CPG Sec. 540.370 Fish and Fishery Products - Decomposition

You may submit written or electronic comments regarding this guidance at any time. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to regulations.gov. 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 (CFSAN)
Office of Regulatory Affairs (ORA)
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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.

I. Introduction:

The purpose of this document is to provide guidance for FDA staff on FDA’s direct reference enforcement policy on decomposition in fish and fishery products.

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:

Fish and fishery products are susceptible to degradation resulting from time/temperature exposure. Proper commercial handling, including adherence to Current Good Manufacturing Practice (21 CFR part 110), helps prevent the products from becoming decomposed prior to reaching consumers. Nevertheless, decomposed fish and fishery products are periodically detected in interstate commerce and warrant regulatory action.

FDA’s enforcement policy on decomposition in shrimp and fish was previously provided in part in CPG Sec. 540.575 Fish – Fresh and Frozen – Adulteration Involving Decomposition (CPG 7108.05), CPG Sec. 560.650 Canned and Cooked/Frozen Shrimp – Adulterated by Decomposition (CPG 7119.13), and CPG Sec. 540.400 Shrimp - Fresh or Frozen, Raw, Headless, Peeled or Breaded - Adulteration Involving Decomposition (CPG 7108.11). CPG Sec. 540.575 was withdrawn on July 18, 2008 (73 FR 41361). CPG Sec. 560.650 and CPG Sec. 540.400 were revoked on July 5, 1995 (60 FR 35038), and December 24, 1996 (61 FR 67837), respectively.

III. Policy:

The following regulatory action guidance is applicable to all fish and fishery products, except scombrotoxin-forming species of fish, which are addressed in CPG Sec. 540.525 Decomposition and Histamine Raw, Frozen Tuna and Mahi-Mahi; Canned Tuna; and Related Species (CPG 7108.24). The guidance also does not apply to dried fish or fish sauce/paste products.

The Federal Food, Drug, and Cosmetic Act (FD&C Act or Act), section 402(a)(3) [21 U.S.C. 342(a)(3)], states that a food shall be deemed to be adulterated "if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food." The criteria in this guidance do not establish an acceptable level of decomposition in food. FDA may choose to take regulatory action against adulterated food that does not meet the direct reference criteria.

IV. Regulatory Action Guidance:

The following represents criteria for direct reference import detention or 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*:

> Using a two-class, pass/fail, evaluation approach, the presence of decomposition is detected in a minimum of two (2) subsamples from a lot when up to 24 subsamples are examined from the lot.

The presence of decomposition is detected in a subsample, i.e., the subsample “fails” the decomposition evaluation, when:

1. 20% or more of the edible portion contains definite and persistent sensory attributes indicative of decomposition as determined by qualified FDA seafood sensory analysts (a current list of qualified FDA seafood sensory analysts may be obtained from the *Office of Regulatory Science (ORS))*; or

2. An appropriate chemical indicator of decomposition (CID) is detected by original and check analysis using a method approved by CFSAN. For this direct reference authority, indole at levels greater than or equal to 25 micrograms indole per 100 grams sample, based on the AOAC, 18th Edition, Method 35.1.35 (981.07), is an appropriate CID for all shrimp products.

Note: A sample may meet the direct reference criteria when subsamples fail for a combination of reasons, i.e., one due to sensory detection of decomposition and another due to decomposition detected by CID.

An import shipment offered for entry may be detained if one or more lots in the shipment are deemed violative. A "line by line" examination or decomposition evaluation of each lot in the shipment is not a prerequisite to detention of the shipment.

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 the Act, 21 U.S.C. 342(a)(3), in that it consists in whole or in part of a decomposed substance.

Import Detention

The article of food is subject to refusal of admission, pursuant to section 801(a)(3) of the FD&C Act [21 U.S.C. 381(a)(3)] in that it appears to be adulterated within the meaning of section 402(a)(3) of the FD&C Act [21 U.S.C. 342(a)(3)], in that it consists in whole or in part of a decomposed substance.

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