CPG Sec. 540.275 Crabmeat – Fresh and Frozen – Adulteration with Filth, Involving the Presence of *Escherichia coli*

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition

Office of Regulatory Affairs

April 2016

Table of Contents

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction:

The purpose of this document is to provide guidance for FDA staff on adulteration with filth involving the presence of *Escherichia coli* in fresh and frozen crabmeat. In the remainder of this guidance, “we” or “our” refers to FDA.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Escherichia coli (*E. coli*) has traditionally been used as a microbiological indicator of insanitation during processing. *E. coli* is commonly associated with feces of warm blooded animals. Its presence in foods and water suggests fecal contamination. In the production of

commercially processed fresh or frozen crabmeat, the cook step (boiling or steaming the in-shell crabs) destroys nonsporeforming bacteria including *E. coli*, if they are present on the raw product. Therefore, the presence of *E. coli* in finished product indicates that either the cook step was inadequate or the product was recontaminated after the cook step. As applied to fresh or frozen crabmeat discussed in this CPG, cooking is a heat treatment, usually performed before the product is placed in the finished product container and distributed either refrigerated or frozen.

Recontamination of the crabmeat after the cook step could be a result of either insanitary practices by the employees in the processing plant or the presence of insects in the processing plant that may have served as vectors for the dissemination of bacteria to the food after the cook step. Strict in-plant sanitation measures should be instituted to prevent the presence of *E. coli* in the finished product. Although most strains of *E. coli* are harmless, some strains can cause severe illness. The confirmed presence of *E. coli* at levels of 3.6 Most Probable Number per gram (MPN/g) or greater in crabmeat indicates insanitary conditions, which may include poor employee hygiene practices, improperly sanitized utensils and equipment, or insects or other pests.

III. Policy

FDA may consider that crabmeat has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth and, thus, is adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(4)) when, based on examination of a sample consisting of a minimum of six subsamples of fresh or frozen crabmeat:

• *E. coli* at levels of 3.6 MPN/g or greater is present in two or more of six subsamples, with or without inspectional evidence to indicate the most probable source of the *E. coli*, or

• *E. coli* at levels of 3.6 MPN/g or greater is present in only one of six subsamples, and available inspectional evidence indicates the most probable source of the *E. coli* (i.e., evidence demonstrating an inadequate cook step or likely contamination after cooking). Such inspectional evidence may include observed insanitary conditions, such as poor employee hygiene practices, improperly sanitized utensils and equipment, the presence of insects or other pests, and possible routes of contamination of the cooked crabs or crabmeat (e.g., contact between raw crabmeat and cooked crabs or crabmeat).

Under section 801(a)(3) of the FD&C Act (21 U.S.C. 381(a)(3)), FDA may refuse admission of crabmeat that is offered for import into the United States and that appears to be adulterated within the meaning of section 402(a)(4) of the FD&C Act.

IV. Regulatory Action Guidance

Direct Reference

The following represents criteria for direct reference seizure recommendations to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

When upon examination of a sample consisting of a minimum of six subsamples of fresh or frozen crabmeat, *E. coli* at levels of 3.6 MPN/g or greater is present in two or more of six subsamples, with or without inspectional evidence to indicate the most probable source of the *E. coli*.

Recommendations

The following represent criteria for recommending seizure or import refusal to CFSAN, Office of Compliance, Division of Enforcement (HFS-605): When upon examination of a sample consisting of a minimum of six subsamples of fresh or frozen crabmeat, *E. coli* at levels of 3.6 MPN/g or greater is present in only one of six subsamples, and available inspectional evidence indicates the most probable source of the *E. coli*.

Available inspectional evidence indicating the most probable source of the *E. coli* (i.e., evidence demonstrating an inadequate cook step or likely contamination after cooking) should be included in the recommendation. Such inspectional evidence may include observed insanitary conditions, such as poor employee hygiene practices, improperly sanitized utensils and equipment, the presence of insects or other pests, and potential routes of contamination of the cooked crabs or crabmeat (e.g., contact between raw crabmeat and cooked crabs or crabmeat).

While assessing recommendations based on the criteria above, the Division of Enforcement will also assess whether a charge under section 402(a)(3) of the FD&C Act (21 U.S.C. 342(a)(3)) can be supported.

V. Specimen Charges

Domestic Seizure

The article of food was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 342(a)(4), in that the food has been prepared, packed, and held under insanitary conditions whereby it may have been contaminated with filth.

Import Refusal

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(4) of the FD&C Act in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth.*

Material between asterisks is new or revised

Issued: 10/1/82

Revised: 10/30/89, 3/95, 5/2005, 11/29/2005, 4/25/2016