bacteria responsible for histamine formation. Postmortem disintegration of the intestine releases the microbial contents of the intestine which contaminate the anterior muscle tissue, making these sites particularly vulnerable to an accumulation of the amine (Refs. 5 and 6). The preponderance of scientific evidence demonstrates that the presence of histamine equal to or greater than 50 ppm, in a sample, is evidence that the fish is in a state of decomposition (Refs. 3, 5, and 6).

Defect Action Level for Decomposition

Results of research conducted in the 1970's by FDA in cooperation with major universities, industry research associations, individual canners, and the National Marine Fisheries Service demonstrate that histamine levels in freshly caught tuna and mahi-mahi are less than 1 ppm. Acceptable commercial fish generally contain about 5 ppm and rarely as much as 20 ppm histamine (Ref. 3). In a notice published in the **Federal Register** of September 14, 1982 (47 FR 40487), FDA stated that histamine levels in tuna that are judged to be of acceptable quality, based on organoleptic and physical analyses, are on the order of 10 to 20 ppm. FDA data from 1990 to 1992 show that the average histamine levels in acceptable commercial raw frozen fish (number of samples in parentheses) are 2 ppm for mahi-mahi (4), 4 ppm for albacore tuna (7), 2 ppm for yellowfin tuna (10), and 2 ppm for skipjack tuna (10) (Ref. 3). Other investigators also have reported that raw freshly caught scombroid fish contain very little histamine (Refs. 5 and 6).

FDA conducted workshops in 1974 and 1976 in association with the Tuna Research Foundation. Test packs of canned tuna were prepared by the industry and classified by FDA experts using organoleptic evaluation. The average levels of histamine in the packs of canned tuna (numbers of cans in parentheses) found to be acceptable by organoleptic evaluation were 22 ppm for albacore (36), 12 ppm for skipjack (112), and 11 ppm for yellowfin (82). The average histamine level for all 230 samples was 13 ppm. These tuna packs were not authentic packs but confirmed that commercially canned tuna of acceptable quality does not contain high levels of histamine. Similarly, commercially canned tuna collected from retail stores, in a survey conducted in 1981, was found to contain an average of approximately 6 ppm histamine (Ref. 3).

The provisions of the current CPG 7108.24 announced in the September 14, 1982, notice, established a DAL of 200 ppm histamine for canned albacore, skipjack, and yellowfin tuna. The agency also stated that it would consider regulatory action against any canned tuna found to contain between 100 and 200 ppm histamine when a second indicator of decomposition (e.g., spoilage odors or honeycomb formation) is present.

Since the studies on which the previous histamine DAL was based were conducted, the analytical methodology available for determination of histamine to 5 ppm levels has become standard practice. The official method for histamine detection published in 1977 (Ref. 7) was refined in 1993 (Ref. 8). The 1993 methodology has successfully undergone collaborative evaluation and testing. Refinement in the methodology for histamine determination and experience in using the methodology have made the determination of 50 ppm histamine levels a routine practice.

Given the findings of these studies (Refs. 3, 5, and 6); the research that shows that the histamine levels in freshly caught fish are less than 2 ppm; the fact that commercially canned tuna classified as acceptable by FDA averages 6 ppm histamine; and the fact that levels at or above 50 ppm are only found in samples classified as decomposed by FDA organoleptic expert examination, the presence of 50 ppm histamine is evidence that raw, frozen, or canned tuna, and raw or frozen mahi-mahi, are in a state of decomposition. See *United States* v. *1,200 Cases, Pasteurized Whole Eggs*, 339 F. Supp. 131, 137 (N.D. Ga. 1972). Therefore, when 50 ppm or more histamine is found in these types of fish, the agency may recommend regulatory action against the fish under section 402(a)(3) of the act.

In the past two decades both industry and government have used organoleptic analysis of volatile odors for the detection of decomposition in raw and thermally processed fishery products. This analytical technique is acquired through extensive training and experience on samples and requires the analyst be periodically standardized in the application and performance of the analytical technique. However, organoleptic analysis is not quantifiable, and its application to stored and thermally processed commercial products, such as canned tuna, is difficult because the usual odors of decomposition found in raw product are often removed or altered during thermal processing. Unlike odors of decomposition, nonvolatile spoilage compounds such as histamine remain in the product and can be reliably measured by chemical analysis (Ref. 3). Therefore, confirmatory organoleptic examination for decomposition in regulatory samples would not be necessary when histamine levels at or above 50 ppm are detected by chemical analysis.

Although the agency intends to use this DAL in deciding whether to recommend regulatory action, it does not consider that the fact that a fish or fishery product has a histamine level below 50 ppm establishes that the fish or fishery product is acceptable. Other spoilage mechanisms are possible that do not result in the formation of histamine. Thus a finding of histamine levels between 20 and 50 ppm should be viewed as indicating that the fish or fishery product has deteriorated and should cause a producer to further evaluate or test the product.

Histamine Formation in Species Other Than Tuna and Mahi-Mahi

The agency's use of histamine level as a reliable indicator of decomposition is based primarily on agency experience with tuna and mahi-mahi. However, other species have been implicated in a significant number of incidents of histamine poisoning. These other species also contain high levels of free L-histidine in their muscle tissue and are known to form histamine as they decompose. Therefore, on a case-by-case basis, when these other species contain levels of histamine equal to or greater than 50 ppm, the agency may determine that these fish are decomposed particularly when such a judgment is supported by other scientific data, including the presence of other amines associated with decomposition in these fish.

Action Level for Health Hazard

In addition to being an indicator of decomposition, when ingested at sufficiently high levels histamine causes scombroid poisoning. The term ''scombroid fish poisoning'' developed because fish of the families Scombridae and Scomberesocidae are commonly implicated in instances of histamine poisoning deriving from advanced stages of decomposition in these fish. Tuna and mackerel are most frequently involved in instances of histamine poisoning, but this fact is attributable, in part, to the large amounts of these species that are consumed worldwide (Ref. 9).

Nonscombroid fish, such as mahi-mahi (*Coryphaena hippurus*), is also involved in histamine poisoning. Bluefish (*Pomatomus saltatrix*) has been responsible for several scombroid poisoning outbreaks in the United States