

SEAFOOD SAFETY SAVVY: A HACCP UPDATE

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

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A Message from the Editors:

Happy 2016, everyone - we hope you have a great year! As many of you may know, the Food Safety Modernization Act (FSMA), was signed into law January 2011. FSMA is the most significant food safety legislation since the passage of the 1938 Food, Drug and Cosmetic Act. The Act resulted in seven different Rules, one of which deals with new or updated GMPs and preventive controls for human food (21 CFR 117). Seafood processors have been wondering whether this new rule will impact them. This newsletter will try to answer that question.

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Which Parts of the Food Safety Modernization Act (FSMA) and the New Preventive Controls Rule Apply to Seafood Businesses?

As of 2011, the Act (FSMA) already included provisions that impacted FDA-inspected facilities, including seafood. The Act gave FDA the authority for both instituting mandatory recall and potentially charging fees for repeat inspections. While registration of processing facilities was already required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (aka "Bioterrorism Act"), FSMA now requires processing facilities to re-register every two years.

In August 2015, the FDA finalized the first of its seven mandated Rules, Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food (21 CFR Part 117). This Rule has raised some questions among seafood processors as to what actually applies to them. While there are seven sub-parts to this Rule, only a few impact the seafood industry.

First, the seafood industry has its own seafood HACCP regulation (21 CFR 123), which you all know and love. Congratulations! Because you have been under this regulation since 1997, your seafood products are EXEMPT from Sub-part C of 21 CFR Part 117, the new FSMA Preventive Controls Rule, which covers Hazard Analysis and Risk-based Controls for Human Food. However, you ARE subject to Sub-parts A (General Provisions), Good Manufacturing Practices), B (Current GMPs) and E (Withdrawal of Qualified Facility Exemption).

Sub-part A requires that the owner/operator of a processing facility must ensure that only "qualified individuals" manufacture, process, pack or hold food, which means a training requirement is now in place for all individuals who have assigned duties that impact the food. Training for all employees (including seasonal or temporary) must include principles of food safety/hygiene and personal hygiene; records documenting that the training took place are required. This can be the function of a knowledgeable supervisor; it does not have to be a formalized curriculum. This is in addition to any seafood HACCP training that has been required by 21 CFR 123 for key employees.

Sub-part B (Current GMPs) includes several key changes to the GMPs that we will address here. First, all the "shoulds" have been omitted and have been replaced with "must" or "shall". Education and training are now part of GMP regulatory requirements. Management is required to ensure that all employees who manufacture, process, pack or hold food must be qualified to perform their duties. Finally, GMPs address allergen issues. Sanitation controls must be in place to prevent allergen cross-contact. Under the sanitation provisions of Part 123 of the seafood HACCP regulation, processors can meet this requirement.

We have now used a new term, "**cross-contact**" vs. the term we've always used, "cross-contamination". What is the difference? Per FDA, "cross-contact" relates to allergens only and is defined as the unintentional incorporation of a food allergen into another food. Food processing establishments must develop/adopt a food allergen control plan that prevents allergen cross-contact during processing.

Why change to cross-contact? Previously, inadvertent incorporation of an allergen from one food into another was referred to as "cross-contamination". Cross-contamination is still used to refer to contamination of food with bacterial, chemical and physical hazards from food contact surfaces such as food, people and equipment. However, cross-contact is now being applied to unintentional transfer of allergens (food proteins) from one food containing these proteins to one that does not since allergens are a normal component of a food, they are not a contaminant, and pose no risks to most individuals. Therefore, FDA is using allergen cross-contact to describe this inadvertent incorporation of any allergen in a food rather than cross-contamination to better reflect both scientific literature and for clarity. In summary, **cross-contact = unintentional incorporation of food allergens into food** and **cross-contamination = contamination of food with bacterial, chemical, or physical hazards.**



Seafood processors are also exempt from Sub-parts D, F and G. Sub-part E (Withdrawal of Qualified Facility Exemption) *could* apply to seafood processors, if they do not remain in compliance with 21 CFR Part 123. If they lose their exemption, they will be subject to ALL of the Prevention and Control Rule (21 CFR Part 117). However, this would be a remote possibility and FDA prefers that seafood processors comply with their own rule. Furthermore, we are still not clear whether this could even apply to seafood facilities as this sub-part may be specific to facilities covered by the regulation (clarification is needed).

Business Size	Implementation time	Implementation date
Very small businesses (< \$1 million/year human food)	3 years	9/17/2018
Small businesses (<500 full-time employees)	2 years	9/18/2017
All other businesses (Large)	1 year	9/19/2016

Finally, questions have been raised about whether the new Prevention and Control Rule applies to seafood processors if they use other FDA-regulated ingredients like flour, soy, etc. in their products. The FDA indicates that other ingredients used in a product where seafood is the characterizing ingredient all fall under the seafood HACCP

regulation (21 CFR Part 123). See <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461791.htm> for the full answer as well as other Q&A related to FSMA.

Training Courses



Basic Seafood HACCP Training Courses

May 24-26, 2016 Narragansett, RI*
 October 25-27, 2016 Groton, CT**

Segment Two Follow-up to Internet Course

September 13, 2016 Groton, CT**

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New HACCP course dates will be shared with Connecticut and Rhode Island seafood businesses by mail; we will also post the courses on the AFDO training calendar and the Connecticut Sea Grant website.