

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0264]

DDM

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Certifier A. Carbin

**Compliance Policy Guide Sec. 540.370—Fish and Fishery Products—
Decomposition; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of Compliance Policy Guide Sec. 540.370—Fish and Fishery Products—Decomposition (the CPG). The CPG provides guidance for FDA staff on decomposition in fish and fishery products.

DATES: Submit written or electronic comments on the CPG at any time.

ADDRESSES: Submit written comments on the CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Submit written requests for single copies of the CPG to the Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240-632-6861. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG.

FOR FURTHER INFORMATION CONTACT: Robert D. Samuels, Center for Food Safety and Applied Nutrition (HFS-325), Food and Drug Administration, 100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2300.

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of July 18, 2008 (73 FR 41361), FDA announced the availability of draft CPG Sec. 540.370—Fish and Fishery Products—Decomposition and gave interested parties an opportunity to submit comments. The agency received no comments on the draft CPG but on its own initiative made a few editorial changes for clarification purposes. The CPG provides guidance for FDA staff on decomposition in fish and fishery products. The CPG also contains information that may be useful to the regulated industry and to the public.

FDA is issuing this CPG as a level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The CPG represents the agency's current thinking on FDA's direct reference enforcement criteria related to decomposition in fish and fishery products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The CPG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *<http://www.regulations.gov>*.

III. Electronic Access

Persons with access to the Internet may obtain the CPG at *[http://www.fda.gov/ora/compliance__ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm)*.

Dated: 1/12/2009
January 12, 2009.

Michael A. Chappell
Michael A. Chappell,
Acting Associate Commissioner for Regulatory Affairs.

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