agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before September 5, 1995, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: July 21, 1995.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

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[Docket No. 95D–0157]

Decomposition and Histamine—Raw, Frozen Tuna and Mahi-Mahi; Canned Tuna; and Related Species; Revised Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of revised Compliance Policy Guide (CPG) 7108.24, entitled ''Decomposition and Histamine—Raw, Frozen Tuna and Mahi-Mahi; Canned Tuna; and Related Species.'' Revised CPG 7108.24 lowers the histamine level at which FDA may consider the fish subject to action under the Federal Food, Drug, and Cosmetic Act (the act) and states that the histamine defect action level (DAL) and the histamine action level (AL) now apply to raw, frozen tuna and mahi-mahi in addition to canned tuna. Furthermore, the revised CPG 7108.24 states that the AL also applies to related species of raw, frozen, and canned fish implicated in instances of histamine poisoning, such as bluefish, amberjack, and mackerel, in addition to tuna and mahi-mahi. Additionally, for these related species, levels of histamine less than the AL may be considered as evidence of decomposition on a case-by-case basis when supported by additional scientific data. The title of the revised CPG reflects these changes.

DATES: Written comments by September 5, 1995.

ADDRESSES: Submit written requests for single copies of CPG 7108.24, ''Decomposition and Histamine—Raw, Frozen Tuna and Mahi-Mahi and Canned Tuna; and Related Species,'' and Laboratory Information Bulletin no. 3794 to the Director, Office of Constituent Operations, Industry Activities Staff (HFS–565), Food and Drug Administration, rm. 5827, 200 C St. SW., Washington, DC 20204. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on CPG 7108.24, ''Decomposition and Histamine—Raw, Frozen Tuna and Mahi-Mahi; Canned Tuna; and Related Species,'' to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of revised CPG 7108.24, ''Decomposition and Histamine—Raw, Frozen Tuna and Mahi-Mahi; Canned Tuna; and Related Species,'' the *Official Methods of Analysis of the Association of Official Analytical Chemists 15th Ed.* (1990), section 977.13, and Laboratory Information Bulletin no. 3794, and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Mary I. Snyder, Office of Seafood (HFS–416), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3160.

SUPPLEMENTARY INFORMATION: Histamine is a chemical compound that forms postmortem in the muscle of scombroid fish, such as tuna, and in other species, such as mahi-mahi, by the action of certain bacteria that are common in fish. Bacteria that have the ability to form histamine do so by the decarboxylation of L-histidine, an amino acid found in the fish muscle. The decarboxylation reaction is catalyzed by an enzyme, histidine decarboxylase, produced by the bacteria. Fish species that are particularly vulnerable to the development of histamine are those with high levels of free L-histidine in their muscle tissues. Additional histidine may be released during decomposition and spoilage by proteolysis, whereby the protein structure is degraded, and amino acids are liberated (Ref. 1). The level of histamine produced in scombroid or other histidine-containing fish by these processes serves as an indicator of the decomposition that has occurred. When present at higher levels, histamine represents a health hazard. Therefore, FDA uses histamine to indicate that these fish are adulterated within the meaning of section 402(a)(1) and (a)(3) of the act (21 U.S.C. 342(a)(1) and (a)(3)).

In the fishing industry, decomposition and bacterial histamine production are controlled primarily by the use of low temperature storage (Ref. 2). Significant decomposition and histamine formation can be avoided by good fish handling practices including icing or rapid immersion of the catch in water chilled to -1 °C (30 °F), followed by uninterrupted frozen storage. Under high temperature storage conditions, histamine may form before other indicators of decomposition are evident, especially the odor and appearance of decomposed fish (Ref. 3).

Histamine also may form during low temperature storage conditions. However, in low temperature storage, the rate of histamine formation is slower, and it is usually accompanied by the typical odor of decomposition. Research sponsored by the Department of Health and Human Services has suggested that freezing may be more damaging to histamine-forming bacteria than it is to nonhistamine producing spoilage bacteria (Ref. 4).

Canned fish is frequently prepared from fish preserved by frozen storage before delivery to canneries. These fish are thawed before processing and are subjected to additional handling that may result in histamine levels in canned fish being somewhat higher than the levels observed in raw, freshly caught fish.

Histamine is generally not uniformly distributed in a decomposed fish. A level of less than 50 parts per million (ppm) in one section may accompany a level in excess of 1,000 ppm elsewhere in the same fillet (Ref. 3). The anterior section of an individual fish generally is higher in histamine content than the posterior section, because the intestine, which is located in the forward end, is apparently the major source of the