



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1842]

Crabmeat--Fresh and Frozen--Adulteration with Filth, Involving the Presence of Escherichia coli; Compliance Policy Guide; Draft Guidance for Food and Drug Administration Staff;

Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for FDA staff entitled "Compliance Policy Guide Crabmeat--Fresh and Frozen--Adulteration with Filth, Involving the Presence of Escherichia coli." The draft Compliance Policy Guide (CPG), when finalized, will update the previously issued "CPG Crabmeat--Fresh and Frozen--Adulteration with Filth, Involving the Presence of the Organism Escherichia coli." This revised draft provides guidance for FDA staff on the level of Escherichia coli (E. coli) in crabmeat at which we may consider the crabmeat to be adulterated with filth.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft CPG before it begins work on the final version of the CPG, submit either electronic or written comments on the draft CPG by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft CPG to the Office of Policy and Risk Management, Office of Regulatory Affairs, Office of Global Regulatory Operations and Policy, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send

two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the CPG.

Submit electronic comments on the draft CPG to <http://www.regulations.gov>. Submit written comments on the draft CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary E. Losikoff, Center for Food Safety and Applied Nutrition (HFS-325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2300.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of the draft CPG entitled "Compliance Policy Guide Sec. 540.275 Crabmeat--Fresh and Frozen--Adulteration with Filth, Involving the Presence of Escherichia coli." The draft CPG, when finalized, will update the previously issued "CPG Sec. 540.275 Crabmeat--Fresh and Frozen--Adulteration with Filth, Involving the Presence of the Organism Escherichia coli," which provides guidance for FDA staff on the level of E. coli in crabmeat (i.e., 3.6 Most Probable Number per gram (MPN/g) of E. coli) at which FDA may consider the crabmeat to be adulterated with filth under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(4)). We revised the CPG for clarity and to update the format. Revisions generally include the addition of sections on Background and Policy, updates to the sections on Regulatory Action Guidance and Specimen Charges, and FDA office names. Specifically, in the section on Regulatory Action Guidance, we clarify that FDA's Districts have direct reference authority for both domestic seizure and import refusal based on the criteria described in the draft CPG. We also clarify the specific types of legal

action to which the criteria for recommendations apply. In addition, we provide specimen charges relating to domestic seizure and import refusal. The draft CPG also contains information that may be useful to the regulated industry and to the public.

We are issuing the draft CPG consistent with our good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent our current thinking on the level of E. coli in fresh or frozen crabmeat at which we may consider the crabmeat to be adulterated with filth under section 402(a)(4) of the FD&C Act.

The draft CPG does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding the draft CPG to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document from FDA's Office of Regulatory Affairs CPG history page at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: December 10, 2014.

Melinda K. Plaisier,

Associate Commissioner for Regulatory Affairs,

Office of Regulatory Affairs.

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