, or the FDA website at <http://vm.cfsan.fda.gov/>. As a last resort, you can contact one of us for a photocopy of the generic plan(s).



## ***Additional Training Course Offerings***

### **ISSC HACCP Training Course**

For shellfish shippers and reshippers, the ISSC and FDA have developed a 11/2-day course based on the Seafood HACCP Alliance training course and the most recent NSSP *Guide for the Control of Molluscan Shellfish*. This course focuses on the hazards associated with shellfish and provides detailed HACCP plan and sanitation monitoring recommendations. If you do not already have a copy of the NSSP model ordinance, we urge you to obtain one by contacting the FDA regional offices at either: Stoneham District Office, State Programs Branch, One Montevale Ave., Stoneham MA 02180 or New York Regional Office, 850 Third Ave., Brooklyn NY 11232-1593. If you would like to be notified of the next course, contact Nancy Balcom.

### **Encore HACCP Training**

The FDA has developed a one-day "refresher" course dealing with the most prevalent problems that processors are encountering in trying to successfully implement HACCP and SSOP. The cost is \$20.00. For those

who have received untitled or warning letters, the FDA is recommending voluntary attendance and you either have or will receive notification. However, anyone who has taken the three-day course and wants additional help is welcome.

The following times/dates have been scheduled:

**MA:** Contact Linda Sperandio, 617-983-6767. Thursday, May 20, UMass Dartmouth, North Dartmouth; Thursday, May 27, MA Department of Health, Jamaica Plain; Thursday, June 10, MA Division of Law Enforcement, Gloucester.

**ME:** Contact Rebecca Maxim, 207-622-8268 ext. 13. Thursday, May 13, U. Maine, Cooperative Extension, Hancock County, Ellsworth; Wednesday, May 19, U. of Southern Maine, Portland.

**RI:** Contact Lori Pivarnik, 401-874-2972. Monday, May 17, Powers Administration Building, Providence.

**CT:** Contact Nancy Balcom, 860-405-9127. Wednesday, May 12, CT Dept. of Environmental Protection, Old Lyme.

### **SSOP Training Course**

This new course, written by the Seafood HACCP Alliance, will focus on developing and implementing SSOP's. The issues associated with sanitation were not well covered in the original HACCP training course and therefore, this area has proven to be one of the more difficult aspects of the regulation for compliance. This one-day course should be available in the Fall, 1999. We will notify you.

### **HACCP Regulation Questions and Answers**



A large number of questions regarding the interpretation of the regulation have been raised by the seafood industry, regulators, consumers, and others. In response, the FDA developed a booklet entitled *HACCP Regulation for Fish and Fishery Products: Questions and Answers*, which can be found on-line: <http://vm.cfsan.fda.gov/~dms/qa2haccp.html>. Periodically updated, it provides answers to some of the more common questions raised.

The booklet covers new interpretations and guidelines for GMP, hazard analysis and HACCP requirements, SSOP, imported products, and raw molluscan shellfish. The most recent issue (#3) covers changes that are particularly noteworthy, such as PSP in lobsters, cooked, ready-to-eat products, and histamine control and sampling. **This document reiterates that sanitation monitoring IS NOT a substitute for HACCP controls for time/temperature abuse.** If you cannot obtain a free copy by downloading it from the Internet website listed above, you may obtain a copy from one of us at a cost of \$4.50, which covers photocopying and postage. Please call to find out how to order this booklet.

### **Seafood HACCP Implementation Survey Evaluation Report**



Last summer, some of you received a survey questionnaire coordinated by Ken Gall of NY Sea Grant. The survey was intended to document the time, effort and resources that industry has devoted to implementing HACCP and identify any problems that occurred during this process. The results have been compiled and a summary of the more significant information will be provided in the next issue of the newsletter.

### **Recall**

As many of you know, recall of products considered a health hazard is voluntary. However, a FDA request for a "voluntary" recall should be taken very seriously and acted on immediately. If the framework for a recall is not in place, a difficult situation will be made even worse. The National Fisheries Institute (NFI) recommends that "all firms learn what a product recall entails, and establish a plan as a proactive measure. The worst time to be initiated to product recalls is during one."

*On the following page is an article written by Paula Fairfield, Supervisor, Public Affairs Office, FDA New England District Office. It provides general information and guidelines on recall.*

Product recalls have become a major means of consumer protection under the laws enforced by the U.S. Food and Drug Administration (FDA). FDA prefers when possible to promote compliance of the law by other means than going to court. A recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. A recall is an alternative to a FDA initiated court action for removing or correcting violative, distributed products.

A recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the FDA. A request by FDA that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is recalled.

A recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of a product have been widely distributed.

Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by FDA, or when the agency has reason to believe that a recall would not be effective, or discovers that a violation is continuing.

When a product is recalled or being considered for recall, a health hazard evaluation will be undertaken and the recall will be classified. The evaluation of the health hazard presented by a product will be conducted by an ad hoc committee of FDA scientists and will take into account, but need not be limited to the following:

1. Whether any disease or injuries have already occurred from the use of the product.
2. Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individuals making the health hazard determination.
3. Assessment hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention being paid to the hazard to those individuals who may be at greatest risk.

4. Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

5. Assessment of the likelihood of occurrence of the hazard.

6. Assessment of the consequences (immediate or long range) of occurrence of hazard.

On the basis of the health hazard determination, the FDA will classify a recall to indicate the relative degree of health hazard being presented by the product being recalled.

**Class I recall:** reasonable probability that the use of, or exposure to the product will cause serious injury or death.

**Class II recall:** use of, or exposure to a product may cause temporary or medically reversible adverse health consequences or where the probability of serious health consequences is remote.

**Class III recall:** use of, or exposure to a product is not likely to cause adverse health consequences (e.g. mislabeling).

It is recommended that all manufacturers or distributors develop plans which can be put into effect if a recall emergency arises. Guidance on FDA recall procedures can be found in the Code of Federal Regulations (21 CFR 7).

Accurate and complete production and shipping records are vital to the success of a product recall. Products should be code labeled to show place and date of manufacture.

The first step, when a product needs to be recalled, is for the manufacturer or distributor to get in touch with the nearest FDA field office (781/279-1675).



*We hope you found this newsletter informative and useful. The next issue will arrive this fall. If you have any questions, please call us!*