DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP - 4 2003

6046 '03 SEP -5 A9:35

Mr. Brooks Takenaka
United Fishing Agency, Ltd.
117 Ahui Street
Honolulu, HI 96813

Re: Docket No. 99D-0392

Dear Mr. Takenaka:

This letter responds to your citizen petition dated April 3, 2002, requesting that the Food and Drug Administration (FDA) exercise enforcement discretion for some of the requirements of FDA's seafood Hazard Analysis Critical Control Point (HACCP) regulation (21 CFR Part 123) as provided for under the agency's Seafood HACCP Transition Guidance of December 1999. FDA developed the Transition Guidance to provide seafood processors, or other interested parties, the opportunity to prepare and present scientific support that demonstrates, in addition to whether a hazard is reasonably likely to occur, whether a particular preventive measure is sufficient to control a hazard that is reasonably likely to occur.

Your petition asks the agency to "consider exercising enforcement discretion on certain matters under the seafood HACCP regulation pending their scientific resolution." In your petition you state that the HACCP control guidance provided by FDA for controlling histamine formation in scombrotoxin-forming fish at receipt by primary processors is too "restrictive" and inappropriate for the Hawaii fisheries, particularly the longline fishery. You state that typical fish handling practices in Hawaii "provide an equivalent level of histamine control" to FDA's guidance and propose to conduct research "to strengthen the scientific justification for the industry's position." The petition includes a nine-point (bullet) proposal of actions to be taken by your firm to maintain control of existing operations, in addition to research to be conducted to verify the adequacy of the controls used by your firm.

In accordance with 21 CFR 10.30(e)(3), this letter is to advise you that, as explained below, FDA is denying your petition.

Of particular concern to FDA is the formation of compounds associated with human illness as a consequence of bacterial growth and enzyme production that FDA believes can occur in fish that remain dead in the sea for lengthy periods of time after capture and before landing on the vessels using fishing techniques such as longlining. Bacteria, including those that form certain metabolites referred to as biogenic amines, such as histamine, can begin invading the flesh of the fish immediately after the fish's natural defense mechanisms cease upon death. Longer exposures at warmer ambient temperatures allow greater bacterial activity and accumulation of these metabolites. Accumulation of some of these amines can cause scombrotoxin illness when the fish is consumed.

99D-0392 PDN1

FDA currently recommends that harvesters of scombrotoxin-forming fish take measures within 6 to 12 hours of death of the fish (depending on the type of fish and harvest/handling conditions) to adequately chill the fish to inhibit histamine-forming bacteria (FDA's "Fish & Fisheries Products Hazards & Controls Guidance: Third Edition" [the Guide], p. 88). However, longline harvest techniques allow exposures of fish to ambient water temperatures for as many as 18 hours or more before retrieval and chilling aboard the vessels is begun (Kaneko, J., "Development of a HACCP-based Strategy for the Control of Histamine for the Fresh Tuna Industry," a report to the National Oceanographic and Atmospheric Administration, Award No. NA86FD0067, July 31, 2000, [Kaneko, 2000], p. 20). Available science suggests that these time exposures at temperatures reported in waters near Hawaii are conducive to histamine formation (Frank, H.A., et. al., "Histamine Formation and Honeycombing During Decomposition of Skipjack Tuna, *Katsuwonus pelamis*, at Elevated Temperatures," 1981, Marine Fisheries Review 43(10):9-14; and Baranowski, J.D., et. al., "Decomposition and Histamine Content in Mahimahi (*Coryphaena hippurus*)," 1990, Journal of Food Protection 53(3):217-222). It has also been reported that longline-caught fish with elevated histamine levels have been delivered to Hawaii auctions (Kaneko, 2000, p. 33).

The agency has evaluated the scientific support and the proposed research efforts presented in the petition and has concluded that they will not provide the information needed to satisfactorily address the issue of histamine formation and prevention in longline-caught scombrotoxin-forming fish before the fish are landed aboard the harvest vessels. For example, adopting a 20-hour HACCP critical limit for longline sets so as to encompass current industry harvesting practices (section 4.2.7 of the petition) is not an appropriate preventative criterion because current industry practices have resulted in fish with elevated histamine levels as cited above. Also, measuring post-capture, onboard chilling rates of fish (section 5.2.1 and Appendix A, pp. 5-6, of the petition), and measuring the histamine content of random fish with little meaningful pre-boarding history (sections 5.2.1 and 5.2.2, and Appendix A, p. 6, of the petition) will not advance understanding of the potential, or appropriate preventative control parameters for histamine formation in the fish before they are landed on the harvest vessels. To develop appropriate critical limits, the conditions that result in the occurrence of the hazard need to be identified so that the limits can be reliably established safely away from those conditions. Further, to establish that existing conditions do not result in the hazard, the research should focus on the commercial conditions that present the most likely opportunity for the hazard to develop, not a random or average set of operating conditions because the average fish is not scombrotoxic.

Therefore, for the reasons stated above, we are denying your petition.

So that you fully understand FDA's concerns with the actions proposed in the petition, some of our most significant concerns are described in more detail in the enclosed addendum.

Sincerely yours,

John R Taylor (for)

John Taylor
Associate Commissioner
for Regulatory Affairs

Enclosure

Addendum

Review of the Actions Proposed in United Fishing Agency's April 3, 2002, Citizen Petition

FDA is denying the United Fishing Agency's petition requesting enforcement discretion related to the firm's means of controlling histamine formation in scombrotoxin-forming fish upon receipt from harvest vessels. FDA does not believe that the petition's proposed controls or studies sufficiently address the issue of histamine formation in fish that are caught using longline-type harvest methods.

FDA developed the guidance document, "Fish & Fisheries Products Hazards & Controls Guidance: Third Edition" [the Guide], primarily to assist processors of fish and fishery products in the development of their HACCP plans to comply with the seafood HACCP regulation that went into effect on December 18, 1997. Chapter 7 of this guidance addresses the hazard of histamine formation in scombrotoxin-forming fish. Part of this guidance (p. 88) recommends parameters for onboard harvest handling practices that ensure rapid chilling of the fish flesh to inhibit histamine formation from the time the fish dies and is vulnerable to bacterial invasion that results in the potential health risk. The recommendations listed, i.e., take measures within 6 to 12 hours of death of the fish (depending on the type of fish and harvest/handling conditions) to adequately chill the fish to inhibit histamine-forming bacteria, are one set of criteria, or critical limits, that can be used by primary processors (first receivers) of these types of fish to ensure that the fish they receive have been handled in a preventative manner. These criteria include:

All lots received are accompanied by harvest vessel records that show:

- Generally, the fish were:
  - Placed in ice, or in refrigerated seawater or brine at 40°F (4.4°C) or less, within 12 hours of death; or
  - Placed in refrigerated seawater or brine at 50°F (10°C) or less within 9 hours of death and chilling continued to bring the internal temperature of the fish to 40°F (4.4°C) or less;

OR

- Fish exposed to air or water temperatures above 83°F (28.3°C), or large tuna (i.e., above 20 lbs.) that are eviscerated before onboard chilling, should be placed in ice (including packing the belly cavity of large tuna with ice) or in refrigerated seawater or brine at 40°F (4.4°C) or less within 6 hours of death;

OR

- Large tuna (i.e., above 20 lbs.) that are not eviscerated before onboard chilling: The internal temperature of the fish was brought to 50°F (10°C) or less within 6 hours of death and chilling continued to bring the internal temperature of the fish to 40°F (4.4°C) or less;

OR

- Other critical limits for onboard handling (e.g., maximum refrigerated brine or seawater temperature, maximum fish size, maximum fish to brine/seawater/ice ratio, maximum ambient temperature exposure time before chilling) necessary to achieve a cooling rate that will prevent development of histamine in the specific species, as established through a scientific study...

In the Introduction of the Guide, FDA also explains the scope and limitations of the guidance (p. 2) that, in part, states:

> The controls and practices provided in this guidance are recommendations and guidance to the fish and fishery products industry. This guidance provides information that would likely result in a HACCP plan that is acceptable to FDA. However, it is not a binding set of requirements. Processors may choose to use other control measures, as long as they provide an equivalent level of assurance of safety for the product. However, processors that chose to use other control measures (e.g. critical limits) are responsible for scientifically establishing their adequacy.

To the extent that the petition represents the petitioner's selection of alternative control measures and/or intended studies to establish alternative measures to control histamine formation in scombrotoxin-forming fish, FDA has significant concerns. FDA's concerns with the nine-bullet proposed actions summarized on page 12 of the petition include:

1. A critical scientific matter needing to be addressed, as discussed in a phone conference with FDA officials and the petitioner and his research partner, Dr. John Kaneko, on February 25, 2002, prior to submission of the petition, is the degree of histamine formation that might occur in fish that remain dead in the sea for lengthy periods of time after capture and before landing on the vessels using fishing techniques such as longlining. The only two of the nine bulleted actions (bullets #2 and #7) that directly address the outstanding issue concerning longline harvest techniques were deficient for the following reasons.

   Some longline fishing methods that may deploy up to 60 miles of hooks introduce the potential for fish to be hooked and perish at sea for many hours prior to retrieval by the harvest vessel. FDA is concerned that, in conjunction with the time required to chill the fish once brought aboard the vessel, the exposure at sea in tropical environments may provide sufficient exposures for the action of bacteria to produce scombrotoxic fish, or to set the stage by permitting the growth and multiplication of substantial numbers of bacteria and their enzymes for the production of scombrotoxic fish under subsequent nominal time/temperature exposures.

   a. Bullet #2 - Apply *the modified Critical Limit of ≤ 20 hours total for longline set duration.*

      FDA provides a number of recommended timeframe options for harvesters to chill scombrotoxin-forming fish to prevent histamine formation (the Guide, p. 88). The recommended time limits range from as little as 6 hours to as great as 12 hours after death of the fish depending on the species being harvested and the conditions during the harvesting and chilling operations. From our inspectional observations, we know that your firm receives some of the fish (e.g., large tuna,

mahimahi, etc.), and these fish are harvested under some of the conditions (e.g., uneviscerated, exposures ≥ 83°F), that cause greatest concern to FDA and which FDA currently believes may necessitate the more aggressive chilling approaches.

Nevertheless, the petition proposes to adopt a 20-hour critical limit "because this is within the documented maximum set time that produced safe fish in the Hawaii longline fishery." The proposed limit is based on a determination that existing longline practices allow the fishermen to retrieve the fish within 18 hours of death and cites a study (Kaneko, J.J., "Development of a HACCP-based Strategy for the Control of Histamine for the Fresh Tuna Industry," a report to the National Oceanographic and Atmospheric Administration, Award No. NA86FD0067, July 31, 2000, [Kaneko, 2000], p. 8) that you believe demonstrates that Hawaiian longline-caught fish do not pose a high histamine risk.

FDA's seafood HACCP regulation defines a critical limit as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard" (21 Code of Federal Regulations (CFR), section 123.3(c)). It would be inappropriate to adjust or establish the critical limits simply to conform to existing operations without identifying the level at which the hazard occurs and without taking into consideration existing scientific knowledge about the hazard.

The study referenced in the petition (Kaneko, 2000) did an excellent job of confirming that fish handling, once fish were brought aboard the observed Hawaiian hook and line operations, was generally rapid. However, it did not demonstrate that onboard care prevented shoreside landing of fish with elevated histamine levels in fish from longline operations.

The petition suggests that evidence from the Kaneko, 2000, study showed that 276 fish, from 42 longline trips over the course of 14 months, for sale at the petitioner's facility were all below the defect action limit of 50 parts per million (ppm) histamine (section 4.2.6.4 of the petition). However, these data do not account for the researcher's findings associated with 119 "rejected" longline-caught fish delivered to the processor containing as high as 1960 ppm histamine (extremely scombrotoxic) (Kaneko, 2000, p. 33). Instead, the conclusion appears to be based on non-problematic fish, 74% of which were judged by the researcher to be of the best 2 of 5 sensory grades, while discounting delivery of abused and hazardous fish.

Finding that the mean or average fish caught under commercial conditions do not contain high histamine does not show that existing conditions are safe. It is the occasional abused fish, or lot of fish, that, if marketed without proper controls, presents the greatest threat. A properly designed HACCP program should prevent such abuses from occurring or prevent product that has been abused from being distributed to consumers. A study designed to identify the effective critical limits to be used in a HACCP plan should be based on scientific evidence that shows the boundary of the measurable conditions which, if exceeded, results in the hazard. The referenced study did not establish this boundary. It did not

show that scombrotoxin-forming fish could remain dead in the warmest of Hawaiian waters for up to 18 hours, in addition to onboard chill times, without developing elevated histamine levels.

FDA is not aware of any scientific support for the proposed critical limit of 20-hour longline sets. The parameter simply identifies existing industry practices. There is no evidence in the petition that this critical limit is effective at preventing, eliminating, or reducing to an acceptable level the food safety hazard of histamine formation.

b. Bullet #7 - *Conduct the proposed research to further verify the effectiveness of the Critical Limit for Hawaiian style longline sets (≤ 20 hours total set duration).*

The petition includes a May 7, 2001, Statement of Work entitled "Verification of a HACCP System for the Control of Histamine for the Fresh Tuna Industry." The work is a continuation of the Kaneko, 2000, study referenced above and is to be conducted by the same research partner.

As previously discussed with the petitioner and his research partner, further work examining handling practices on longline vessels would be welcome in conjunction with studies planned by FDA to examine the potential for histamine development in scombrotoxin-forming fish prior to being brought aboard the vessel. However, we are concerned that the proposed study appears to be inadequate to provide meaningful data that would be useful in designing scientifically based HACCP critical limits.

For example, the study proposes to collect time/temperature handling and chilling data of fish brought aboard five longline vessels during each of four quarters. It is not clear how the vessels will be selected. It would be desirable to specifically identify vessels known to bring in extremely high quality fish and vessels that bring in marginal or lower quality fish and compare handling practices aboard the two groups of vessels. Sufficient data from five different vessels in each quarter, rather than the same five vessels, would be desirable. It would also be desirable to have researchers on the vessels to make appropriate observations and recordings rather than relying on vessel operators whose skills, training, and focus during harvesting could make it difficult for them to identify important factors that could influence the data.

The sampling design of the study proposes to measure the histamine content of only 12 fish per longline vessel (2 fish per species; 6 species per trip). This is apparently associated with the limited number of data loggers available. Although the cumulative number of data points proposed for the entire study may seem large, the representation as a random collection from each vessel is minimal and the inference of the data would be limited to the fish examined and not a reflection of the entire vessel's catch or groups of fish from the particular catch.

The study proposes to examine only two of each species from each trip, with hopes of selecting one dead fish and one live fish per species. The single resulting data point for any set of variables makes it extremely difficult to

formulate any meaningful science-based inferences. Great caution must be taken in grouping or aggregating data from different vessels on different trips based on selected attributes, e.g., tuna retrieved dead, or large marlin that were slow in cooling, etc., while ignoring other variables inherent in the sampling design. Here again, the proposed study does not focus on fish presenting the greatest risk of histamine accumulation and is not designed to closely examine comparisons of fish under controlled sets of circumstances. Rather, the study will provide data on the histamine content of fish in general, or on average, under general commercial conditions. As stated earlier, this kind of data is not beneficial in identifying conditions that must be controlled to prevent histamine formation and is inappropriate to verify, or establish, the effectiveness of HACCP critical limits.

Additionally, the petition includes some statements and conclusions regarding longline-caught fish derived from data or conclusions in the Kaneko 2000 study that may not be fully accurate and deserve to be addressed. For example, in sections 4.2.6.1 and 2 of the petition (pages 6-7) it states that research results found that longline-caught fish brought onboard dead tended to be on average 10°F cooler than longline fish brought onboard alive, and thus it is concluded that "chilling had begun in the water." However, FDA notes that other factors not discussed in the study could have contributed to the researcher's finding. The temperature of the thermocline and deep water frequently targeted for fishing by longline fishermen is cooler than surface temperatures (buoy data from the National Weather Service shows that sea surface temperatures around Hawaii fluctuate little, maintaining constant temperatures around 77 - 81°F). But, longliners catch some fish during retrieval of their sets. In addition to slightly elevated body temperatures resulting from struggling that has been demonstrated with some tuna, and the spawning of fish, including bigeye tuna, in the warmer shallower waters, fish caught at the shallower depths during retrieval could contribute to some of the live fish having warmer core temperatures than their dead counterparts caught and held at greater depths. Also, the fact that longliners' mainlines do not entirely remain at the targeted depth and that portions have been shown to commonly drift into shallower water could contribute to the significantly greater standard deviations experienced by the researcher for dead fish. In other words, the fish captured dead may have been exposed to various temperatures at various depths other than the targeted fishing depth. The researcher did not provide depth or seawater temperature measurements at depths to support the presumptions or conclusions made.

More importantly, the average core temperature of fish brought onboard dead in the researcher's study was 69°F and judging from the standard deviations, a number of fish were around the 80°F mark. These temperatures, including those of fish caught at great depth, i.e., bigeye tuna, could be conducive to the growth of histamine forming bacteria. Therefore, the data available from the study should not lead one to conclude that the sea provides a natural chilling medium for the preservation of dead fish. If indeed the water was always cold enough to sufficiently begin the cooling process and handling practices on longliners were always sufficiently effective to further chill the fish (as suggested in the referenced study), scombrotoxic fish such as those found by the researcher would not be found at the auction.

It is inappropriate to try to identify conditions that prevent or cause histamine formation by placing greatest emphasis on those fish, i.e., bigeye tuna, that are caught, as the researcher suggests, at the greatest depths with the coldest waters, without consideration of other scombrotoxin-forming species, such as mahimahi and yellowfin tuna, which are also caught by longliners and which epidemiological data suggest deserve greater focus in these studies.

It is worth noting that Table 2 in the petition is not found in the Kaneko 2000 report as referenced and the numbers of fish in the live and dead fish categories do not correspond well to fish in the referenced study. Further, findings of fish with histamine levels up to 9 ppm in the small number of unfocused samples examined are not insignificant. The summarized data provided suggest that time/temperature exposures were conducive to growth and activity of histamine-forming bacteria into the flesh of the fish and that the onboard vessel harvesting and handling conditions should not be ignored.

Moreover, at the beginning of section 4.2.6.1 (page 6 of the petition), a statement is made, "Harvest Vessel Records require measurements of air and sea surface water temperature," which is then contested as not appropriate for fish held at great depths. FDA recommends harvest vessel record measurements of air and water temperatures to which the fish are exposed. This guidance is neither a requirement, nor does it specify sea surface temperatures. The intent of the recommendation is for the primary processor to gather assurances about the conditions of time/temperature to which the fish delivered to his/her facility were exposed. Ambient temperatures at the depths where the fish are captured and held until retrieval would be a legitimate monitoring measurement if available and reliable. If not, harvest vessel operators should monitor the conditions at their disposal, either surface temperatures or down temperatures.

In summary, the issues of the potential for histamine development as a consequence of the longline fishing technique and/or as a consequence of inadequate handling practices aboard the vessels are not sufficiently addressed in the study proposed in the petition.

2. The petition introduces challenges to the science-based parameters for onboard chilling recommended by FDA (bullets #3 and #8). These issues are tangential to the concerns regarding longline harvest techniques that were understood to be the focus of the petition.

   a. Bullet # 3 - *Apply the Critical Limit of placing all histamine-forming fish into ice ≤ 12 hours of death to all fish (including large tuna > 20 lb) unless there is significant exposure to ambient temperatures ≥ 83°F for over 30 minutes.*

      The petition compared two of FDA's recommendations:

      - Chill uneviscerated large tuna at sea to an internal temperature of ≤ 50°F within 6 hours of death (recommended for onboard chilling control, the Guide, p. 88), and

- Ensure that the internal temperature of fish delivered [to the processor] within 12 to 24 hours from time of death is ≤ 50°F (recommended for primary processors upon receipt of the fish, the Guide, p. 89),

and mistakenly concluded that the recommendations are inconsistent (section 4.3 of the petition).

The FDA recommendations for onboard chilling and for internal temperature checks at receipt by the processor are not exclusive and were designed to work together providing the primary processor with indications of control over conditions and operations that could result in histamine formation in the fish delivered to the processing facility.

Nevertheless, the comparison made in the petition misled the petitioner to conclude that FDA's guidance for onboard chilling of fish in general, i.e., to place the fish in ice within 12 hours of death, is prevention enough for large tuna as well. Thus, without presenting appropriate scientific support, and without full consideration of the appropriateness or safety of the measure, the petition proposes to adopt limits that are more workable within the processor's existing operations.

Moreover, a closer examination of the proposed critical limit reveals an inconsistency with the parameters presented within the petition itself, i.e., longliners do not retrieve some fish for 18 hours or more from the time of death. The longline suppliers would therefore be unable to truthfully attest to meeting the petitioner's newly adopted limit of beginning to chill the fish within 12 hours of death.

This proposed HACCP control has no scientific basis and has no practicality to the issue at hand.

b. Bullet #8 - *Conduct the proposed research to further evaluate the relationship between time and temperature parameters and histamine formation in large blue marlin with an emphasis on troll-caught fish.*

This again does not focus on the parameters understood to be the focus of this petition, i.e., histamine accumulation as a consequence of harvest and handling conditions on longline operations.

The petition proposes to determine the commercial chill rates of twenty, randomly selected, large, troll-caught, blue marlin and analyze these for histamine. Using similar logic as in item #2.a. above, the petition proposes to convert FDA's recommended land-based internal temperature indicator to an at-sea handling control limit, i.e., allowing as many as 24 hours to chill large uneviscerated fish to 40°F or less, provided this small, random sample of fish does not display elevated histamine levels.

As with the longline portion of the study, this proposal is not properly designed to determine appropriate safe critical limits for harvesting, onboard handling, or

receipt of these fish. Rather, it is a random sampling of commercial fish with a known time/temperature history.

Previously, the bluefin tuna industry approached FDA with a similar concern about chilling uneviscerated large fish to an internal backbone temperature of ≤ 50°F within 6 hours of death using conventional onboard icing methods. FDA accepted the industry's proposal that proper evisceration combined with proper chilling could be an appropriate alternative control approach. FDA and the industry reasoned that proper evisceration allows the bluefin tuna industry to remove the bacteria-laden viscera and immediately chill the visceral cavity where histamine-forming bacteria are believed to initiate invasion of the fish flesh. While deep flesh near the backbone may not completely chill for quite some time, these regions are not predisposed to bacterial activity for some time, and are further protected by the immediate inhibition of invading bacteria at the surfaces and in the visceral area of properly chilled eviscerated fish. Without evisceration, the difficulty of drawing heat out of the large fish allows the bacteria in the viscera to become active and produce histamine-forming enzymes.

This evisceration approach was included in FDA's revised guidance. However, the petition did not appear to take the evisceration option into consideration.

There are some additional perceptions presented in the petition that deserve to be addressed. In section 4.2.4 of the petition (page 5) a discussion is presented comparing 82.9°F to FDA's recommendation established at 83°F. Similarly, in section 4.2.5.2 of the petition (page 6) a discussion is presented comparing a 21-pound tuna to a 210-pound tuna, to challenge FDA's recommendation established for tuna below 20 pounds, versus those at 20 pounds or above. FDA recommendations are based on available science that is restricted to studies done under controlled conditions at set parameters. Insufficient data disallow FDA from making arbitrary extrapolations. It is not feasible for FDA to develop chilling curves for all species of scombrotoxin-forming species, at all sizes and weights, accounting for all seasonal and regional variables, at all matrixes of time/temperature exposures and initial chilling temperatures, using all available cooling mediums at various chill temperatures. FDA currently does not have the resources to conduct such studies to prepare guidance that is specific to every industry sector under all circumstances. Nevertheless, we encourage industry to conduct scientifically sound studies to better establish limits applicable to their fishing sector under conditions that will include identification of the threshold exposures that result in elevated histamine. The petition's proposed work does not encompass such a study.

3. Three of the issues presented in the petition (bullets #1, #4 and #6) are associated with HACCP controls discussed with the petitioner in a separate forum and are not directly related to the pre-boarding harvest exposures and onboard handling exposures which are understood to be the focus of this petition.

   a. Bullet #1 - *Apply the Harvest Vessel Records Approach*

b. Bullet #4 - *At receiving, continue to apply the recommended Critical Limit guidance* [for internal temperatures of fish at receipt as recommended by FDA].

c. Bullet #6 - *Conduct verification procedures of the Harvest Vessel Records Approach including random sampling and testing of large tuna > 20 lb.*

Discussions associated with these issues would not affect the agency's final decision on enforcement discretion requested in this petition related to the concern about scombrotoxin-forming fish harvested by longline-type harvest techniques. Therefore, discussions on these issues are better left in the context of the other correspondence.

4. The remaining two proposed actions in the petition (bullets #5 and #9) are largely non-controversial and are encouraged by FDA. However, these activities also would not affect the agency's final decision on the enforcement discretion requested in this petition at this time.

a. Bullet #5 - *Monitor Hawaii department of Health Epidemiological reports for the number of histamine cases or incidents during the study period.*

FDA encourages the industry to stay appraised of epidemiological feedback that affects their business. We also encourage the petitioner to communicate with the State and local health departments to ensure active identification and reporting of scombrotoxin illnesses so that a more concise understanding of this problem could be formulated. However, great care must be taken before drawing conclusions from the available epidemiological data.

For example, in the 2000 Kaneko report referenced in the petition, it was pointed out that an evaluation of 459 reported histamine illnesses in Hawaii between 1989 and 1999 found that tuna and mahimahi accounted for 80% of the total number of illnesses. Forty-eight percent of the illnesses were caused by imported fish, mostly mahimahi. The author suggests that recreational and subsistence fishing could have contributed to the number of illnesses.

The author emphasized data indicating that many of the illnesses associated with mahimahi were from imported product. However, further examination of the data shows that 86% of the Hawaiian histamine poisoning outbreaks were associated with domestic fish. Fifty-two percent of the illnesses, i.e., 239 illnesses, were associated with domestic fish. Further, the referenced National Academy of Sciences report, available at http://www.nap.edu/books/0309043875/html/index.html, cautioned that scombroid poisonings were thought to be severely underreported and that reported cases had been on the increase in more recent years of their study. The available statistics are convincing that histamine presents a serious health hazard in Hawaii and supports the need for appropriate controls of commercial practices where the hazard can occur.

b. Bullet #9 - *At the end of the research project...present findings to FDA for a decision on whether to allow the Hawaii fishery to continue to apply the*

modified Critical Limit for longline sets and possibly adopt a new Critical Limit specific for blue marlin.

FDA will be pleased to review all of the methods, data, and findings from pertinent studies. However, FDA believes that the studies as currently described in the petition are inadequately designed to address the issue of histamine formation in fish that are caught using longline-type harvest methods.

Administrative Record

Response to Citizen Petition
Submitted by United Fishing Agency, Ltd.,
Dated April 3, 2002

Docket No. 99D-0392

1. Hilmer A. Frank et al., *Histamine Formation and Honeycombing During Decomposition of Skipjack Tuna,* Katsuwonus pelamis, *at Elevated Temperatures,* 43 Marine Fisheries Review 9-14 (Oct. 1981).

2. John D. Baranowski et al., *Decomposition and Histamine Content in Mahimahi* (Coryphaena Hippurus), 53 Journal of Food Protection 217-22 (Mar. 1990).

3. John Kaneko, Development of a HACCP-based Strategy for the Control of Histamine for the Fresh Tuna Industry, Jul. 31, 2000.