A Message from the Editors:

It’s been two years since we last issued a newsletter, a fact we can hardly believe. Lest you fear we’ve forgotten about you (how could we?!), we decided to send this end-of-year update.

In this issue, we provide information regarding some recent developments on the seafood front that could affect seafood processors. Food safety-related bills are moving through Congress, FDA has issued reports on their assessment of the risks and benefits associated with eating fish, and there are new procedures for obtaining health certificates for exports to the European Union. We also touch on FDA’s proposal to require post-harvest treatment of Gulf oysters. As for the new version of the Fish and Fishery Products Hazards and Control Guide, we are still waiting for it to be issued.

HACCP Training for seafood processors continues. Through more than 60 courses offered in southern New England since 1997, 700-800 individuals have completed the required training in the application of HACCP principles to seafood processing. The next set of seafood HACCP training opportunities will be in spring 2010 in Rhode Island. Please contact Lori for more information.

The national calendar listing available training courses can be found at: http://seafood.ucdavis.edu/events.html#section3. The Internet course offered by Cornell University (http://seafoodhaccp.cornell.edu) must be followed by a Segment Two class.


Happy Holidays to you and yours!

Nancy and Lori

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<th>Training Courses</th>
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<td>Seafood HACCP Training Course (3-day)</td>
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Contact Lori Pivarnik (401) 874-2972

Not Sure Which Market Name to Use? Check the FDA Seafood List!

In 2008, an updated list of approved market and scientific names for seafood products was issued. FDA market names generally should be used to label seafood products sold in interstate commerce. If you are not sure how to select an appropriate and acceptable market name, consult the Seafood List Guidance. The guidance explains what FDA considers to be acceptable market names for seafood (sold in interstate commerce) and assists manufacturers in labeling seafood products.

The 2008 Seafood List
http://www.accessdata.fda.gov/scripts/SEARCH_SEAFOOD/index.cfm?other=complete

The Seafood List Guidance
http://www.fda.gov/Food/GuidanceCompliance-RegulatoryInformation/GuidanceDocuments/Seafood/ucm113260.htm
New Procedures for EU Health Certificates

If you are exporting to the European Union, you probably already know that the EU requires health certificates to accompany all shipments of seafood. The FDA now refers all requests for certificates to the NOAA Seafood Inspection Program (SIP). The FDA will, however, continue to produce the EU Export Certificate List.

Due to increases in food safety responsibilities and declines in resources, the FDA found it necessary to focus its resources on higher priority programs (based on public health significance) and determined that it can no longer allocate staff time to issuing EU Export Certificates. Meanwhile, the NOAA Seafood Inspection Program has the resources available to issue these certificates and includes this work in its mission.

The instructions and procedures for obtaining EU Export Health certificates can be found at: http://www.seafood.nmfs.noaa.gov/EU_Export.html. Please note, if you are not already paying for the NOAA SIP continuous on-site inspection program, there will be a cost associated with this service.

Instructions on how to complete the EU Export Certificate Request are posted at http://www.seafood.nmfs.noaa.gov/Request_Cert.html.

Improving the Safety of Food in the U.S.

President Obama has directed that nation’s food safety system be upgraded. In response, the White House Food Safety Working Group (FSWG) was created. To provide information about the group’s activities and progress, FSWG launched a website (http://www.foodsafetyworkinggroup.gov). The goal is the development of a modern, coordinated and effective food safety system. A safer food supply is now an important national priority.

At the same time, two food safety bills (one House, one Senate) have been working their way through the legislative process this year. In the House, the Food Safety Enhancement Act of 2009 (H.R. 2749) passed this summer. On the Senate side, the FDA Food Safety Modernization Act of 2009 (S. 510) has not yet been voted on, but it enjoys wide bipartisan support, and is likely to pass. Once both bills have been passed, they will be reconciled in conference.

How Does this Affect You?

Both bills seek to provide FDA with more power and resources to address food safety issues before they occur for all food commodities for which FDA has oversight. However, given that seafood already has a specific regulation governing food safety, we are not sure how these bills will ultimately affect the seafood industry. Proposals include a requirement to increase inspection frequency for high risk facilities, improve traceability, enhance safety of imported food, and provide the FDA with new authority and enforcement tools.

There is still a lot of work to be done but if you have time, take a look at the bills or summaries. We will keep you informed as to the outcome.

Summary of House Bill H.R. 2749

Summary of Senate Bill S. 510
http://www.fpa-food.org/content/govt_affairs/FDAFSMAsecbysec.pdf

To see either bill in its entirety, go to http://www.govtrack.us/ and search by the appropriate Bill number (H.R. 2749 or S. 510).
FDA Risk & Benefit Assessment Report

The FDA issued a draft Risk & Benefit Assessment Report that investigates the risk and benefit to consumers resulting from the consumption of fish and seafood in January 2009. Two draft documents make up the report.

The first document is called the “Report of Quantitative Risk and Benefit Assessment of Commercial Fish Consumption, Focusing on Fetal Neurodevelopmental Effects (Measured by Verbal Development in Children) and on Coronary Heart Disease and Stroke in the General Population”. The document describes an analysis done by FDA that attempts to quantify the impact of eating commercial fish on three human health endpoints: 1) neurodevelopment, as measured by verbal development, to assess effect from prenatal exposure to methylmercury as passed from the mother to the developing fetus; (2) risk of fatal coronary heart disease; and (3) risk of fatal stroke. Each of these health endpoints has been associated in the scientific literature both with adverse effects of methylmercury exposure (including through fish consumption) and beneficial effects of regular fish consumption.

Sections of this document cover the following topics: 1) the purpose of risk and benefit assessment for methylmercury; 2) exposure to methylmercury in the U.S.; 3) the scientific basis for risk and benefit assessment; 4) quantitative risk and benefit assessment modeling for selected indicators of fetal neurodevelopment, coronary heart disease, and stroke; and 5) quantitative risk and benefit assessment results for selected indicators of fetal neurodevelopment, fatal coronary heart disease, and fatal stroke.

The second draft document, called “Summary of Published Research on the Beneficial Effects of Fish Consumption and Omega-3 Fatty Acids for Certain Neurodevelopmental and Cardiovascular Endpoints”, is a compendium of research prepared by FDA for use in developing its quantitative risk and benefit assessment.

The draft report is a work in progress that has generated a lot of comments since its release. These comments are currently being reviewed, before the final report is issued. The report, including both documents, can be retrieved from: http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogensContaminants/Methylmercury/ucm088758.htm

Update on Oysters and Post-Harvest Processing

There has been an uproar since mid-October when the FDA announced its intention to require, starting in 2011, the post-harvest treatment of raw oysters from the Gulf of Mexico during warmer months, to prevent or reduce the number of illnesses due to the naturally-occurring marine pathogen, *Vibrio vulnificus*. Consumption of raw oysters containing *V. vulnificus* by individuals with compromised health conditions leads to severe illness or death (mortality rate is about 50%). While the states (through the Interstate Shellfish Sanitation Conference or ISSC) and the oyster industry have worked since 2001 to reduce or eliminate *V. vulnificus*-related illnesses following a risk management program that includes educating consumers of raw oysters, the FDA determined that the program had not met its goal of reducing severe illness and death by 60% in seven years. Therefore, the FDA put forth a plan mandating new control measures, specifically post-harvest processing (PHP) of certain Gulf of Mexico oysters destined for raw consumption, which it estimates equals about 13% of all oysters harvested in the U.S.

Currently available PHP technologies include individual quick freezing, high hydrostatic pressure, mild heat, and low dose gamma irradiation. Although about 15% of Gulf oysters now undergo PHP, some raw oyster aficionados claim that there is no comparison between the flavor and texture of an untreated versus treated live oyster. Industry members are concerned about the additional costs associated with PHP as well as the...
shipping to/from the limited number of treatment facilities currently available, and the reduction of already-slim profit margins. FDA counters this argument, saying that post-harvest processed oysters can command a higher price due to their increased safety, increasing the value of Gulf of Mexico raw oysters.

Shellfish producers nationwide quickly raised concerns that 1) this measure will cause tremendous economic losses, including jobs and revenues, to the industry, and 2) that the FDA policy ultimately may not be restricted to just oysters harvested in the Gulf where V. vulnificus is known to be distributed widely.

To FDA’s credit, it announced in mid-November that it would not proceed with its new policy regarding PHP until it conducted an independent study to assess how PHP or other equivalent controls can feasibly be implemented in the Gulf Coast in the fastest, safest and most economical way.

Meanwhile, Congresswoman Rosa DeLauro (D-CT; Chairwoman, House Appropriations Subcommittee on Agriculture Rural Development, Food and Drug Administration, and Related Agencies), has asked the Government Accountability Office (GAO) to conduct an audit of the ISSC’s risk management plan for V. vulnificus. The audit is to determine whether the risk management plan used by industry, and promoted by the ISSC, is effectively reducing illnesses/deaths due to consumption of raw oysters contaminated with V. vulnificus bacteria, thus achieving its intended public health benefits. The evaluation would include the effectiveness of the current control measures, and new controls proposed by the ISSC involving time and temperature to be initiated in spring 2010. The GAO would also assess the states’ abilities to oversee industry compliance with the new controls and collect enough data to evaluate their effectiveness, given current constrained budgets.