

Letter to Industry – Guide Implementation



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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The Center for Food Safety and Applied Nutrition has received multiple inquiries regarding the implementation timeframes of the guidance for industry titled “Fish and Fishery Products Hazards and Controls Guidance, Fourth Edition.”

FDA is already using the information in the Fourth Edition of the guidance to evaluate Hazard Analysis Critical Control Point (HACCP) plans for fish and fishery products. In the Federal Register of April 28, 2011, FDA announced the availability of the Fourth Edition of the guidance (76 FR 23823), and indicated that it was “being implemented without prior public comment because the Agency determined that prior public comment was not feasible or appropriate” (76 FR 23823). The Agency made this determination because the updated information in the guidance significantly enhances the seafood industry’s ability to protect the public health and provides important recommendations for conducting a hazard analysis and implementing a HACCP plan.

The fish and fishery products industry should review the entire new edition, with emphasis on the summary of the changes from the Third Edition of the guidance, and should assess the adequacy of any HACCP plans which may be affected by these changes. This summary can be found in the discussion section of the Fourth Edition of the guidance.

Although FDA is using the information in the Fourth Edition of the guidance to evaluate HACCP plans for fish and fishery products, FDA intends to consider the extent to which a firm may have used previous recommendations from the Third Edition of the guidance when determining what actions will be taken when violations of FDA’s HACCP regulations are observed.

Sincerely,

/S/

William R. Jones, Ph.D.
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Center for Food Safety and Applied Nutrition