

## MEMORANDUM

**From:** Joseph A. Levitt  
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**Date:** August 29, 2019

**Re: FDA Issues Updates to Fourth Edition Seafood HACCP Guidance**

The U.S. Food and Drug Administration (FDA) recently released an updated Fourth Edition of its Guidance for Industry entitled, “Fish and Fishery Products Hazards and Control Guidance, Fourth Edition – August 2019” (“the Seafood HACCP Guide”).<sup>1</sup> The Seafood HACCP Guide is intended to assist processors of fish and fishery products in developing their Hazard Analysis Critical Control Point (HACCP) plans. Technically, the Seafood HACCP Guide is not binding, but in practice, FDA will expect companies either to follow the Seafood HACCP Guide or to be able to support the appropriateness of deviations from the guidance.

The Fourth Edition of the Seafood HACCP Guide was originally released in 2011, and the August 2019 updates reflect the agency’s ongoing effort to update the document. FDA determined specific chapters and appendixes of the Seafood HACCP Guide warranted updating based on the availability of new science and chose to publish those portions instead of withholding until a fully revised Guidance was ready for publication. The introduction chapter summarizes the changes and marks the updated portions with “as of August 2019” language. Going forward, FDA plans to treat the Seafood HACCP Guide as a “living document,” making updates to individual chapters on an as-needed basis and posting updates to FDA’s Seafood website ([www.fda.gov/seafood](http://www.fda.gov/seafood)).

On the whole, the updates largely reflect incremental changes in the Seafood HACCP Guide and do not reflect fundamental shifts in agency policy. FDA updated three chapters and two appendixes. Perhaps most significantly, however, FDA has added two new appendixes focused on allergen control. Processors should review the August 2019 changes carefully and in light of current company programs and practices, and the allergen control recommendations may also be useful for companies not operating under seafood HACCP.

The most noteworthy additions focus on allergen controls, found in Chapter 19 and in newly added Appendixes 9 and 10. FDA has reorganized some of the content in Chapter 19, placing much greater emphasis on controlling allergen cross contact during processing and controlling allergens through sanitation practices. The Seafood HACCP Guide also adds two new appendixes on

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<sup>1</sup> The Seafood HACCP Guide is available online at <https://www.fda.gov/media/80637/download>, and a copy is attached.

allergen controls, Appendix 9 and Appendix 10. These new appendices provide detailed recommendations for establishing programs for allergen cleaning, sanitation, and cross-contact prevention.

Appendix 9 covers cross-contact prevention and discusses practices and procedures for the receiving, storage, processing, re-work and work-in-progress stages. Appendix 9 emphasizes factors such as facility design, process design, scheduling, and the use of color coding and tagging systems to prevent cross-contact, among others. Appendix 10 provides detailed recommendations on the development of written SSOPs, including both cleaning and validation processes. Appendix 10 emphasizes that sanitation processes designed to control microbiological conditions may not be adequate to prevent allergen cross contact. It also includes extensive discussion about the use of sampling to verify and validate the effectiveness of sanitation controls.

The full list of new and revised sections is:

### **New Appendices<sup>2</sup>**

- Appendix 9: Allergen Cross-Contact Prevention
- Appendix 10: Cleaning and Sanitation for the Control of Allergens

### **Revised Chapters and Appendices**

- Chapter 3: Potential Species-Related and Process-Related Hazards
- Chapter 6: Natural Toxins
- Chapter 19: Undeclared Major Food Allergens and Certain Food Intolerances Causing Substances
- Appendix 5: FDA and EPA Safety Levels in Regulations and Guidance
- Appendix 8: Procedures for Safe and Sanitary Processing and Importing of Fish and Fishery Products

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We will continue to monitor FDA's updates to the Fish and Fishery Products HACCP Guidance, as well as other guidance and rulemaking related to seafood. Please contact us with any questions regarding this or other matters.

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<sup>2</sup> We note that the Seafood HACCP Guide's Table of Contents seems to have switched the titles for Appendices 9 and 10. The titles provided here are as they appear on the first page of each Appendix in the Guide and reflect the actual content.