To: Dockets Management Branch - HFA-305

From: Donald W. Kraemer, Associate Director
Office of Seafood - HFS-400
CFSAN

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Re: Docket # 99D-0392

Please find attached a submission to docket # 99D-0392 (Seafood HACCP Transition Policy) that was sent to this office directly. We have retained the original submission and have begun the review. We are forwarding this copy for inclusion in the docket.

99D-0392

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Petition for Transitional Policy

Submitted to:

The FDA Office of Seafood

August 24, 2001

Submitted by

The United Fishing Agency
117 Ahui Street
Honolulu, Hawaii 96813

UNITED FISHING AGENCY, LTD.

117 AHUI STREET
HONOLULU, HAWAII 96813
TEL: (808) 536-2148 • FAX: (808) 526-0137

August 24, 2001

Darlene Almogela
Consumer Safety Officer
FDA San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070

Re: United Fishing Agency's Citizen's Petition for Transitional Policy enforcement discretion based on the July 21, 2001 483 Inspection Report findings.

Dear Ms. Almogela,

The attached document is submitted to you in response to the July 21, 2001 483 Inspection Report of our company. The document describes our understanding and position regarding how we are controlling histamine in fish received directly from fishing vessels. The document also presents recently completed research, two research proposals submitted prior to the July 21, 2001 Inspection Report and our plan of action to resolve this issue.

We ask your assistance in submitting this petition to the appropriate people at the Office of Seafood for consideration.

Thank you for your help.

Sincerely,

Brooks H. Takenaka

Brooks Takenaka
Assistant General Manager
United Fishing Agency

Transitional Policy Request

Submitted to: The FDA Office of Seafood

Submitted by: The United Fishing Agency and the Hawaii Longline Association.

Issue: Control of histamine by primary processors at the receiving step.

Problem statement:

The FDA recently inspected the fish auction facility at United Fishing Agency (UFA) in Honolulu, Hawaii. This inspection resulted in a 483-report identifying a problem with UFA's approach to controlling histamine as a primary processor (first receiver) of histamine-susceptible fish species received directly from fishing vessels. Specifically, the 483-report (July 21, 2001, FEI No. 3000121150) states,

> *"Failure to maintain adequate receiving records for fresh scombroid fish received directly from the harvester. Specifically, the Letter of Assurance (LOA) or the Vessel Standard Operating Procedure (VSOP) that the firm receives from the harvester does not document monitoring information to demonstrate that the internal temperature of the fish is 40° F or less within 24 hours of death."*

All fish caught by Hawaii's troll and handline vessels are alive when brought aboard. The time of death is immediately after the fish is placed on the deck, and chilling these fish to <40° F within 24 hours of death is achievable. Many of the fish caught by Hawaii's dominant longline fleet are dead when brought aboard. Documenting when fish die on the line is not possible without expensive research tools. However, studies on Hawaii's longline fishery have demonstrated that with the current standard fishing and fish handling practices, even fish retrieved after dying on the line do not pose an unreasonable risk of high histamine concentration.

At the crux of the 483-report item above is that fishing vessels (and/or) UFA are not monitoring fish temperatures at sea. Instead, UFA is applying an alternative system that explains proper fish handling and histamine prevention methods to fishermen, and requires a letter of assurance from the fishermen guaranteeing compliance with proper fish handling practices at sea. This is backed up by sensory evaluation of the fish at the time of receiving to cull decomposed fish that have been shown to be more likely to contain a high histamine content than those fish without odors of decomposition. UFA believes this system is effective in controlling histamine risk because of the unique features of the Hawaii fresh tuna industry.

The following explanation describes UFA's approach to resolving this issue and request to FDA Office of Seafood for a transitional policy exemption in the interim period.

Background:

Prior to December 1997 when the FDA Seafood HACCP regulation came into effect, UFA had been struggling to adopt FDA recommendations for histamine controls. These recommendations were the *Histamine Testing Approach* and the *Harvest Vessel Record Approach* described in the first edition of the FDA Fish and Fisheries Products Hazards and Controls Guide (FDA, 1996).

After close examination, neither approach was concluded to be appropriate for the unique function of UFA as a fish auction operation with its close working relationship with fishermen. A detailed critique of these alternatives has been a supporting document of UFA's HACCP Plan since December 1997 and is attached in the Appendices (Kaneko, 1997). This position paper describes the rationale behind the alternative histamine control system implemented at UFA. Applying industry knowledge of how fish are caught and handled at sea, understanding the relative risk of histamine associated with these fish and taking full advantage of the unique relationship in Hawaii between the fishers and the auction company, the Vessel Standard Operating Procedure and Letter of Assurance (VSOP/LOA) system was developed and adopted. The VSOP/LOA system has been in place at UFA and effectively used since December 1997.

To provide scientific support of the VSOP/LOA system, a two-year research study was conducted in Hawaii between May 1998 and July 2000 (Kaneko, 2000). A copy of the final report to NOAA (National Oceanographic and Atmospheric Administration) is attached in the Appendices. The aim of this study was to conduct a detailed hazard analysis of the Hawaii fresh tuna industry by documenting the time and temperature histories of a list of pelagic market species, analyzing the resulting histamine concentrations, and evaluating the relationship between quality indicators and odors of decomposition with histamine concentration to evaluate sensory evaluation as a HACCP critical control measure. The results of this study helped to provide the scientific support of the rationale and effectiveness of the VSOP/LOA system.

The results of the study confirmed that Hawaii fishing fleets (longline, handline and trolling) are capable of meeting key time and temperature targets for handling histamine-susceptible fish species for fish brought aboard alive. For fish brought aboard after dying on the line, the time of death (time zero) could not be determined. However, testing confirmed that at the end of the trip (receiving at UFA) the histamine concentration of fish (monitored with temperature loggers at sea) was below defect action limits regardless of whether fish were dead or alive at the time of hauling.

The study also demonstrated that rejecting fish at the auction with odors of decomposition was a practical and highly effective measure for culling high histamine fish from the market sample. In this study, 583 mixed pelagic fish sampled from the auction floor were subjected to sensory evaluation and tested for histamine concentration. During the study, a special emphasis was placed on accumulating samples from decomposed (odor rejects) that occur at very low frequency in this fishery. Eventually 119 odor rejects were sampled. A total of 14 fish exceeded the defect action limit for histamine. All of these fish were first rejected from auction sales due to odors of decomposition. Based on these findings and supported by industry experience and knowledge, UFA believes that high histamine concentration is not reasonably likely to occur in fish in the Hawaii fishery that pass sensory evaluation. These findings help to support the VSOP/LOA system and provide a better understanding of why histamine is not a more pervasive problem with tuna and related species caught by Hawaii's commercial hook and line fleets and sold through the auction system.

The final report of this study was submitted to FDA Office of Seafood as scientific justification for the VSOP/LOA system. However, the recent FDA 483 inspection report reflects the continued fundamental disagreement between the FDA and UFA concerning UFA's approach to controlling histamine at the first receiving step.

UFA's understanding of HACCP principals guiding its approach to histamine controls on fishing vessels.

- HACCP is focused on prevention of seafood safety hazards that are reasonably likely to occur.

- HACCP emphasizes prevention over end product sampling and testing.

- Hazard Analyses and HACCP Plans should be developed based on the best available scientific knowledge, but with respect for local and industry knowledge and practical experience.

- The FDA Fish Hazards Guide provides excellent guidance, but is not a set of "one-size-fits-all", prescriptive regulations. The guidance should always be held up against local, industry and focused scientific studies and knowledge.

- Hazard Analyses and HACCP Plans must be tailored to special conditions related to the particular fishery, production and market setting.

Key features of UFA and the Hawaii fresh tuna industry.

- Commission-based auction sales link the interests of fishermen directly to UFA. Fishermen and UFA are partners, not adversaries. UFA helps fishermen produce higher quality fish through better fish handling.

- Auction sales focus on high quality fish, where high quality is rewarded with higher prices. When fish harvesting and on-board fish handling practices can make the difference between a tuna worth $17/lb and $0.50/lb whole weight, both fishermen and UFA naturally strive for better handled and better quality fish with low risk of histamine accumulation.

- Fish are caught, handled, graded and sold individually through a display auction with open, competitive bidding. Fish are not sold in large lots, or boatloads where prices are set based on representative lot sampling. Each fish is closely evaluated.

- Buyers have no obligation to bid on, or to buy fish. Therefore, at the point of sale, both seller and buyer have agreed that the fish sold/purchased were acceptable in terms of quality, lack of decomposition and histamine risk factors.

Key differences between UFA and FDA in regard to histamine controls at the first receiving step. UFA believes that,

- The recommended Histamine Testing Approach (FDA, 2001) would be ineffective in Hawaii's hook and line fisheries landing fresh fish and is not an option.
- The recommended Vessel Harvest Record Approach (FDA, 2001) is unsuitable as written for Hawaii's hook and line fisheries and is not an option.
- Hawaii's pelagic fisheries have unique characteristics calling for an innovative approach to histamine control. The VSOP/LOA system is appropriate, effective and supported by scientific and industry knowledge.
- The relative risk of high histamine is a function of fish species, harvesting method, fish handling methods and environmental factors.
- Screening fish for odors of decomposition is a practical and useful tool for culling fish with high histamine content.
- An LOA signed by an American fisherman is at least as reliable as those currently accepted by the FDA from foreign processors and fish farmers.
- Controlling histamine formation requires a focus on prevention through training of fishermen, processors, retailers and consumers.

Discussion

The recommended Histamine Testing Approach (FDA, 2001) would be ineffective in Hawaii's hook and line fisheries landing fresh fish and is not an option.

The histamine testing approach currently recommended by the FDA appears to be designed for larger scale, net fisheries (purse seine caught tuna) supplying fish to tuna canneries. The new version of the Histamine Testing Approach calls for establishing fish lots by species. For Hawaii's longline fishery that lands and markets at least 10 different species of histamine-susceptible fish, the creation and testing of numerous lots would be prohibitively time consuming, costly and most likely unnecessary. As written, the testing method would encourage discards and waste of the resource as fishermen are forced to consider the reduced economic incentive of retaining the fish they hook based on testing requirements. This is counter to international and domestic efforts to promote sustainable and responsible fishing practices. If 18 fish per lot or species were sampled multiplied by 10 different species, 180 histamine samples would need to be collected for testing each longline vessel delivery. Even if composited, the cost and time required for testing would be prohibitive for a fresh fish auction.

Beyond these factors are the fundamental differences between hook and line fisheries and large volume net fisheries using purse seines. Hook and line fishing methods such as longline gear, catch fish individually, with unique hooking times and time and temperature histories. This makes representative sampling ineffective in all but cases of extreme departure from conventional fishing and fish handling methods where a high percentage of the fish are temperature-abused. Other differences have been described in the supporting document by Kaneko (1997) included in the Appendices.

The recommended Vessel Harvest Record Approach (FDA, 2001) is unsuitable as written for Hawaii's hook and line fisheries and is not an option.

The new version of the Vessel Harvest Record Approach provides monitoring requirements for fishing vessels at sea. One significant change is that the primary processor can now report certain harvest data on behalf of the fishermen at the time of receiving the catch. This approach encourages processors to complete monitoring records without specific data and without their actual knowledge. This encourages a meaningless paper exercise, degrades the efforts to apply HACCP and does nothing to improve food safety.

The reliability of vessel harvest records collected by fishermen would certainly be questioned. Understandably, fishermen are wary of what they perceive as unreasonable record keeping burdens imposed by government regulations. It is more common for industry-generated data to be collected and used against fishermen. For example, when the Hawaii longline fleet was required to report the limited interactions with protected species, NGO's and government agencies were quick to implement restrictions on fishing to avoid infrequent protected species interactions. This occurred even when it is known that some unregulated foreign fleets have far greater negative impacts on the same protected species. This has allowed foreign fleets with no reporting requirements to displace American fisheries products in the US market because of an imbalanced application of environmental protection laws. This is a form of non-tariff trade barrier in reverse.

It is not in the interest of fishermen to report that fish were mishandled. As an example, longline fishing vessel crews are required by federal regulation to fill out detailed catch logbooks. While requiring self-monitoring, the government (NOAA/NMFS) inherently distrusts the fishermen and in response operates an extensive and costly observer program to verify the discrepancy between logbook data completed by fishermen and data recorded by federal observers. The forgone conclusion has always been that fishermen will generate whatever data is required to demonstrate compliance. This begs the question on wasting limited resources on an additional program that will be ineffective in generating accurate data and may do nothing to improve food safety.

Hawaii's pelagic fisheries have unique characteristics calling for an innovative approach to histamine control. The VSOP/LOA system is appropriate, effective and supported by scientific and industry knowledge.

No other location in the US receives fresh tuna and associated pelagic fish from longliners, trollers and handliners and sells the landings through a display auction system. Hawaii has a long cultural history of catching and eating high quality fresh tuna and related pelagic fish. Local experience and knowledge of pelagic fisheries and fisheries products is highly developed. As an example, the Hawaii fresh tuna industry was concerned about the FDA position and misperception of a serious parasite hazard from eating raw tuna species when the agency presented its proposal for the HACCP program. This led the State of Hawaii to fund a study to provide the scientific evidence that supported local knowledge about parasite hazards (Kaneko and Bartram, 1994). The scientific literature demonstrated that there was no evidence that any of the large tuna species harbor parasites of public health concern or had caused a single case of human parasitism. Had a needless freezing requirement been implemented, this would have been a serious economic blow to the Hawaii and other fresh tuna fisheries supplying the US market.

Local knowledge based on long-term experience and backed by scientific evidence has also led UFA to develop and implement the VSOP/LOA approach to controlling histamine on fishing vessels. To our knowledge there is no evidence that fish produced by the commercial fleets in Hawaii sold through the UFA auction are posing a significant health risk due to histamine. While histamine cases are reported in Hawaii, these are more likely to have been caused by imported fish, fish sold through alternate channels or fish caught in Hawaii's extensive recreational fishery. We also do not have any reason to believe that the histamine risk in fish caught by our commercial fleets has increased since the implementation of the VSOP/LOA system in late 1997. In fact, because of the diligent work of the HACCP team at UFA, our fishermen now have a greater understanding of how to prevent histamine and produce higher quality fish and greater economic returns to the vessel than prior to HACCP.

The relative risk of high histamine is a function of fish species, harvesting method, fish handling methods and environmental factors.

The revised fish handling guidelines for harvesting vessels for the control of histamine appear to be a guidance program meant to be suitable for all histamine forming fish species under all circumstances. As such, they are inherently restrictive to cover the highest risk situations and species. Susceptibility of histamine formation among the tuna species is variable. Histamine formation in albacore tuna is less likely under the identical conditions than other species such as skipjack and yellowfin tuna. The method of capture also has an influence on the initial body temperature and physiological condition of the fish at the beginning of on-board handling. This in turn influences the magnitude of the required temperature drop needed to control bacterial growth and histamine formation. Tunas caught on trolling and handline gear are all retrieved alive and with internal body temperatures exceeding surface water temperatures. By contrast, longline fish caught and retrieved alive are retrieved with body temperatures significantly lower than surface water temperatures.

Fish caught on longline gear that are retrieved after dying are significantly cooler than fish retrieved while alive because the dead fish are hooked and die at depths where the water temperature immediately begins the initial cooling period. It is estimated that the water temperature at the hooking depth for these fish is near 60° F. Scientists at the NMFS Honolulu Laboratory are compiling and summarizing important data collected by water temperature/depth recorders (TDRs). Greater detail and analysis of these data are anticipated. Kaneko (2000) determined that the temperature of longline fish retrieved alive averaged 79° F, while those retrieved dead were 69° F indicating that significant cooling had occurred while the fish were dead in the water. This helps to explain why fish caught by Hawaii longline vessels do not pose a greater potential histamine hazard than predicted by the FDA hazards control guidance.

Screening fish for odors of decomposition is a practical and useful tool for culling fish with high histamine content.

The VSOP/LOA system utilizes the concept of standardizing operating procedures, training of fishermen on proper fish handling practices and collecting a letter of guarantee that these proper procedures were applied. This system is useful and successful in Hawaii because UFA and the buyers all have an opportunity to judge the quality of the fish and screen for indicators of decomposition at the auction before purchase. Hawaii-based studies have demonstrated that odors of decomposition are reliable and practical tools for culling high histamine-risk fish from the marketing channels.

In the NOAA/SK funded study, Kaneko (2000) evaluated, sampled and tested 583 chilled pelagic fish for quality grade, odors of decomposition and muscle histamine concentration. A total of 14 fish were found with histamine concentration exceeding the 5 mg % defect action limit. All of these fish were first rejected from the market because of odors of decomposition. These findings support industry knowledge and provide evidence that screening for decomposition is the practical tool for culling high histamine fish from the market. In response to the continued concern expressed by the agency about the VSOP/LOA system, a research proposal was prepared and submitted to NOAA/SK for funding to further verify the scientific foundation of the VSOP/LOA system. A copy of this proposal is included in the Appendices.

An LOA signed by an American fisherman is at least as reliable as those currently accepted by the FDA from foreign processors and fish farmers.

A signed LOA is written documentation of a person's word. While the word of major suppliers of seafood to the US market is currently accepted, the word of American fishermen is apparently not. For example, to control the concentration of residual antibiotics in farm-raised fish, the farmer provides an LOA giving assurance that antibiotics were not used in the growing cycle or that proper withdrawal times were met. This LOA suffices as a HACCP critical limit for processors receiving fish directly from fish farmers without reviewing monitoring records.

US seafood importers are required to take affirmative steps to ensure HACCP compliance by their overseas suppliers. One accepted set of affirmative steps for importers is Option D, that requires the importer to have a copy of the exporter's HACCP Plan on file, a signed seafood product safety specification form on file and an LOA giving assurance that the fish in the shipment were handled according to the HACCP Plan on file and meet the product specifications. The receiver is not required to review supplier's monitoring records.

These are two examples where the word of the farmer/producer/shipper in the form of an LOA serves as a key component of an acceptable HACCP Plan. There is general concern about the equal application of the HACCP regulation, which favors one industry sector over another and especially foreign producers over American fishermen and companies. In the above two situations, the word of the domestic and overseas fish farmer and the fish exporter in the form of a signed LOA, suffices as a HACCP food safety measure. The analogy with the VSOP/LOA system is a very close fit. However when applied to American fishermen, their word and their LOA is not accepted as a food safety measure. Perhaps what is needed is to have Hawaii fishermen also sign a seafood product safety specification form to be kept on file.

Effective control of histamine formation requires a focus on prevention through training of fishermen, processors, retailers and consumers.

If we conclude that the harvest data collected by fishermen will likely be less than accurate, and the FDA concludes that the word of the Hawaii fishermen in the form of an LOA is meaningless; we must look for an alternative approach. The VSOP/LOA serves as a constant reminder of the proper on-board fish handling practices that are necessary to effectively control histamine accumulation. The VSOP/LOA approach is focused at resolving the root of the histamine problem in all fishery settings; the lack of understanding of how histamine forms and how to prevent its accumulation.

UFA managers routinely consult with their fishermen on how to improve fish quality and returns through proper fish handling. This also helps to reduce histamine risk in fish delivered by these fishermen. Training workshops have also been conducted for fishermen to help them understand their responsibility in controlling histamine formation and at the same time improve their own economic bottom line. A more comprehensive fisherman's training program has been proposed to the USDA for possible funding support (Kaneko, 2001) and is presented in the Appendices.

Why we believe the VSOP/LOA system is effective.

The fish auction serves as a marketing agent for the fishermen. In this respect, the interests of the auction and the fishermen are directly linked. The higher the quality of the catch, the greater the value and auction commission. At this time, every fisherman who sells fish through the UFA auction has signed a VSOP (on file) and signs a LOA each time fish are delivered. This close connection with fishermen is not common in the fishing industry, where buyers or primary processors and fishermen are more often at odds over fish quality assessments and prices. This adversarial relationship creates distrust and is not conducive to improving fish quality and food safety. In this type of situation which may be the norm elsewhere, the vessel harvest records approach is not viable and histamine testing may be the only way try to address the histamine issue.

Hawaii fishermen understand the interrelationship between financial returns to the vessel, the price of fish received, the quality of fish delivered and proper fish handling at sea. Without good fish handling practices at sea, fishermen cannot succeed in the Hawaii market. By focusing on preserving quality, Hawaii fishermen at the same time control conditions that allow histamine formation. This is why the VSOP/LOA system is effective when supported by sensory evaluation for decomposition. Rejecting decomposed fish from the market is a strong incentive for fishermen to re-evaluate the length of fishing trips and handling procedures to control this economic loss.

Keeping with our belief that histamine formation can only be controlled when fishermen and all others in the processing, distribution, marketing and consumer chain understand its cause and how simple prevention is, we are focusing on training. To strengthen the VSOP/LOA system, we are considering a mandatory training program for fishermen. To accomplish this, we are supporting an effort to obtain funding to conduct a training program for Hawaii fishermen on the VSOP/LOA system, on how following the VSOP will help to improve fish quality and returns to the vessel and at the same time control histamine accumulation. We may consider using the presence of fish rejects for decomposition in any delivery as a critical limit at the first receiving step, triggering an additional training (corrective action) for the vessel crew.

What we propose to do.

- Continue to apply the VSOP/LOA system at UFA.
- Add a Seafood Product Safety Specification (SPSS) form requirement for each vessel supplying fish to UFA.
- Support a proposal to verify specific issues that form the foundation of the VSOP/LOA system.
- Support a proposal for training for fishermen on histamine formation and controls to strengthen the VSOP/LOA system.
- Conduct random histamine sampling and testing of fish from the auction floor to verify that the VSOP/LOA system continues to be effective.
- At the end of the studies, re-evaluate the VSOP/LOA system.
- If the study supports the VSOP/LOA system, we will keep it in place.
- If the study does not support the VSOP/LOA system, we will modify accordingly.

Hawaii industry and government cooperative effort.

This response reflects the views of not only UFA, but also the **Hawaii Longline Association (HLA)**. A workable solution cannot be made by UFA in isolation and requires active participation by the fishermen who are also impacted. The HLA is the industry organization representing Hawaii's substantial pelagic longline fishing fleet. Membership includes all of the active vessels among the 165 registered longline vessels permitted to fish in Hawaii's limited entry fishery. HLA President, Mr. Sean Martin has provided a letter of support for this request for a transitional policy exemption. In addition, the **Western Pacific Regional Fishery Management Council (WESPAC)**, the government agency charged with management of the fisheries of Hawaii and the rest of the US Pacific Islands has been made aware of the importance of food safety issues and HACCP regulations on the fisheries under its jurisdiction. WESPAC's Executive Director, Ms. Kitty Simonds has provided us a letter of support for this transitional policy request. **The National Marine Fisheries Service (NMFS) Honolulu Laboratory** provides WESPAC with fishery research of importance to the management of the Hawaii, American Samoa and Guam fisheries. Pelagic fisheries specialists at NMFS (pelagic fishery biology, fishing methods and economics) have been contacted and alerted to the key HACCP issues facing the Hawaii pelagic fishery. **The working group made up of UFA, HLA, WESPAC and NMFS** represents the level of industry and government cooperation in Hawaii aimed at managing and sustaining our pelagic fisheries. This working group is already addressing key fishery management related issues and supporting efforts on histamine controls by Hawaii tuna vessels. This working group will cooperate to resolve the issue of histamine controls by fishing vessels and assist UFA in keeping the FDA Office of Seafood updated on our progress.

References

FDA, 1996. Fish and Fisheries Products Hazards and Control Guide (1st ed.)

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Kaneko, J.J. and P. Bartram 1994. The Wholesomeness of Raw Tuna: Are parasites a public health hazard? Part 4. Critical review of FDA position on parasite hazards in tuna. A critical Review of the newly proposed FDA HACCP System for the seafood industry: The Hawaii Industry Perspective. DBEDT, State of Hawaii pp 46.

Kaneko, J.J. 1997. Rationalization of HACCP for the Fresh Tuna Industry: The Hawaii Approach to Controlling Histamine Problems. A Position Paper. In: The Development and Practical Application of a generic HACCP Model for the Hawaii Seafood Industry. Dept. of Business, Economic Development and Tourism, State of Hawaii.

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Kaneko, J.J., J.W. Bell and A.S. Hodgson 2001. Proposal to USDA/CREES Program. Training program development to strengthen seafood HACCP systems (histamine). Submitted May 8, 2001.

117 Ahui Street, Honolulu, Hawaii 96813

August 20, 2001

Akira Otani
President
United Fishing Agency
117 Ahui Street
Honolulu, Hawaii 96813

Re: Letter support the UFA Transitional Policy Exemption request

Dear Mr. Otani,

The Hawaii Longline Association (HLA) recognizes the need for close cooperation with UFA in efforts to reach compliance with FDA Seafood HACCP regulations. We believe that UFA continues to serve the HLA and other Hawaii commercial fishermen not only in providing an excellent marketing service, but also in advocating for safe, high quality Hawaii seafood products.

We have reviewed the UFA Transitional Policy Exemption request to the FDA regarding the UFA approach to controlling histamine in our fishery products. We believe the VSOP/LOA system is effective and provides the industry and consumer with a wholesome, high quality seafood product. We support the efforts to further demonstrate the effectiveness of the current VSOP/LOA system and stand behind the safety and quality of our catch.

Thank you for your continued concern about the well-being of our industry.

Sincerely,

Sean Martin
President

Western
Pacific
Regional
Fishery
Management
Council

August 20, 2001

Akira Otani
President
United Fishing Agency
117 Ahui Street
Honolulu, Hawaii 96813

Re: Letter of Support for the UFA Transitional Policy Exemption

Dear Mr. Otani,

The Western Pacific Regional Fishery Management Council is responsible for the management of the US Pacific Island fisheries. This responsibility includes establishing fishery management policy with the overarching objective of sustaining fishery resources and maintaining US fishing industry access to sustainable fisheries in the Western Pacific.

FDA Seafood HACCP regulations present another important facet to our task. We are committed to participating with UFA, HLA, NMFS and the Hawaii seafood industry to help the pelagic fishery reach a workable and practical solution to controlling histamine accumulation in susceptible harvest species. I have read the transitional policy exemption request to FDA and support the UFA/HLA position.

Sincerely,

Kitty Simonds

Kitty M. Simonds
Executive Director

A Council Authorized by the Magnuson Fishery Conservation and Management Act of 1976
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Rationalization of HACCP for the Fresh Tuna Industry: The Hawaii Approach to Controlling Histamine Problems.

A Position Paper.

J. John Kaneko MS, DVM
PacMar, Inc.
October 30, 1997

Identification of the Problem.

Histamine is the single most important public health issue facing Hawaii's fresh tuna industry today. Consumers of fish containing elevated concentrations of histamine (and other related amines) experience what have been called pseudo-allergic reactions. Bacterial enzymes convert free histidine to histamine. Histidine is an amino acid which is found in naturally high concentration in susceptible fish species. Histamine intoxication has also been called *"scombroid fish poisoning"*, however non-scombroid fish species are also implicated.

Fresh tuna, mahimahi and bluefish are the most frequent cause of histamine intoxication from seafood in the US (NAS, 1991). These fish species and others require special care in order to prevent histamine formation. Improper post-harvest handling which results in delayed cooling is known to be the primary cause of histamine formation. This problem is preventable with rapid chilling and strict temperature control from the time of harvest at sea to the final consumer.

The US Food and Drug Administration (FDA) is implementing a HACCP-based (hazard analysis critical control point) mandatory seafood inspection program which becomes effective December 18, 1997. The FDA recognizes histamine formation as one of the most serious public health problems related to seafood consumption in the US. This new program will require fishing vessels, processors and marketing channels to provide assurance that proper handling and storage procedures are applied in order to reduce the likelihood of histamine formation as well as other public health hazards.

The following discussion presents the background and rationale for the Hawaii Approach to histamine control which is designed to be a practical HACCP-based system appropriate for use by the fresh tuna industry.

Industry Responsibility

Although government efforts have assisted in providing HACCP training for industry personnel, the development of generic HACCP Plans and making recommendations for the implementation of HACCP, the FDA cautions that industry must take responsibility to determine if the recommendations are actually appropriate for their operations. **The new regulation is not a prescriptive program and only provides guidelines for compliance.** The industry must make an effort to implement the most appropriate HACCP system based on their individual circumstances. The HACCP systems must be able to provide reasonable assurance of seafood safety.

The industry is free to develop alternative strategies so long as they can demonstrate an adequate degree of control and safety. The development of specific strategies for individual companies and industry sectors, remains the responsibility of industry (Spiller, 1997). Following the recommendations of the National Academy of Sciences (1991), the Hawaii Approach is designed as a multifaceted approach that,

- incorporates standard industry practices and regulation
- controls harvesting and distribution methods
- recognizes the importance of education efforts

Assigning Relative Health Risks

Public health risk from seafood is unevenly distributed by fishing methods, fish source and by consumers. In Hawaii, most cases of seafood illness are attributed to recreationally caught or imported seafood products (NAS, 1991). For this reason, the strategy has been developed which recognizes the relative risk factors and applies control efforts accordingly.

Histamine can be controlled by applying the principles of HACCP and focusing on proper post-harvest handling controls. The National Academy of Sciences (1991) Committee on Seafood Safety recommends that histamine levels be monitored only as a last resort in susceptible species where proper post-harvest handling cannot be ensured. This committee recognizes that the risk of histamine in seafood is related not only to species, but also related to product source, product form and harvest method. For example, imported frozen mahimahi was identified as the cause of 47% of all histamine cases from seafood in the US. In Hawaii, seafood safety risks and hazards are being assigned which are species, product, source and capture method specific.

The Importance of Fishing and On-board Handling Methods

In industrial scale tuna purse seining and canning operations, processors routinely screen tuna deliveries by **lot sampling**, where a representative number of fish are tested for histamine (Figure 1). Intensive lot testing is conducted in lieu of having vessels provide detailed on-board handling data to the processors. Fish are caught in very large purse seine nets (up to 400 T fish per set) and subjected to relatively uniform post-harvest handling conditions using refrigerated seawater cooling and brine freezing systems (USTF, 1995). Lot sampling programs are effective for industrial scale operations where fish lots are related to fish storage wells and may range from 40 up to 90 tons of frozen fish per lot. Fish lots can easily be sampled and tested for histamine levels by quality control personnel. This intensive system of lot sampling and testing is highly effective and has made canned tuna an extremely safe seafood product.

By contrast, the fresh tuna industry differs in many significant ways which make the lot testing protocol inappropriate and ineffective (Figure 1). Fresh tuna are caught by hook and line fisheries including longline, handline and trolling gear. Fish are caught individually and handled with great individual care because of the direct linkage between careful post-harvest handling, fish quality and dockside price. For this reason, fishing and handling methods are significant factors when assigning relative risk of high histamine levels. The application of lot sampling methods to hook and line fisheries is inappropriate because fish are caught, handled and sold individually. This recognition is critical to the development of a rational approach to dealing with the potential for histamine formation in fresh tuna, mahimahi and other susceptible species from hook and line fisheries.

Figure 1.

Comparison of Fishing and On-Board Handling Methods

Fishing Gear	Cooling Method	Catch and Handling	Stored and Delivered	Lot Size
Longline	Ice, some with refrigeration	Individually	Fresh	1 fish
Handline	Ice	Individually	Fresh	1 fish
Trolling	Ice	Individually	Fresh	1 fish
Purse Seine	Refrigerated seawater and brine freezing. Dry storage in refrigerated wells.	Sets can exceed 300 T. Wells 40-90 T.	Frozen	40-90 T. 4000 to over 9000 fish.

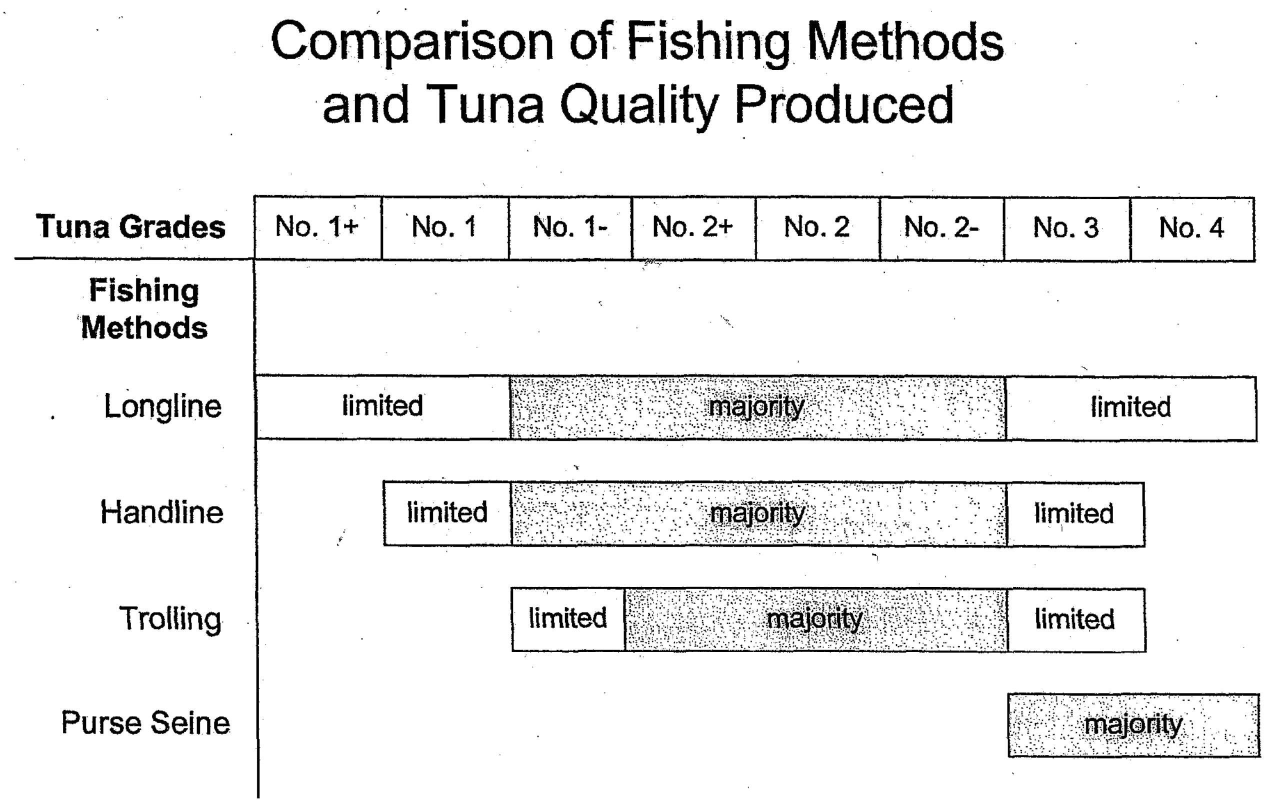
FDA assumption about Fish Quality and Histamine.

The FDA in its *Fish and Fishery Products Hazards and Controls Guide* (1996) states that sensory evaluation of tuna quality is not an adequate indicator of histamine. This is because histamine can be formed in some cases without associated indicators of bacterial decomposition (odors). What is at issue is the actual range of tuna quality on which this observation has been made.

Fishing and On-board Handling Methods determine Fish Quality

Fish quality is dependent upon the fishing method and especially the immediate post-harvest handling and storage period. This is particularly true of fresh tuna which is prized for its bright red color. Tuna color is a primary quality determinant and the red pigments in tuna muscle are extremely sensitive to temperature and biochemical changes associated with post-mortem conditions. Proper post-harvest handling prolongs the period of time that the tuna muscle retains its red color and delays the onset of changes which result in brown color and lower quality grades. In the case of hook and line fishing methods, the product is generally destined for the fresh market. The individualized care each fish receives is responsible for the high quality and high value of fish landed in Hawaii. Fish landed by these methods are suitable for the fresh market from the grilling grades up to the highest sashimi quality grades (Figure 2).

Figure 2.



In sharp contrast, purse seine caught fish are handled in large lots and brine frozen. The resulting quality of fish is generally only suitable for canning raw material and not for fresh market applications. The capture, chilling, freezing and storage methods on seiners also create a higher risk for histamine formation than with the hook and line gears.

Fresh Tuna Quality Grades and Histamine.

Fresh tuna quality grading in the Hawaii Seafood Industry goes far beyond simply detecting odors of decomposition and is actually applied at a completely different range on the quality spectrum. Figure 2 displays the fresh tuna quality grades produced by the different fishing methods. The key is that previous statements about fish quality and histamine appears to have been made based upon purse seine caught tuna which never actually reach above the No. 3 quality grade.

In the fresh tuna business, tuna quality grades can be used as reliable indicators of histamine risk because these grades are much higher in quality and quality grading is capable of detecting significant mishandling on-board the fishing vessel. This standard industry practice provides a high degree of seafood safety.

In order to produce the higher fresh tuna quality grades (No. 2- and better), fish must be carefully handled on-board, chilled rapidly and stored at 32°F under ice. The estimated time/temperature abuse necessary to develop toxic levels of histamine, cannot simultaneously result in higher fresh tuna quality grades. Therefore, we conclude that the fresh tuna quality grading system that is already in place as a standard industry practice, can be extremely useful as a practical screening tool for histamine.

Fish that meet the No. 2- quality grade standard should be considered safe in terms of histamine. The No. 3 fish must be considered suspect, however, there is evidence that even this fish when caught on longline gear and stored in ice is unlikely to have high histamine levels. It is the No. 4 quality fish which must be considered suspect and higher risk.

Supporting Epidemiological Evidence

Epidemiological evidence indicates that in Hawaii, most cases of histamine poisoning are caused by recreationally caught and imported fish (NAS, 1991, Mits Sugi, Hawaii Dept. of Health Epidemiologist, personal communication, 1997). Commercial troll, handline, pole and line and longline caught fish are rarely implicated. These fleets routinely deliver fish in the No. 3 and better quality grades and on-board handling practices are very good overall. In Hawaii, fresh longline caught No. 3 tuna are routinely sold and utilized in the local fresh seafood market trade in retail and restaurants. These markets do not report a high incidence of histamine problems and do not consider these fish to be high risk.

In Guam, processors of fresh, longline caught No. 3 tuna routinely have their product tested for histamine as the product enters the European market. After 3.5 years and an estimated 350 tons of fresh No. 3 tuna sold, the shipments have passed inspection with an average histamine level of less than 20 ppm, often less than 1 ppm. This operation carefully grades fresh tuna and selects fish with in what it considers a safe quality range in terms of histamine (Hawaii Fish Distributors, Inc., 1997). This evidence leads us to conclude that the No. 3 grade of tuna caught by longline gear is unlikely to have elevated histamine levels.

Importance of Standard Industry Practice for Post-harvest Handling

The HACCP concept is well suited for application as a process Quality Assurance (QA) program in the fishing industry. HACCP depends on the careful monitoring of critical control points and the application of best practices or standard operating procedures. Recommendations for proper on-board tuna handling methods have been published (Craven et al, 1995, USTF, 1995, Price and Melvin, 1994, Nakamura et al, 1987, Burns, 1985). Many of the recommendations are considered standard industry practice at this time. Industry has made significant market-driven improvements in on-board handling methods to improve the quality and value of the landings.

QA on-board fishing vessels is the critical initial step in the quality chain (Andersen, 1997). In order to develop a system which can be applied to the fresh tuna industry, certain key information is required. Studies on histamine formation in skipjack tuna held at various high temperatures have been conducted in an effort to simulate fishing and on-board handling practices (Frank et al 1981, 1983). Studies on fresh albacore tuna have been conducted which compared on-board handling methods for cooling rates and corresponding histamine levels (Craven et al, 1995).

Fishers in Hawaii tend to pay close attention to careful, efficient rapid initial processing and chilling of tuna and related species. The fish are quickly stunned, bled and placed immediately into ice or ice slurry for initial chilling. Special attention is placed on keeping the fish properly iced. Only with special attention to proper icing are fishers capable of delivering a high percentage of high quality and value fish. The Hawaii Approach to histamine control depends on documenting, verifying and promoting standard operating procedures on-board vessels in order to assure product safety. This is extremely important in recognition that it is the initial stages of product handling that sets the quality "time clock" in motion and that most quality and safety issues must be first controlled at sea.

HACCP Histamine control measures recommended by FDA

The FDA has made recommendations on how seafood processors might deal with the issue of histamine. Crucial to the FDA strategy is the use of lot sampling and histamine testing, detailed temperature histories for fish while on-board fishing vessels and sensory evaluation. Fishing vessels must demonstrate that fish were initially chilled to below 50°F within the first 6 hours and then from 50°F down to below 32°F within an additional 18 hours. The goal is to drop the fish temperature to 32°F within the first 24 hour period. The first receivers must review fish handling and temperature records, measure unloading temperature and evaluate the fish for sensory evidence of decomposition. Entire lots of fish are rejected if the rejection level exceeds 2.5%. If vessel records are not provided, lot sampling and histamine testing is required.

Other factors affect temperature control and histamine production.

Standardized temperature/time handling parameters while ideal for management purposes, may not be universally appropriate across fish species, source and capture methods. Figure 3 compares fish species, fish size, initial cooling method and the time required to reach internal fish temperature goals. The use of *ice brine* or *slurry* is thought to be the optimum method for the initial cooling period for fresh tuna. Ice brine is significantly more efficient at heat transfer than ice alone.

Even with optimum fish handling, fish size also plays a significant role in determining the rate of cooling. Consider the giant bluefin tuna. These fish are the highest valued fish in the world and single fish have exceeded $80,000 selling at auction in Japan for over $111/lb to the first receiver. This phenomenally priced fish species receives optimum care because improper post-harvest handling can easily reduce the price of these fish to less than $0.50/lb if the fish is mishandled and the resulting quality is significantly compromised. Using ice brine, it is estimated to take 48 hours to chill a large bluefin tuna to 40°F. The point being that these fish routinely exceed the FDA recommendation of chilling to 32°F within 24 hours and yet are the highest price fish in the world and are not likely to have elevated histamine levels. Clearly, additional research on proper chilling methods and rates in fish species needs to be supported.

Figure 3. Fish size and Cooling rates

Fish	Size	Cooling	°T goal	Time	Source
albacore	12 lbs	ice brine	40°F	4 - 5 hrs	Craven et al, 1995
albacore	20 lbs	ice brine	40°F	6 - 7 hrs	Craven et al, 1995
yellowfin	66 lbs	ice brine	32°F	12 hrs	Yoshimura, 1987
yellowfin	132 lbs	ice brine	32°F	16 hrs	Yoshimura, 1987
yellowfin	176 lbs	ice brine	32°F	20 hrs	Yoshimura, 1987
yellowfin	150 lbs	ice	32°F	24 - 48 hrs	Nakamura et al, 1987
bluefin	660-880 lbs	ice	40°F	120 hrs	Yoshimura ,1987
bluefin	660-880 lbs	ice brine	40°F	48 hrs	Yoshimura, 1987
suscep-tible fish	all sizes	all methods	50°F	6 hours	FDA, 1996
suscep-tible fish	all sizes	all methods	32°F	24 hours total	FDA, 1996

The present level of understanding of the factors influencing histamine formation is not fully developed. As displayed in Figure 4, reports on histamine formation are extremely varied. It is estimated that it can take up to 10 hours at 100°F to produce elevated levels of histamine in skipjack (20 ppm) and action levels (50 ppm) would take longer (Whetstone, 1996) whereas much higher rates of histamine formation are also reported (Frank, et al, 1983, Patterson and Burns, 1984). Time and temperature are not the only factors involved as empirical evidence exists where large albacore (40 lbs +), stored at ambient (tropical, 85 to 90°F) temperature for 10 to 12 hours are routinely landed and processed without elevated histamine concentration. There is very recent evidence that troll caught albacore held unrefrigerated (60 to 75°F) for over 24 hours resulted in negligible histamine levels (< 4 ppm) (Dr. Haejung An, personal communication 1997). Histamine formation is not simply a matter of time and temperature, but must also include other variables, such as species, fish size, cooling method, sanitation, the type of bacteria involved, etc.

Figure 4. Fish storage temperature and histamine production.

Fish	Storage °T	Time	Histamine	Source
skipjack	100°F	10 hrs	20 ppm	Whetstone 1996
albacore	90°F	6 hrs	unsafe level (?)	FDA, 1994
albacore	75°F	24 hrs	<4 ppm	Ben-Gigirey et al, 1997
skipjack	85°F	12 hrs	500 ppm, toxic level	Frank et al, 1983
skipjack	85°F	6 hrs	500 ppm, toxic level	Patterson and Burns, 1984
skipjack	70°F	24 hrs	unsafe level (?)	FDA, 1994
skipjack	40°F	400 hrs	20 ppm	Whetstone 1996

The Logic and Rationale of the Hawaii Approach to controlling histamine.

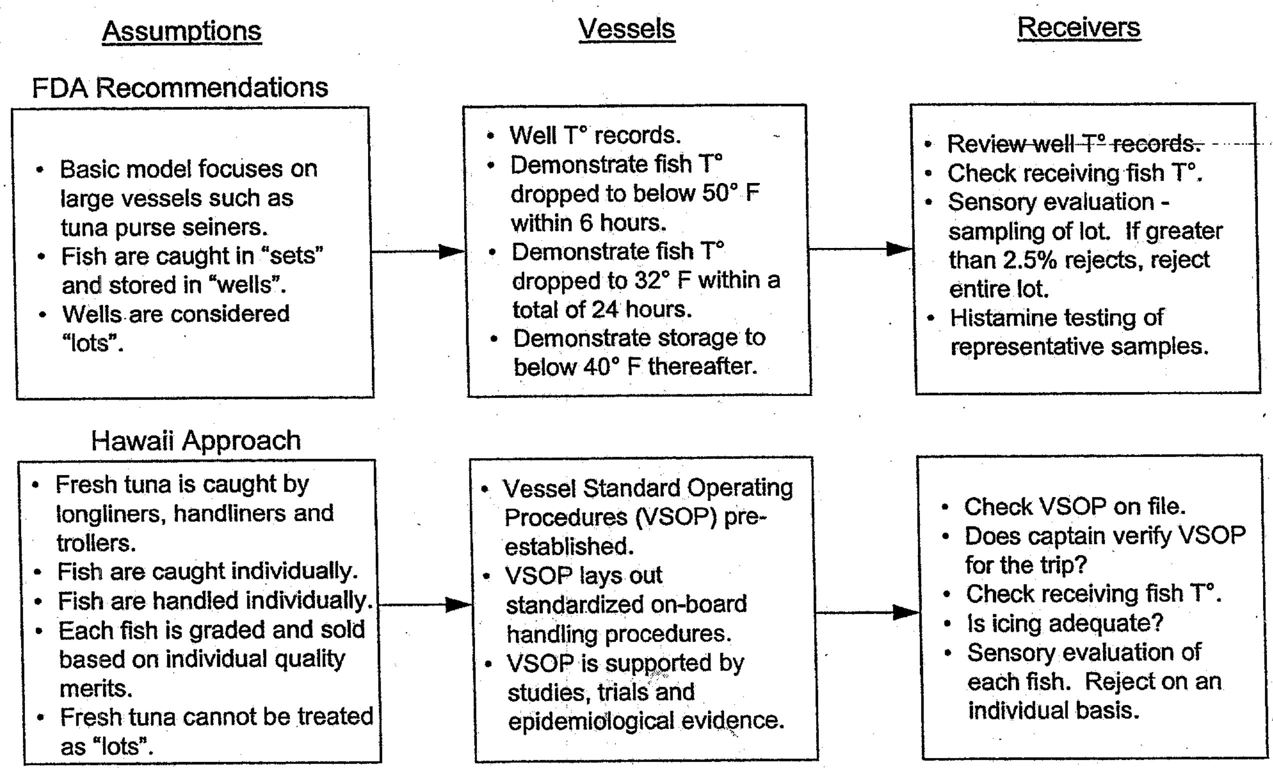
Figure 5 makes a comparison of the two strategies for controlling histamine in pelagic fisheries. The fish caught by hook and line are landed, chilled, processed and marketed individually. Lot sampling and testing methods are not appropriate to this type fish production system. If lot size in hook and line fisheries is effectively reduced to individual fish, it is impractical and nearly impossible to monitor individual fish temperature histories on-board. Therefore lot testing in hook and line fisheries is also inappropriate. The alternative Hawaii Approach to be presented accepts this rationale as its basic premise. Equally critical to the approach logic is the relationship between fresh tuna quality grades and post-harvest handling. The Hawaii Approach depends upon the standard post-harvest handling practices and the standard industry practice of quality grading as a reliable indicator of proper on-board handling to ensure product safety.

The Hawaii Approach utilizes standard industry practices on fishing vessels and also throughout the production, processing and market chain. On-board handling practices have become standardized and are verified through the use of Vessel Standard Operating Procedures (VSOP) to ensure proper handling of fresh tuna and other susceptible fish. The VSOP is adopted in lieu of the need for detailed vessel records of individual fish temperature histories.

After the vessels, the next step in the chain is the first receiver, generally a processor. With HACCP, at every interface where a product changes hands, the seller must give assurance to the buyer that the product is wholesome and has been handled properly. In the case of fresh tuna, the fishermen give written Letter of Assurance that the product was handled in accordance with the VSOP. This is why the written and verified VSOP is important because it specifies standard handling procedures. The VSOP can be used by fishing operations and processors as an integral part of a practical HACCP system.

Figure 5.

Logic and Rationale of Hawaii Approach to Control of Histamine



The receiver must also exercise due diligence and perform basic inspection of the incoming product. This evaluation naturally includes inspection of the hold, the refrigeration or level of icing and sanitation. The fish unloaded must be evaluated for temperature and undergo sensory evaluation. The fresh tuna industry utilizes a system of quality grades as a normal part of business.

Tuna quality has been determined to be a primary determinant of price in the fresh tuna industry which can routinely make the difference of several dollars per pound (Bartram et al., 1996). For instance, a yellowfin of canning grade might sell for $0.50/lb. whole weight, while a No. 1 grade fish can easily exceed $5.00/lb. Naturally each level of the fresh tuna industry from vessel to the final consumer outlet is very concerned with product quality as an inherent matter of business. This strict attention to quality in the fresh tuna industry is useful as a natural mechanism for the prevention of fish with high levels of histamine from entering commercial channels in a HACCP-based inspection program.

Once the product enters the processing and marketing channels in good condition, it is a simple matter of maintaining proper product temperature and sanitation during all subsequent steps in the processing and distribution system and finally at the consumer level. This is achieved by maintaining proper handling practices of sanitation and temperature control throughout the industry as an extension of the proper initial handling on-board the fishing vessels. We place a great deal of importance on the initial stages of handling because these first steps play a primary role in dictating the quality and safety of the product. If a product is abused at sea, all subsequent steps cannot regain the shelf life, quality and seafood safety assurance lost on-board the vessel due to mishandling.

In summary the Hawaii Approach to histamine control relies on,

- standard industry practices for post-harvest handling (VSOP)
- assurance from vessel personnel that VSOP specifications are met on each trip
- due diligence by the receiver by inspecting the fish hold for sanitation and icing
- tuna quality grading as a natural industry safe guard against unsafe product
- followed by proper handling and storage procedures which provide adequate temperature and sanitation controls

Industry Vigilance

The fresh tuna industry must remain vigilant and closely monitor this histamine control strategy. In-house and industry/government supported studies should be conducted to fine-tune the system by further verifying the key information on which the system is based.

Future activities should include,

- additional studies of time and temperature relationship to histamine production.
- epidemiological studies to continuously monitor incidence rates of histamine intoxication.
- support the refinement of reporting data in cases of histamine intoxication.
- design, plan and implement a comprehensive system for monitoring and evaluation which can help to derive a cost-benefit analysis for HACCP application to the fresh tuna industry at a future date.
- support an educational effort for the industry, recreational fishers and consumers about seafood safety issues.

Statement of Qualifications

Dr. John Kaneko is a consulting veterinarian with training and practical industry experience in seafood quality control and quality improvement. His research and consulting work focuses on the linkage between fish handling practices, fish quality and seafood safety issues. He has been working closely with the tuna industry to develop a set of best practices for tuna handling on purse seiners. He has a special interest in how seafood safety and the new FDA HACCP regulation will impact the Hawaii Tuna Industry. He represented the Hawaii Seafood Industry on the Model Seafood Surveillance Program (MSSP) committee on raw fish. He was also contracted by the State of Hawaii to prepare a critical review of the FDA HACCP proposal. This review resulted in an industry position paper on how the FDA HACCP program might be improved. He is the lead consultant for the State in developing a generic HACCP model to be used as the basis of practical HACCP training for industry members in Hawaii. He is consultant to several key private seafood companies in Hawaii preparing for compliance with HACCP regulations. He is an experienced project manager and is Director of Projects for PacMar, Inc., an international agricultural development consulting company based in Hawaii.

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Development of a HACCP-based Strategy for the Control of Histamine for the Fresh Tuna Industry.

John Kaneko MS, DVM

A report by PacMar, Inc. pursuant to
National Oceanographic and Atmospheric Administration
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July 31, 2000

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Final Report

I. Report Title, Author, Organization, Grant Number and Date

Title: Development of a HACCP-based strategy for the control of histamine for the fresh tuna industry.

Organization: PacMar, Inc., Honolulu, Hawaii

Grant No. NA86FD0067

Date: July 31, 2000

II. Abstract: A brief (one paragraph) description of the final report (for use in the S-K Annotated Bibliography).

Histamine or scombroid fish poisoning is among the top three seafood-related public health problems reported in the US. Epidemiological data from Hawaii between September 1989 and September 1999 indicate that mahimahi (54%) and tuna (25%) were the leading fish species implicated in illnesses due to histamine poisoning. Imported seafood was responsible for 48% and imported mahimahi was responsible for 45% of the total number of illnesses. A practical HACCP-based approach (Hazard Analysis Critical Control Point) for controlling histamine accumulation in susceptible pelagic fish species caught by Hawaii's longline, handline and trolling fleets was explored. The FDA HACCP seafood inspection program guidelines for controlling histamine accumulation recommend that fish be chilled to below 50° F within 6 hours and to below 40° F within 24 hours after death. Vessel Standard Operating Procedures (VSOP) for on-board fish handling were evaluated against these guidelines. Fish temperature profiles were recorded at sea and compared with histamine analyses. Hawaii fishing fleets were capable of meeting the FDA fish handling guidelines for fish brought to the vessel alive. The actual chilling rates for fish that died on the line could not be determined, however, once boarded, fish were chilled to below 40° F within 24 hours. The histamine concentration of all fish (dead and alive) with known on-board temperature profiles was well below the FDA defect action limit of 5 mg/100g (mean = 0.26 mg/100g, range = 0.02 – 0.88mg/100g, SD 0.2 mg/100g). The efficacy of fish quality grading and sensory evaluation at the time of delivery to the first receiver was evaluated as a practical screening method for eliminating fish with high histamine risk from the market. A market sample of 583 fish from 42 commercial longline trips, 45 trolling trips and 32 handline trips was collected, graded for quality, evaluated organoleptically and analyzed for histamine concentration. Fish quality grading and sensory evaluation (for odors of decomposition) were effective in culling out all fish (14 out of 583 fish sampled) with high histamine concentrations. The fish rejected for odors of decomposition included, bigeye, yellowfin and albacore tuna, striped marlin, blue marlin and mahimahi. Within the sample set of odor rejects, only bigeye tuna, yellowfin tuna, albacore tuna and mahimahi were found with histamine levels exceeding the defect action limit. It was estimated that the actual prevalence of high histamine fish in Hawaii's fresh fish landings is less than 0.00117%. A practical HACCP-based approach utilizing VSOP for controlling histamine on fishing vessels and sensory evaluation for screening for fish with high histamine risk in the Hawaii fresh tuna industry is presented.

III. Executive Summary: A brief succinct summary of final report.

A study was conducted to determine how histamine forms during the post-harvest period on-board commercial fishing vessels in Hawaii's fresh tuna industry. A practical and effective, HACCP-based approach to histamine control was developed.

The epidemiological records for outbreaks of histamine poisoning in Hawaii between September 1989 and September 1999 were evaluated. Tuna and mahimahi were the two most important species being implicated in 68% of the histamine incidents and 80% of the number of illnesses.

Further analysis revealed that imported fish caused 48% of the histamine illnesses. Imported mahimahi caused 45% of the histamine illnesses.

The on-board fish handling methods used by Hawaii's commercial troll, handline and longline fleets were monitored and documented at sea using temperature loggers to accurately profile the time and temperature parameters in the post-harvest period.

On-board fish handling methods were compared with FDA fish handling guidelines for the prevention of histamine accumulation. The commercial vessels studied were capable of meeting the guidelines with fish brought aboard alive. For fish brought aboard dead, the actual chilling times (from the time of death) could not be determined.

Histamine analysis was conducted to verify that the handling methods observed adequately controlled histamine accumulation. All fish, dead and alive, with known on-board temperature profiles were well below the FDA defect action limit of 5 mg/100g (mean = 0.26 mg/100g, range = 0.02 – 0.88 mg/100g, SD 0.2 mg/100g) at unloading.

The efficacy of fish quality grading and sensory evaluation of fish for odors of decomposition as a practical means of culling fish with high histamine was evaluated by sampling 583 fish in the Hawaii fresh fish landings. Fish from troll, handline and longline vessels were sampled. Bigeye tuna, yellowfin tuna, albacore tuna, striped marlin, blue marlin and mahimahi were sampled. The sampling protocol called for collecting near equal numbers of fish from each of the 5 grade categories. Grade 5 fish (odor rejects) were rare, however eventually 119 odor rejects were collected for the study. All fish were sampled and analyzed for muscle histamine concentration.

A total of 14 fish out of the entire market sample of 583 fish were found to exceed the histamine defect action level of 5 mg/100 g. All of these fish were first rejected from the market for odors of decomposition (Grade 5).

It was concluded that odors of decomposition are reliable indicators of histamine risk and that sensory evaluation is an effective HACCP control measure in the Hawaii fishery.

It was estimated that the actual prevalence of high histamine fish in Hawaii's fresh fish landings is less than 0.00117%.

A practical HACCP-based system for histamine control in the Hawaii fresh tuna industry was developed that integrates new information generated by the study on the efficacy of VSOP in controlling histamine accumulation and the efficacy of sensory evaluation in screening for high histamine risk fish.

The FDA suggests two basic alternatives for first receivers (referred to as "*primary processors*" by the FDA) for controlling histamine in fresh tuna and associated pelagic species received from the primary producers (fishing vessels).

The Harvest Vessel Controls Approach.

The first method relies on receiving detailed on-board fish handling monitoring records from the vessels that document when fish were caught and details of the temperature history of the fish during the initial cooling period and subsequent storage phase. The FDA has developed fish handling guidelines (Table 1) for time and temperature controls needed to prevent excessive histamine accumulation (FDA, 1998).

Table 1. FDA fish handling guidelines for the prevention of histamine accumulation.

Category of histamine-producing fish.	On-board Fish Handling Guidelines.
For fish other than tuna above 20 lbs., if the fish has not been exposed to temperatures above 83° F (28.3° C),	The fish should be placed in seawater or brine at 50° F (10° C) or less within 9 hours of death. **OR** The fish should be placed in ice within 12 hours of death.
For tuna greater than 20 lbs., **OR** If the fish have been exposed to temperatures above 83° F (28.3° C),	The internal temperature of the fish should be brought to below 50° F (10° C) within 6 hours of death.

Primary processors using the Harvest Vessel Approach shall at the time of delivery,

- Receive detailed fish handling records from the vessel operator.
- Conduct sensory evaluation for decomposition by sampling 118 fish in a lot (or each fish for lots <118 fish) and reject entire lot if rejects exceed 2.5% or 3 fish.
- Check the adequacy of the icing for other cooling media.
- Record the internal body temperature of the fish at the time of delivery.

The Histamine Testing Approach.

The second alternative relies on lot sampling and testing of fish for histamine. The FDA policy for histamine concentration in the edible portion of fish is given in Table 2.

Table 2. FDA policy for histamine concentration in seafood product.

Histamine Concentration	FDA Policy
5 mg/100 g (50 ppm)	Defect Action Limit
50 mg/100 g (500 ppm)	Estimated toxicity level

The FDA recommends that the primary processor collect muscle samples for histamine analysis from 1 fish per ton for large fish (>20lbs.) and 2 fish per ton for smaller fish (<20lbs.) where the fish are from common origin (FDA, 1998). The lot sampling and testing of fish landings is not based on HACCP, does not emphasize prevention of the hazard through processing controls and is a form of end product testing. Lot sampling and testing may not be an effective method for detecting histamine in fresh fish from hook and line fisheries because of the way fish are caught and handled in the post-harvest period.

Primary processors using the Histamine Testing Approach, shall at the time of delivery,

- Lot sample and test for histamine.
- Conduct sensory evaluation for decomposition by sampling 118 fish in a lot (or each fish for lots <118 fish) and reject entire lot if rejects exceed 2.5% or 3 fish.
- Check the adequacy of the icing or other cooling media.
- Record the internal body temperature of the fish at the time of delivery.

For many years the tuna canning industry has relied on a Histamine Testing Approach to screen frozen tuna for elevated histamine concentration. The sampling frequency is 1 fish per ton for fish greater than 20 lb round weight, and 2 fish per ton for fish that are less than 20 lb. In the western Pacific purse seine fishery, many of the fish that are caught are less than 20 lb. Lot size may be as large as 90 tons with the assumption being that each fish well should be considered a single lot. Fish wells on US purse seiners hold from 20 to 90 tons of fish. In this fishery individual sets can exceed 400 tons of fish and fill multiple fish wells. Fish are loaded into the well, usually from the same purse seine set, chilled in refrigerated seawater, frozen in brine and stored frozen. With 5 lb fish for example, this is equivalent to 400 fish per ton or up to 36,000 individual fish per 90-ton lot. This amounts to a sampling frequency of 0.25%. This low sampling rate is only likely to be effective in situations where there has been gross mishandling of the fish resulting a high percentage of fish with elevated histamine in the lot.

The sampling rate is not sufficient to detect the few individual fish with high histamine or decomposition that may occur in a lot at extremely low frequency. Because of this Quality Control personnel at the canneries detect and cull individual decomposed fish from production lines by having "*sniffers*" screen each fish entering the pre-cooking stage. This step in combination with lot sampling and testing for histamine is effective in reducing the histamine risk and makes canned tuna a very safe product.

In contrast, the way in which fresh tuna are caught (hook and line gear), graded for quality and sold on individual quality merits, makes the application of representative lot sampling ineffective. These fish are caught individually and not in large sets as with purse seines. Even within a single longline set, the series of fish caught have unique histories from the time they were hooked until they were placed into the hold. Each fish has its own time and temperature history at the end of the trip and there is no reason to consider all fish from the trip or each longline set a "lot". For this reason, the Histamine Testing Approach of lot sampling is of questionable value when applied to the fresh tuna industry.

Measures to control histamine accumulation in the fresh tuna industry should instead focus on prevention by applying time and temperature controls and sanitation procedures on vessels and continuing through the processing and distribution channels. The Harvest Vessel Approach relies on detailed on-board handling records from fishers that may be impractical to collect and may actually be counterproductive to the objectives of good handling practices for vessels storing fresh fish in ice. Monitoring the temperature of a fish once it is placed in the ice requires removing the fish and inserting a thermometer into the edible muscle. This slows the chilling process, creates an entry for bacteria and may lead to localized decomposition of adjacent muscle.

The practical question is how to design a HACCP-based system that emphasizes prevention, establishes a set of standard operating procedures for fish handling on vessels using ice that can reliably prevent histamine accumulation and can reduce the likelihood of the histamine hazard. The responsibility for verifying proper on-board handling by fishers lies on the primary processor. How to document and verify that fish have been properly handled on-board fishing vessels is the practical challenge.

The project was aimed at the development and verification of a practical alternative, HACCP-based approach to controlling histamine risk in the fresh tuna industry. Essentially, the project conducted a histamine Hazard Analysis of the fresh tuna fishery in Hawaii. This is the first step in developing a HACCP-based program. Hazard Analysis identifies the likely food safety hazards, in this case the presence of fish containing high histamine concentration and the on-board handling conditions that allow histamine to accumulate to toxic levels. The project focused on integrating effective histamine control measures by the fishing vessels and verification methods for use by the primary processor. This initial transfer of responsibility from the vessel to the on-shore distribution chain is critical. The fish handling steps at sea are the most important in setting the quality and safety parameters. Without proper fish handling at sea, the control of histamine in subsequent steps is unlikely.

The alternative VSOP HACCP-based strategy relies on,

- Establishing a set of Vessel Standard Operating Procedures (VSOP).
- Verifying that the VSOP are able to meet FDA time and temperature guidelines.
- Determining that the VSOP are effective at preventing histamine accumulation.
- Ensuring that the VSOP are followed on fishing vessels.
- Verifying that sensory evaluation of fresh fish is a practical and effective critical control measure for histamine.

B. Objectives of the project.

Objective 1. Evaluate epidemiological data on histamine poisoning in Hawaii.

Objective 2. Develop Fleet on-board handling profiles (trollers, handliners and longliners).

Objective 3. Verify the post-harvest fish handling procedures.

Objective 4. Verify the relationship between post-harvest fish handling procedures and histamine accumulation.

Objective 5. Determine the importance of fish quality grades and odors of decomposition as indicators of histamine concentration.

Objective 6. Develop a HACCP-based strategy for the control of histamine for the fresh tuna industry.

Objective 7. Communication of results to the FDA Office of Seafood.

V. Approach:

A. Detailed description of work that was performed.

Methods Obj.1. Evaluate epidemiological data on histamine poisoning in Hawaii.

The Epidemiology Branch of the State of Hawaii Department of Health, was contacted in order to obtain 10 years of available data on cases of histamine poisoning in Hawaii between 9/20/89 and 9/28/99. Information requested included the number of outbreaks (incidents), number of cases (people made ill), the species of fish implicated, origin of the fish, product form and the market segment involved. Information was evaluated for completeness and accuracy in determining the relative risk of histamine accumulation within the different fish species, fishing methods, product forms, product origin and market segment. Epidemiological data from CDC (The Centers for Disease Control and Prevention) were also requested in order to determine if additional detail on outbreaks in Hawaii might be available from that authoritative source.

Methods Obj.2. Develop Fleet on-board handling profiles (trollers, handliners and longliners).

Efforts were made to rapidly characterize the major fishing fleets in Hawaii (troll, handline and longline) specifically in terms of capture, fish handling and storage methods. Fishers were interviewed to determine the on-board handling procedures. Available literature was reviewed. Concise fleet profiles were prepared describing fishing methods and post-harvest fish handling methods which typify the standard practices on vessels representative of the various gear types. The type of fish caught and the associated quality issues were also described for each gear type.

Methods Obj. 3. Verify the post-harvest fish handling procedures.

The project team made research trips on commercial fishing vessels to observe, monitor and verify the fishing methods and fish handling procedures to complete the fleet profiles and VSOP. Participating fishing vessels were selected as representatives of the fish handling practices of the three major fishing gears.

The fishing methods were observed on trolling, handline and longline vessels during commercial fishing trips. Observations were recorded on how the fishing gear was used. For longline gear, the time at the start of the set and when the individual fish were hauled on-board was recorded. The fish species and condition (alive or dead) on retrieval were recorded. The weight of the fish (whole) was determined using a commercial platform scale (State of Hawaii-certified) at the time the fish were unloaded from the vessel and delivered to the first receiver in the market chain.

The fish handling methods were also observed and evaluated. How the fishers handled the fish immediately after being brought aboard was monitored. The processing time (deck time) from boarding to placement in the ice in the fish hold was recorded. The initial core fish temperatures were measured using a water-resistant microprocessor temperature meter (Hanna Instruments, HI 9024).

Continuous fish temperature profiles were recorded during the vessel phase of the post-harvest handling sequence using waterproof temperature loggers (Onset Computer Corporation, Stowaway® Tidbit XT). The stainless steel temperature probes (6-inch) were placed along the longitudinal axis of the vertebral column to record core muscle temperature (Figure 1). The temperature probes (TP) were placed into the muscle from within the gill cavity. The thermistor wires and the temperature loggers (TL) were then secured to the gill arches using cable tie wraps. Fish were identified with pectoral fin clips and heavy-duty plastic flagging ribbon around the caudal peduncle. Loggers were programmed to record temperature at various intervals (24 seconds to 5 minutes, depending on the length of trip) from the time the logger was triggered and placed into the fish until the logger was removed at the end of the trip during vessel unloading.

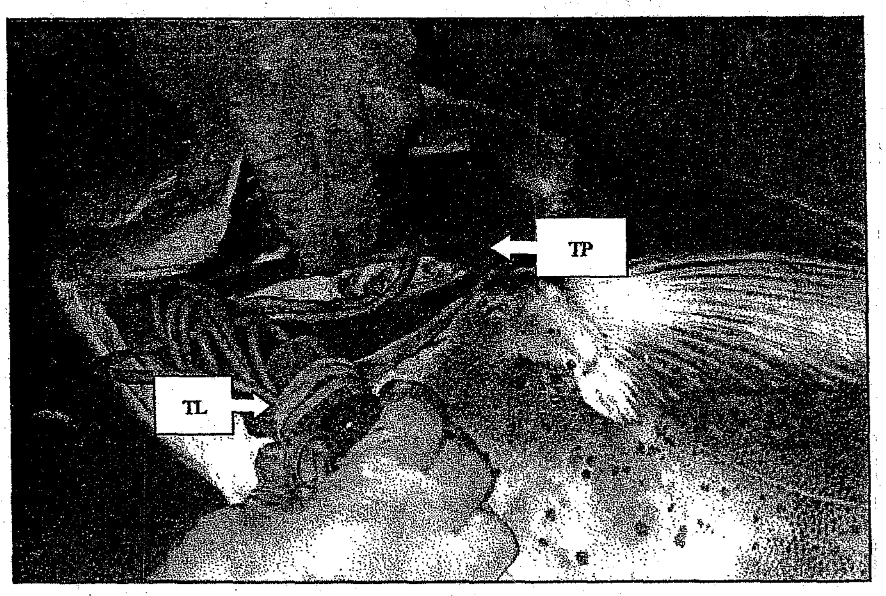

Figure 1. Placement of temperature logger (TL = temp. logger, TP = temp. probe).

Upon landing, the trial fish were identified as they were removed from the fish hold. The loggers were retrieved and the fish were weighed and evaluated organoleptically (sensory evaluation). The fish were also graded for quality using fresh tuna industry grading methods (Bartram et al. 1996). Quality grades used in the Hawaii fresh fish market were also applied to the associated pelagic fish species. A muscle sample was then collected from the dorsal muscle mass just posterior to the cleithrum for histamine analysis. Histamine is known to form earliest and reach the highest concentration in this anterior section of the body making it a logical sampling location (Frank et. al, 1981, Baranowski et. al. 1990). Muscle samples were immediately bagged, labeled, placed in ice and delivered to a freezer within 2 hours. Frozen samples were then delivered to the laboratory for histamine analysis.

The fish handling data collected during fishing trips were compiled and analyzed. The information relating to time and temperature targets for properly chilling fish was focused on the time it took fish to be chilled below 50° F, the time to reach below 40° F, and the fish temperatures at 6 and 24 hours post-harvest. A mean fish temperature profile for all fish monitored at sea was compared with the FDA fish handling guidelines. Temperature profiles for each pelagic fish species were also prepared to estimate the chilling rates.

Data were statistically analyzed using analysis of variance methods (ANOVA, SAS User's Guide, 1985) followed by Least Squares Means analysis to compare specific variable means. Correlation analysis was conducted to analyze the relationship between fish temperature and sea surface water temperature.

Methods Obj. 4. Verify the relationship between post-harvest fish handling procedures and histamine accumulation.

The efficacy of the fish handling methods observed on Hawaii-based commercial troll, handline and longline fishing vessels in Objective 3, for controlling histamine accumulation was evaluated. The mean, range and standard deviation for histamine concentration were calculated for all pelagic fish species combined and for each species group. This comparison determined whether the on-board handling procedures met the FDA handling guidelines, the actual time and temperature parameters achieved and the resulting histamine concentration of fish sampled.

Muscle samples collected from fish with known on-board temperature profiles were analyzed for histamine concentration. The Food Quality Lab (FQL), Honolulu, Hawaii conducted the histamine analyses using the fluorometric method (AOAC, 1995 Official Method 977.13 for Histamine in Seafood). FQL maintained quality assurance and quality control (QA/QC) procedures where single samples were spiked with 1.0 ml of stock histamine solution (1.0 mg/ml) to estimate percent recovery of histamine for each batch of 10 histamine samples tested.

Data were statistically analyzed using analysis of variance methods (ANOVA, SAS User's Guide, 1985) followed by Least Squares Means analysis to compare specific variable means.

Methods Obj. 5. Determine the importance of fish quality grades and odors of decomposition as indicators of histamine concentration.

Additional muscle samples were collected from commercial fish landings at the Honolulu Fish Auction (United Fishing Agency) and the Hilo Fish Auction (Suisan Company Ltd.). These were combined with the fish sampled during the on-board studies (Objectives 3 and 4) to comprise the representative market sample. These two auctions receive and market the majority (an estimated 75 - 90%) of the commercial landings of pelagic fish in Hawaii. Data collected on these fish included fishing gear type, fishing vessel name (kept confidential), date of landing, fish species, weight and quality grade (sensory evaluation). Industry grading methods were used to assign quality Grades No. 1 – 5 to fish, where Grade No. 1 is the highest quality and No. 5 is the lowest quality score. Grades 1 – 4 are acceptable quality fish and the Grade No. 5 category are fish rejected for decomposition. Sensory evaluation for detecting odors of decomposition in the gills and muscle was used to determine if fish should be rejected. Muscle samples were collected, handled and analyzed as previously described.

Data were statistically analyzed using analysis of variance methods (ANOVA, SAS User's Guide, 1985) followed by Least Squares Means analysis to compare specific variable means.

Methods Obj. 6. Develop a HACCP-based strategy for the control of histamine for the fresh tuna industry.

A hazard analysis for histamine poisoning in the fresh tuna industry in Hawaii was prepared by integrating the findings of the Objectives 1 – 5. A Vessel Standard Operating Procedure (VSOP) was drafted for use by the Hawaii fresh tuna industry for the control of histamine.

Methods Obj. 7. Communication of results to the FDA Office of Seafood.

During the course of the project, the PI communicated with staff at the FDA Office of Seafood about the objectives and methods being applied during the project. Dr. George Hoskin, Mr. Don Kraemer, Mr. Walter Staruskewicz and Mr. Jim Barnett were consulted to discuss the project objectives and the research methodologies. FDA inspectors from the San Francisco Office, Ms. Patricia Ziobro, Ms. Darla Bracy and Ms. Jennifer King were also made aware of the project during HACCP inspections of the Honolulu Fish Auction. The implications of the project and its impacts on HACCP controls of histamine in the fresh tuna industry in Hawaii were discussed in detail. The FDA is anticipating the final report in order to make a determination of the validity of the alternative VSOP approach in place at Hawaii's 2 fish auctions for controlling histamine being evaluated by this project.

A workshop directed towards the fishing and seafood industry in Hawaii was held to disseminate the project findings and to get industry feedback for the final report. Another workshop was held for interested personnel from NMFS, the Hawaii Department of Health, and the University of Hawaii involved in seafood safety programs.

B. Project Management: List of individuals and/or organizations actually performing the work and how it was done.

Principal Investigator:	John Kaneko MS, DVM, PacMar, Inc., Honolulu, Hawaii. Designed and managed the project. Conducted some of the vessel-based research. Conducted sensory evaluations, quality grading and collection of muscle samples for histamine analysis. Coordinated statistical analysis. Liaison with SK Program Manager, FDA Office of Seafood staff and seafood industry members. Wrote the final report.
Financial Manager:	Thanh Lo Sananikone, PacMar, Inc., Honolulu, Hawaii. Managed the financial aspects of the project.
Research Assistant:	Donald Hawn, PacMar, Inc., Honolulu, Hawaii. Conducted vessel-based research and assisted in the collection of market samples. Maintained database and assisted in statistical analysis.
Laboratory Services:	Wendy Minor, Food Quality Lab, Honolulu, Hawaii. Conducted the histamine analyses and maintained the laboratory QA/QC procedures.
Statistical Advisor:	Wayne Toma, Statistician, Honolulu, Hawaii. Advised the PI on research design and conducted the statistical analysis.

VI. Findings:

A. Actual accomplishments and findings (corresponding to 7 Objectives).

Results Obj. 1. Evaluate epidemiological data on histamine poisoning in Hawaii.

The Epidemiology Branch of the State of Hawaii Department of Health, provided information on the reported outbreaks of histamine poisoning in Hawaii during the ten-year period between September 20, 1989 and September 28, 1999. Data on reported outbreaks of histamine poisoning in Hawaii were compared with data from the Centers for Disease Control and Prevention (CDC). Discrepancies existed between Hawaii data and the CDC data, which were under reported. Under the advice of Mr. Mits Sugi, epidemiologist with the Hawaii Department of Health, the CDC data was not used in the following analysis.

Table 3. Epidemiology of Histamine Poisoning in Hawaii from September 20, 1989 through September 28, 1999.

Species of Fish involved in outbreaks of Histamine Poisoning in Hawaii (includes confirmed, probable and suspected reports). Common name	(Hawaii market name and Latin name)	No. of outbreaks (%)	No. of illnesses (%)
Tuna (yellowfin and bigeye)	(ahi) (*Thunnus albacares* or *T. obesus*)	83 (44.15%)	117 (25.49%)
Mahimahi	(mahimahi) (*Coryphaena hippurus*)	46 (24.47%)	249 (54.24%)
Marlin (Pacific blue and striped)	(kajiki and nairagi) (*Makaira nigricans or Tetrapterus audax*)	15 (7.98%)	24 (5.23%)
Bigeye Scad	(akule) (*Trachiurops crumenophthalmus*)	11 (5.85%)	16 (3.48%)
Wahoo	(ono) (*Acanthocybium solandri*)	7 (3.72%)	12 (2.61%)
Albacore tuna	(tombo ahi) (*Thunnus alalunga*)	1 (0.53%)	2 (0.44%)
Skipjack	(aku) (*Katsuwonas pelamis*)	2 (1.06%)	3 (0.65%)
Canned Tuna	(light meat) (*K. pelamis and/or T. albacares*)	1 (0.53%)	1 (0.22%)
Spearfish	(hebi) (*Tetrapterus angustirostris*)	1 (0.53%)	2 (0.44%)
Mackerel scad	(opelu) (*Decapterus pinnulatus*)	1 (0.53%)	1 (0.22%)
Jack	(ulua) (*Caranx spp.*)	1 (0.53%)	1 (0.22%)
"Covina"	(unknown spp.)	1 (0.53%)	1 (0.22%)
Bonefish	(oio) (*Albula vulpes*)	1 (0.53%)	1 (0.22%)
Unknown fish		17 (9.04%)	29 (6.32%)
	Total number of outbreaks	**188**	
	Total number of illnesses		**459**

The reported outbreaks and the number of illnesses due to histamine poisoning in Hawaii are summarized in Table 3. The table includes cases confirmed by histamine analysis of the implicated fish, probable cases based on history and clinical signs and suspected cases which have a lower degree of certainty.

Tuna and mahimahi combined were the most important causes of histamine poisoning in Hawaii during this period causing 68% (129) of the outbreaks and 80% (366) of the total illnesses. The fish species involved in 9% (17) of the outbreaks and 6% (29) of the illnesses could not be identified and are listed in Table 3 as "*unknown fish*".

The tuna category includes both yellowfin and bigeye tuna because consumers and investigators are often unable to make the distinction. Tuna caused 83 outbreaks representing the highest percentage (44%) of histamine outbreaks in Hawaii. The number of illnesses caused by tuna was only 117 or 25% of the histamine illnesses during this period. Mahimahi was the other dominant species causing 24% (46) of the outbreaks, but a disproportionate 54% (249) of the total number of illnesses.

The origin of the fish implicated in cases of histamine poisoning is extremely important in evaluating histamine risk due to seafood consumption. Twenty-six (26) or close to 14% of the outbreaks of histamine poisoning in Hawaii were found to be caused by imported seafood (Table 4). These outbreaks however, caused a disproportionate percentage (48%) of illnesses (220) indicating a difference between domestic and imported fish in terms of histamine risk. Records indicate that imported mahimahi alone, caused 10% (20) of the outbreaks and an alarming 45% (210) of the illnesses in Hawaii.

Table 4. Histamine poisoning in Hawaii between 9/20/89 and 9/28/99 caused by imported fish and imported mahimahi.

Type of fish	No. of outbreaks	% of total	No. of illnesses	% of total
Imported fish	26	13.82%	220	47.93%
Imported mahimahi (*Coryphaena hippurus*)	20	10.64%	210	45.75%

The National Academy of Sciences comprehensive study (NAS, 1991) on seafood safety in the US estimated that the highest-risk fish commercially available in the US were imported fresh and frozen fish from tropical areas. The NAS also reported that imported mahimahi was the cause of 47% (55) of the histamine outbreaks in the US between 1978 and 1986. This led the NAS to conclude that embargoing this single product from the US could have a dramatic effect on public health.

The available epidemiological data reflects only those cases that are reported to and investigated by the State of Hawaii Department of Health. From a public health standpoint there are still several important unknowns. The public health impact of fish caught by recreational and subsistence fishers remains uncertain, as these cases of histamine poisoning are likely to be under reported. The NAS (1991) also concluded that recreationally caught fish are likely to be of higher risk for histamine than fish from commercial channels because of inadequate chilling capabilities and lack of awareness of the problem. While government efforts are underway to control histamine in commercial channels through regulatory action, fish from non-commercial sources eventual sale price (Bartram, et al, 1996). Fishermen constantly adjust the ice and seawater mixture in order to maximize the cooling rates and the quality of the fish. Special care is given to individual fish because they are priced and sold based on individual quality mainly through Hawaii's 2 display auctions.

By the time the vessel returns to the dock, the first fish caught in the morning may have been in the ice slurry (and later in ice alone) for over 10 hours. However, the last fish caught may have only been in the ice slurry for 1 hour. This accounts for the range of fish temperatures observed at the time of landing by Hawaii's troll fleet. Fish are then kept in ice, transported to the auctions, weighed, their temperature recorded and then placed in the auction cold storage rooms and buried in ice overnight for sale the following day after the fish are finally chilled to below 40° F. Alternatively, fish that are less than 24 hours out of the water are kept in ice and sold at the auction with the buyer accepting the responsibility to continue to properly chill the fish.

Fish caught and quality factors (trolling).

Hawaii's troll fleet catches mahimahi, marlins, tuna, skipjack and wahoo (Boggs and Ito, 1993). Trollers fish single-day trips and produce fish that are only 1 day out of the water. This fleet produces the highest quality fresh mahimahi, marlins and wahoo available to the Hawaii fresh fish market. These troll-caught fish routinely receive premium prices over fish caught by the other gear types and especially over imported fish. This is in sharp contrast to troll-caught yellowfin tuna which are not considered to be high in quality or long in shelf-life, presumably due to the capture methods, which involve a struggle on the line before death. Troll-caught tuna are susceptible to rapid muscle color change from red to brown resulting in a greatly reduced market value.

During the summer months troll-caught yellowfin tuna may also tend to be affected by the "*burnt tuna syndrome*" (Nakamura, et al., 1987). The affected muscle turns pale, opaque, watery and soft in texture making the fish unsuitable for sashimi and other higher quality, higher-value preparations. Subsequently the value of burnt tuna is reduced considerably.

Both quality problems (rapid color change and burnt tuna syndrome) associated with troll-caught tuna may be related to the fishing method which involves a struggle on the line, elevated body temperature and other physiological factors at the time of death and temperature controls in the post-harvest handling period. There are also likely to be multiple pre-disposing factors that trigger the burnt tuna defect.

Handline fleet profile.

Fishing method (handline).

The typical handline used in Hawaii to catch tuna consists of a nylon rope connected to a mainline of polypropylene or Dacron, which is attached to a leader of monofilament nylon ending with a single baited hook. Each boat deploys 4 handlines and drifts in the current in areas known to aggregate tuna. Parachute sea anchors are used to control the drift.

The Hawaii handline fleet is comprised of two segments. The first operates nearshore and mostly at night during the summer run of yellowfin tuna. These handline fishers leave the dock in the late afternoon and once on the fishing grounds, set the sea anchor and begin a drifting pattern. Fishing continues from sundown until sunup. Once a fish is hooked, the line is retrieved by hand (no reels involved). This takes less than 10 minutes with some fishers able to retrieve, bleed, gill and gut and place fish into an ice slurry in less than 10 minutes from the time of hook-up (Nakamura et al, 1987). After returning to the harbor, the fish are unloaded and delivered to the fish auctions or directly to wholesalers.

The second segment of the Hawaii handline fleet focuses on fishing at offshore seamounts and weather buoys which tend to aggregate small to medium-sized bigeye and yellowfin tuna. The offshore handline fishing fleet differs slightly in that the trips are longer (2-5 days) and the fish are caught at the surface with the handlines. This method is similar to the pole and line or bait boats that harvest actively feeding schools of tuna at the sea surface.

On-board fish handling methods (handline).

Once the fish is brought to the side of the boat it is gaffed and then stunned using a club or a pistol. The fish is then brought on-board with gaffs and bled using knife cuts at the gill arches, under the pectorals or at the caudal peduncle. After a few minutes (5 – 10 minutes) of bleeding while being rinsed with clean seawater, the fish may be gilled and gutted, headed and gutted or left whole and placed into insulated fish boxes containing an ice/seawater slurry.

Attention to the fish in the ice slurry is essentially the same as with the trollers. For the nearshore handline fishery, the first fish caught in the evening may have been in the ice cooling for 12 hours, while the last fish caught might have had less than 2 hours to chill by the time they are landed. This accounts for the range of delivery temperatures for handline fish. In Hilo, Hawaii, the center of the summer nearshore yellowfin handline fishery, these tuna are often sold at auction immediately after landing. Fish are kept in ice and the auction and buyers (wholesalers) assume the responsibility for continuing to properly chill the fish after delivery from the vessel. For handline fishing at the offshore seamounts, many of the fish are over 24 hours on ice by the time they are delivered and should therefore be below 40° F.

Fish caught and quality factors (handline).

The nearshore handline fleet catches primarily yellowfin, bigeye, albacore and an occasional swordfish (Yuen, 1979). Handliners fishing nearshore generally fish short trips and deliver fish to the market that are from a few hours to 2 days out of the water. The quality of handline-caught tuna is generally intermediate between that of troll-caught tuna (lower quality) and longline-caught tuna (higher quality possible). Although the quality of handline tuna can be very good, the total shelf life of these fish is greatly reduced when compared with longline-caught fish. The muscle color of handline yellowfin tuna tends to change rapidly from red to brown. Both handline and troll-caught tuna are also prone to the effects of the burnt tuna syndrome during the summer months (Nakamura et al, 1987).

The offshore handline fishery tends to catch more small to medium-sized bigeye tuna and some yellowfin in contrast to the nearshore fishery that catches primarily large yellowfin. Offshore handliners deliver fish that are mostly on ice for over 24 hours. The bigeye caught by this fleet are generally lower in quality, have a shortened shelf life and tend to have soft muscle texture.

Longline fleet profile.

Fishing method (longline).

Longlining entails the use of a long monofilament longline (5 to 40 miles long) with multiple leaders and baited hooks (200 to 1500 hooks). The average number of hooks fished per day for Hawaii's longline fleet (both tuna and swordfish trips) in 1998 was 1,390 (Ito and Machado, 1999). Each time the longline is deployed and retrieved is called a "*set*". Although each fishing vessel may adopt different strategies for when and where to fish, the set begins with deploying one end of the longline that is attached to a float fixed with a flag and radio beacon. The set is completed when the last hook remaining in the water is retrieved. Fishing trips targeting tuna typically range from 14 to 21 days, while trips targeting swordfish range from 30 to 45 days (WPRFMC, 1995).

As the vessel moves forward, the longline is deployed off the stern and the crew attaches leaders and baited hooks at intervals between additional floats and flags used to mark the location of the line. Deploying the line typically takes 4 hours but may take up to 6 hours depending on the amount of hooks fished per set. After the line is deployed, the crew may take a break to "*soak*" the line before starting the retrieval.

The mainline is deployed so that the hooks are at a depth ranging from 50 to 400 meters depending on targeted species, the position of the hook along the mainline and the skill of the crew and captain. Once a fish is caught it may remain alive on the line until retrieval. Other fish may struggle against the line and expire by the time they are brought to the vessel. Retrieving the line can take an average of 8 hours depending on the number of fish caught and the sea and weather conditions.

On-board fish handling methods (longline).

Once brought to the vessel, the fish are gaffed and hauled on deck. Live fish are stunned, brain spiked (pithed) and then bled. Fish that are retrieved dead are also bled using cuts to the gill arches, under the pectoral fins and/or at the caudal peduncle. After 5 –10 minutes of bleeding while the fish is rinsed with clean seawater, the fish may be gilled and gutted or left whole. The fish are then taken below deck into the fish hold and buried in ice. Longline fishers take great care in handling fish to ensure optimum outward appearance, muscle quality and marketability. Unlike the handling typical of trollers and handliners, Hawaii longliners for the most part do not use ice slurries (ice brine) to pre-chill the fish before placing them in ice.

As the fish cools, the surrounding ice melts. The space that forms creates an insulating layer of air or "*igloo effect*" that greatly reduces the heat transfer efficiency. Direct contact with the ice is needed to maintain optimum cooling rates. Repacking fish in the ice takes place anywhere from 3 hours to 24 hours after first being placed in the fish hold. Fish are stored buried in ice for the remainder of the trip. Only a few of the longline vessels in Hawaii have icemakers and/or refrigerated fish holds. Most of the fleet uses only the ice they have at the start of the trip and depend on insulated fish holds to keep the ice from quickly melting.

Fish caught and quality factors (longline).

Hawaii's longline fleet catches bigeye tuna, yellowfin tuna and swordfish as the primary target fish species. In addition, the fleet catches multiple species of commercially important pelagic fish including albacore tuna, skipjack, Pacific blue and striped marlins, mahimahi, wahoo, spearfish, moonfish, pomfrets and sharks (Boggs and Ito, 1993). Longline-caught fish vary in the length of time out of the water and in quality because of the fishing method, the number of sets and length of the trips. Some of the longline caught bigeye tuna are extremely high quality and value (over $17.00/lb round weight basis occurs) while other fish of the same species from the same vessel trip may be rejected from sales at the time of unloading due to decomposition. The entire range of fish quality is possible within the same load of fresh fish caught by longliners and can be quite varied within sets, between trips and between vessels. Random representative sampling is not used by buyers to judge the quality and value of the load because it is not effective in predicting the quality of the individual fish in the catch.

In other locations in the US longline-caught fish are sold on a "*boat run*" basis with an average price negotiated for the entire load or by broad quality grade categories. By contrast, the fresh tuna industry in Hawaii sells fish on an individual basis and relies on judging the quality of each fish. Every fish is screened for quality attributes (muscle color, clarity, texture and fat content) and as quality grade declines, buyers look more closely for signs of decomposition.

The display auction system in Hawaii allows the buyers to closely inspect individual fish before bidding. Fish quality is a primary determinant of price in the fresh tuna market in Hawaii (Bartram, et al. 1996). Prices are determined by competitive open bidding and prices rise by $0.10/lb increments. The 2 auction houses in Hawaii take responsibility to receive, screen and cull fish for signs of mishandling and decomposition. Once the fish are displayed, the buyers must again carefully screen the fish for signs of mishandling, quality defects and indications of decomposition in order to decide on market value. Buyers are keenly aware of subtle quality differences that result in the range of prices paid. Auction prices for fish can range from over $17.00/lb down to $0.10/lb round weight basis, depending on the quality, species of individual fish and market conditions.

Results Obj. 3. Verify the post-harvest fish handling procedures.

In order to verify the post-harvest fish handling procedures, the standard operating procedures on fishing vessels representative of commercial longline, troll and handline fishing practices were monitored during research trips on commercial fishing vessels during normal operations. On-board research consisted of 7 single-day trips on commercial trolling vessels, 5 single-day (overnight) trips on handline vessels and 21 longline sets during 14-day and 22-day longline trips made by a single vessel.

The results are presented in order to answer key questions about handling procedures.

How much time are fish dead on the line?

Trollers.

None. Troll-caught fish are brought to the boat alive. Although troll-caught fish may not die on the line, it is of interest to know how long the fish might struggle because of the physiological effects on body temperature, energy stores, the onset, strength and duration of *rigor mortis* and the postmortem degradation processes. The time observed fighting on the line averaged 6 minutes with a minimum of 1 minute and a maximum of 30 minutes. The time it takes to get the fish on the boat after hooking depends on the species of fish, its size, the strength of the fish and fisher and the efficiency of the gear. Time on the line is expected to vary greatly on charter boats where anglers are non-professional and may not be able to or interested in quickly retrieving the fish.

Handliners.

None. Handline-caught fish are quickly brought to the boat alive. Fish caught on handlines struggle and the time observed on the line was an average of 4 minutes with a minimum of 1 minute and a maximum of 10 minutes. This is within the range of handling parameters reported by Nakamura et al (1987) in the Hawaii handline fleet. The time fish are on the line depends on the species of fish, the size of the fish and the efficiency of the fisher. Handline fishers are generally aware of the need to minimize the time the fish struggles to maintain fish quality.

Longliners.

None for live fish. For dead fish, up to 20 hours is possible. The time and temperature data reported for fish (dead and alive) monitored during this study began at the time the temperature loggers were placed in the muscle after being brought on-board. For a fish that is retrieved alive, "*time zero*" is when the fish is brought on-board. For fish that die on the line during the set, time zero occurs some time after the hooks are deployed and when the fish dies before being retrieved.

Because of the way in which longline gear is typically deployed and retrieved, there are concerns about the total length of time that fish might be hooked and remain on the line until being retrieved. The time on the line is important because of the potential for histamine formation in fish that die in warm tropical and subtropical waters.

It is not possible to determine the exact time of death on the line without sophisticated equipment. The discussion of chilling rates in later sections of this report does not include the additional time on the line for fish retrieved dead. There have been attempts to estimate the time of death by evaluating the fish temperature at different locations in the body at the time of retrieval, but this method proved inadequate without accurate water temperature and depth of capture data (Pages, 1972). Longline research in Hawaii using hook timers and Time/Depth Recorders (TDRs) attached to longline hooks, determined that bigeye tuna and yellowfin tuna survive much longer after being hooked than previously thought (Boggs, 1992). Over half of the bigeye survived 9 hours after being hooked and the shortest time recorded for death after hooking was 2 hours.

The maximum possible time for a fish to be dead on the line is from the time the first hook enters the water at the start of the line deployment to the time the last fish is retrieved. For the 21 longline sets monitored during the study, the mean maximum possible time was 18 hours (Table 5).

The shortest amount of time possible for fish to be dead on the line is in situations when the fish dies immediately before being hauled on-board. Another more practical determination is the *"soak time"* for the longline gear. This is the lapsed time between the end of the deployment of the longline gear and the beginning of the line-hauling phase.

Table 5. Soak time and time dead on the line.

No. of sets	Soak time for longline gear. (hours)				Maximum amount of time dead on the line. (hours)			
	mean	SD	Min	max	mean	SD	min	max
21	6.74	0.74	5.67	8.15	18.02	1.23	16.12	20.48

How many fish came up alive and how many were dead?

Trollers.

All fish were alive. Trolling gear entices the fish to strike live or dead bait, or artificial lures and all fish are hooked and brought to the boat alive.

Handliners.

All fish were alive. Handline fishers use baited hooks and all fish are hooked and brought to the boat alive.

Longliners.

Some were alive and some were dead. Table 6 displays the breakdown of longline-caught fish observed during the study retrieved alive or dead. Fish from 21 longline sets were evaluated. Bigeye tuna, yellowfin tuna, albacore, striped marlin, blue marlin and mahimahi were sampled from the longline catch because these are the primary market species susceptible to forming histamine. A total of 383 pelagic fish were observed. Of that total, 152 (39.7%) were alive and 231 (60.3%) were dead when brought on-board.

Longlines are set, soaked and retrieved over an extended period of time from 16 to 18 hours from start to finish. What determines if a fish will be alive or dead, depends on the species of fish, the amount of time it stayed on the line and whether it struggled against the line (and died) or was calm and survived until the line hauling began.

What was the deck time for dead and alive fish?

"*Deck time*" is of interest in estimating the time it takes fishers to pre-process each fish from the time it is brought on-board until it is placed in ice in the fish hold. The fish are vulnerable at this time to elevated ambient temperature on deck and to bacterial contamination. Deck time should be kept to a minimum necessary to properly pre-process the fish prior to chilling and storage. Efforts to maintain proper sanitation and prevent contamination are also extremely important.

Trollers.

The average deck time observed was 7.2 minutes (range 3.0 to 10.0 minutes).

Handliners.

The average deck time observed was 8.6 minutes (range 3.0 to 20.1 minutes).

Longliners.

The average deck time observed for live versus dead fish was observed and recorded for longline fish. Table 6 displays the total amount of time it took the longline crew to place fish into the ice after being brought aboard. The average deck time for all species (alive and dead) was 12.2 minutes, with a minimum of 0 minutes and maximum of 83 minutes (SD = 11.4 minutes).

The time it takes for fishers to bleed and process fish prior to placement in the ice depends on many factors including the catch rate, any delays due to mechanical complications with retrieving the gear, weather and sea conditions, the species and size of fish, etc. The average deck time for dead fish across species was 12.0 minutes with a minimum of 0 minutes and a maximum of 83 minutes (SD = 12.4 minutes). The average time for live fish across species was 12.6 minutes, with a minimum of 1.0 minute and a maximum of 63.0 minutes (SD = 9.5 minutes).

Table 6. Deck time for live and dead tuna, marlin and mahimahi caught by longline.

Common name		N	%	Deck time (minutes)			
				mean	minimum	maximum	SD
Bigeye tuna	all	86		11.9	0.0	28.0	6.5
	live	41	47.7	13.4	4.0	27.0	6.9
	dead	45	52.3	10.6	0.0	28.0	5.8
Yellowfin tuna	all	29		12.0	0.0	29.0	7.8
	live	10	34.5	15.3	7.0	22.0	4.8
	dead	19	65.5	10.2	0.0	29.0	8.5
Albacore tuna	all	103		7.7	1.0	57.0	6.9
	live	26	25.2	7.9	2.0	24.0	4.7
	dead	77	74.8	7.7	1.0	57.0	7.5
Striped marlin	all	73		16.6	1.0	83.0	15.0
	live	17	23.3	16.7	8.0	34.0	7.9
	dead	56	76.7	16.6	1.0	83.0	16.6
Blue marlin	all	5		26.2	10.0	54.0	15.3
	live	2	40.0	18.5	17.0	20.0	1.5
	dead	3	60.0	31.3	10.0	54.0	18.0
Mahimahi	all	87		13.5	1.0	63.0	14.0
	live	56	64.4	12.3	1.0	63.0	12.6
	dead	31	35.6	15.6	1.0	62.0	16.0
All species	all	383		12.2	0.0	83.0	11.4
	live	152	39.7	12.6	1.0	63.0	9.5
	dead	231	60.3	12.0	0.0	83.0	12.4

Fishers are generally aware of the need to quickly prepare the fish, minimize the deck time and begin the chilling process. It is possible that fishers may prioritize the handling of pelagic fish based on the value of the fish species and possibly the susceptibility of the particular species to quality defects related to handling and temperature controls. The maximum deck time for the high value fish species, bigeye and yellowfin tuna is relatively low compared with the two marlin species and mahimahi which generally receive significantly lower prices in the market even for high quality fish.

It should be stressed that the observed maximum deck time of 83 minutes was an unusual situation and occurred when a striped marlin was retrieved and the mainline became tangled in the propeller shaft in rough seas, greatly extending the deck time.

What was the initial core body temperature at the time of boarding for live and dead fish caught by longline?

The initial core body temperature of 134 mixed pelagic fish caught by longline gear was measured and recorded in order to establish a baseline for live fish and those that died on the line. The initial body temperature at the time the fish were brought on-board determined the magnitude of the temperature drop required to properly chill the fish. The single blue marlin monitored was not included in this comparison.

The results are presented in Table 7. Fish that died on the line tended to be 10° F colder than those that were retrieved alive. Within each species group, the mean initial core temperature of dead fish was significantly lower than for fish brought up alive. Live fish across all species had a mean initial core temperature of 79.54° F. Live fish struggle as the line is hauled and tend to have an elevated body temperature and a greater temperature drop required for proper chilling.

Table 7. Comparison of initial core temperature of pelagic fish caught by longline retrieved alive and dead.

Fish species	Live fish Initial core temp (° F)			Dead fish Initial core temp (° F)			Probability
	N	mean	SD	N	mean	SD	
Bigeye	17	78.71	1.54	13	65.14	8.16	0.0001
Yellowfin	9	79.81	1.64	10	71.43	6.96	0.0027
Albacore	14	80.25	5.07	34	67.76	7.60	0.0001
Striped marlin	8	79.59	1.25	13	74.49	5.81	0.03
Mahimahi	12	79.64	1.02	4	70.78	8.00	0.0013
All species	60	79.54	2.69	74	69.14	2.69	0.0001

Fish that died on the line had an average core temperature of 69.14° F. Dead fish tended to have a lower body temperature than live fish presumably because of the heat transfer to the water at the relatively cooler temperature found at the hooking depth.

Experimental longline fishing within the area in the central North Pacific typically fished by Hawaii's longline fleet confirmed the highest catch rate for bigeye tuna at 360 to 400 meter depths where water temperatures range from 46-50° F (Boggs, 1992). Bigeye are known to aggregate in water depths where corresponding water temperature is in the range of 46-50° F. This is fortuitous because if the fish dies, it is in water that is cold enough to begin the chilling process immediately. Histamine formation is known to be rapid at temperatures above 70° F and especially high at close to 90° F (FDA, 1998). The relatively cool temperatures at the hooking depth, even in tropical Pacific waters, may be one of the reasons histamine accumulation is not a more common problem with longline-caught tuna and other pelagic species in Hawaii.

The initial core temperature of fish is presumed to be correlated with water temperature. The correlation between sea surface temperature (SST) and the initial core temperature was analyzed for each of the pelagic species monitored during the 21 longline sets. SST was recorded at the beginning of each set and compared with initial core temperature of live and dead pelagic fish. SST is recorded by a thermistor placed on the vessel's hull, 9 to 12 feet below the sea surface and is readily available information on commercial longline vessels. Correlations for all pelagic fish except the 1 blue marlin are reported in Table 8.

Initial body temperature correlated with SST only for bigeye and striped marlin brought on-board alive. For live bigeye tuna the correlation coefficient was 0.62 ($P<0.01$) and for live striped marlin the correlation coefficient was 0.82 ($P<0.01$). Correlations may exist between initial core temperature of the other categories of fish and the water temperature at the depths where fish are hooked and not the sea surface. The time the fish is held at the particular water depth (and water temperature), species anatomical and physiological differences and fish size are other potentially important variables.

Table 8. Correlations between sea surface water temperature (SST) and initial core body temperature of pelagic fish brought on-board alive and dead during longline sets.

Fish	Alive SST vs Initial Core Temp		Dead SST vs Initial Core Temp	
	Corr. coef.	Probability	Corr. coef.	Probability
Bigeye	0.62	0.01	0.28	0.35
Yellowfin	0.22	0.57	0.49	0.15
Albacore	0.13	0.66	-0.05	0.77
Striped marlin	0.82	0.01	0.06	0.84
Mahimahi	0.48	0.11	0.83	0.17
All species	0.11	0.36	0.13	0.22

What was the temperature profile for fish stored in ice?

After the initial core temperature of the fish was recorded, the temperature loggers were placed in a sample set of 80 mixed pelagic fish to record detailed time and temperature histories during the remaining period of ice storage on the longline vessels.

The key parameters considered were, the temperature after 6 hours, the temperature after 24 hours, the time to below 50° F and the time to below 40° F. Using the combined data from all of the fish (dead and alive) monitored in longline sets with detailed temperature histories, the average core temperature at 6 hours was 46.15° F (Figure 2). The average core temperature at 24 hours was 33.2° F. Disregarding the additional time for fish that died on the line, on average, these longline-caught fish were handled on-board in compliance with the FDA handling guidelines. Once they were brought aboard fishers were capable of chilling fish to below 50° F within 6 hours and to below 40° F within 24 hours to control histamine accumulation.

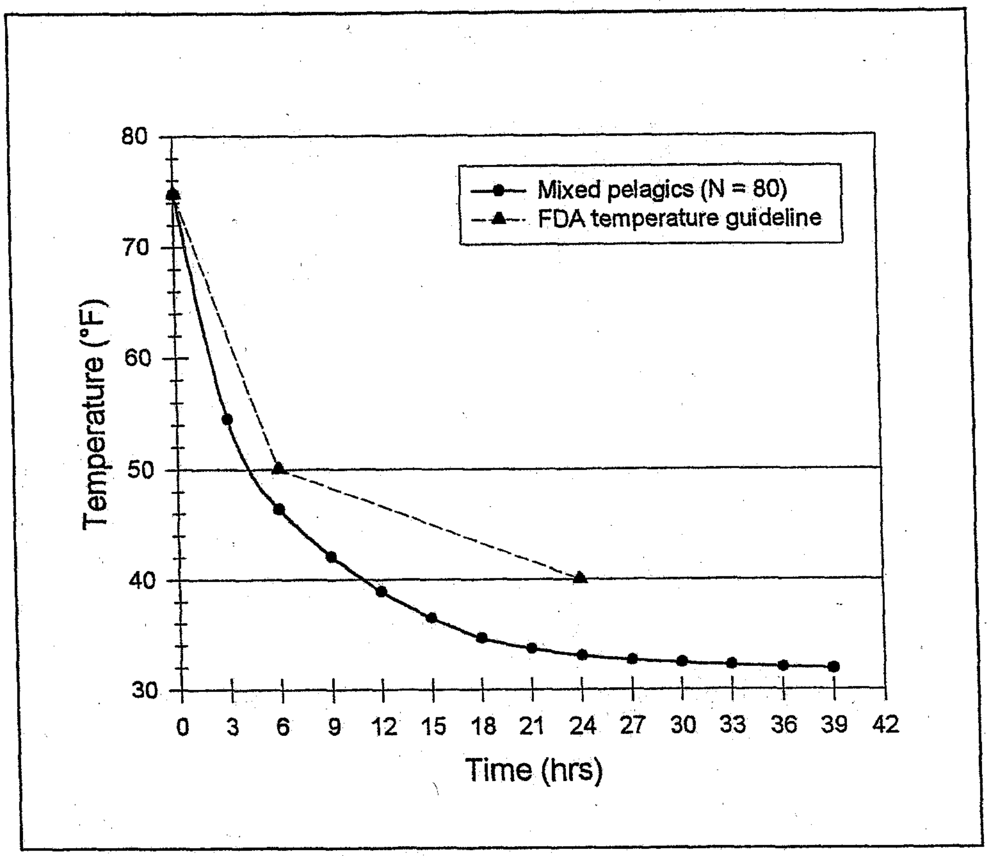

Figure 2. Mean On-board Fish Temperature Profile for mixed pelagic fish retrieved dead and alive by longline gear, chilled and stored in ice.

The chilling patterns for each species were also evaluated. Chilling patterns for bigeye, yellowfin, albacore are presented in Figure 3, and for striped marlin, blue marlin and mahimahi in Figure 4.

Bigeye tuna brought aboard alive, did not meet the 6-hour to below 50° F guideline, but were below 40° F within 24 hours after death. After 6 hours, live bigeye were 51.2 ° F and after 16 hours these fish were below 40° F. Dead bigeye began the on-board chilling sequence at about 65° F, were below 50° F in just over 4 hours and below 40° F within 13 hours after boarding.

Yellowfin tuna brought to the boat alive did not meet the 6 hours to 50° F guideline, but met the 40° F guideline well within the 24-hour period after death. After 6 hours, live yellowfin were a few degrees above 50° F and after 14 hours were below 40° F. Dead yellowfin, did not meet the 6-hour to 50° F guideline, but met the 40° F guideline within 14 hours after being brought on-board. The initial temperature difference between live and dead yellowfin was made up within the first 4 hours of chilling.

Albacore tuna brought to the boat alive easily met both the 40° and 50° F guidelines. Dead albacore were chilled to below 40° F after 2 hours and to below 40° F within 8 hours of boarding.

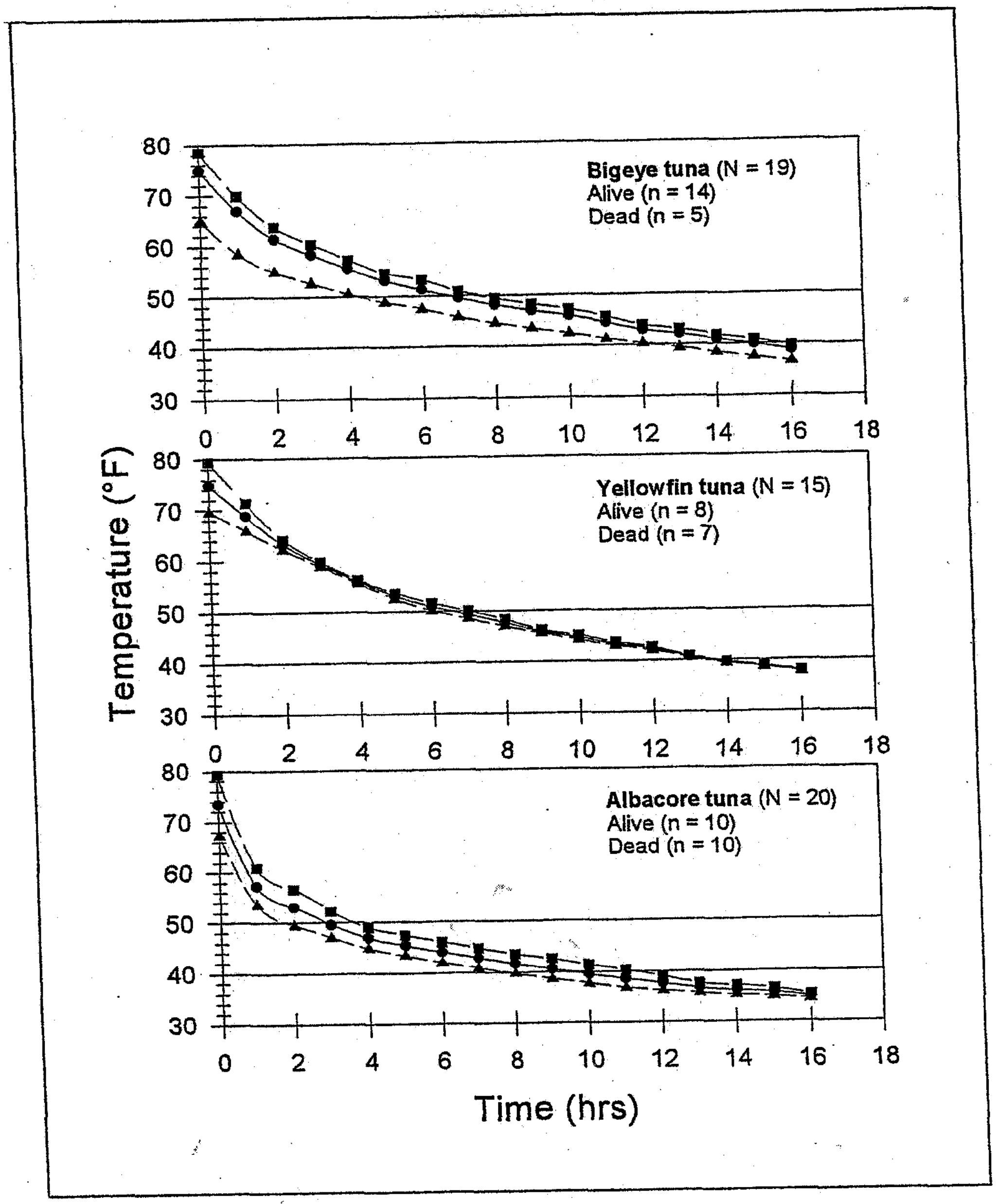

Figure 3. Fish Temperature Profiles (chilling patterns) for bigeye, yellowfin and albacore tuna caught by longline. (alive=■, dead=▲ , all=●)

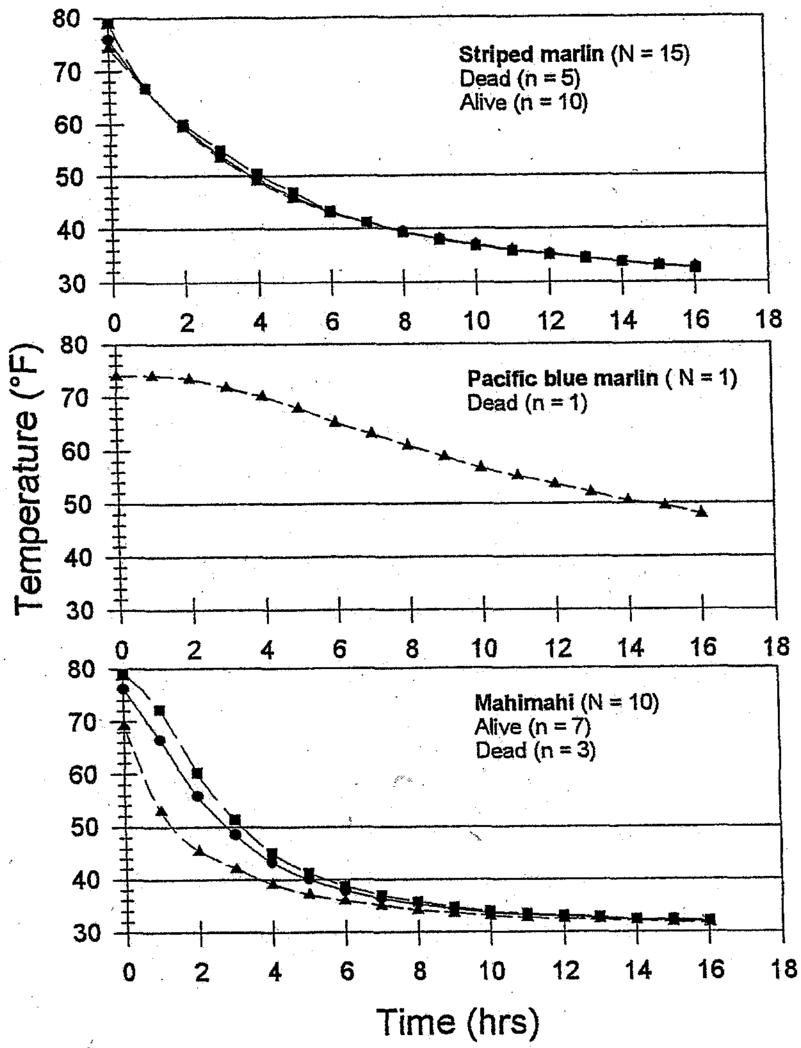

Figure 4. Fish Temperature Profiles (chilling patterns) for striped marlin, Pacific blue marlin and mahimahi caught by longline. (alive=■, dead=▲, all=●).

Striped marlin brought to the boat alive were chilled to below 50° F after 4 hours and to below 40° F after 8 hours after death. Dead striped marlin were chilled to below 50° after 4 hours and to below 40 ° F within 8 hours.

A single Pacific blue marlin was monitored at sea. This fish died on the line. After boarding, this fish took over 14 hours to be chilled to below 50° F but dropped below 40° F within 24 hours. This fish was large (369 lbs round weight), did not meet the 50° F guideline but was cooled to below 40° F, 23.9 hours after being brought aboard.

Mahimahi brought to the boat alive were chilled to below 50° F after 3 hours and to below 40° F within 6 hours after death. Live mahimahi complied with both of the FDA guidelines. Mahimahi that died on the line were chilled to below 50° F after 1 hour in ice and to below 40° F within 4 hours after boarding.

Did the fish chilling method make a difference?

The chilling method is of potential importance. Hawaii handliners and trollers tend to use an ice slurry to pre-chill fish before storage in ice alone. By contrast, longliners tend to pack fish directly into ice and after an initial cooling period, they repack the fish in ice to be sure that the ice is in full contact with the fish skin and that cooling proceeds effectively.

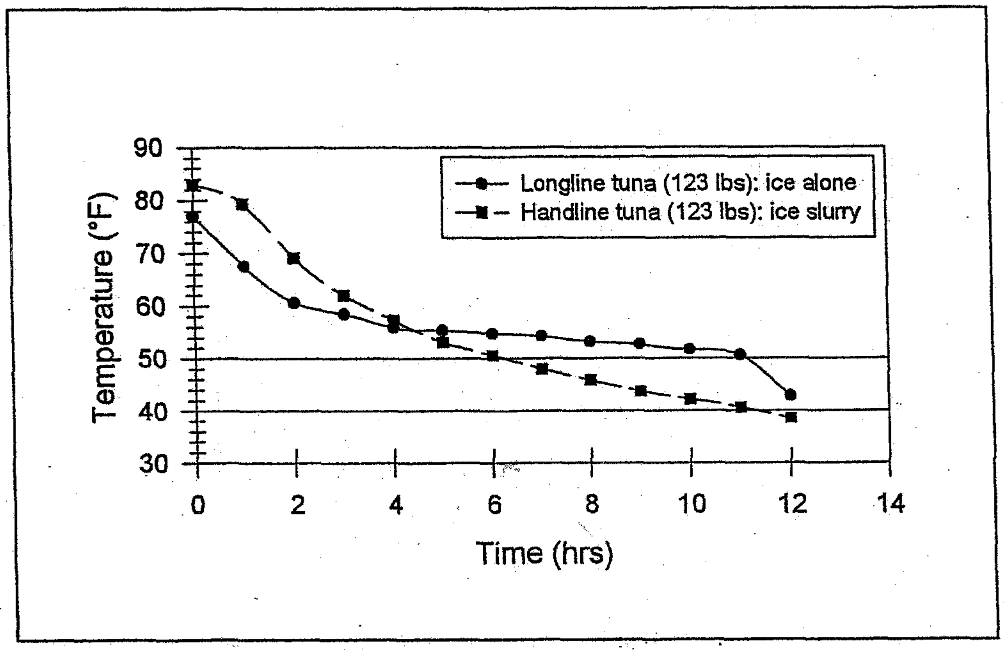

Figure 5. Fish Temperature Profiles (12 hours) comparing chilling rates for individual tuna (123 lbs each) caught by longline and handline, chilled by ice alone and ice slurry.

The comparison of these chilling methods in Figure 5 illustrates the difference in heat transfer efficiencies between ice alone and ice slurries (seawater and ice). Both tuna were of equal weight and were both brought to the vessel alive. The initial body temperature differed with handline-caught fish being higher (82.9° F) than the longline-caught fish (77.0° F). Although the handline fish started the chilling process at a higher temperature, the ice slurry method was much more efficient in heat transfer and after 4 hours, the handline fish was cooler than the longline fish. The chilling rate in the ice slurry continued to be faster, bringing the handline fish to 50° F after 6.2 hours and to below 40° F after 11.1 hours.

The longline fish held in ice alone had a much different cooling pattern. The temperature dropped steeply for the first two hours. After that, the cooling rate slowed greatly with little change until a steep temperature drop occurred after 11 hours. Initially the ice was in direct contact with the fish and chilling was efficient. After two hours, the ice melted immediately adjacent to the fish, forming an air space surrounding the fish. The heat transfer capacity of cold stagnant air is much less than water (20X) and the heat transfer rate slows substantially. After 11 hours, the crew repacked the fish in ice to ensure direct contact between the fish and the ice and the chilling rate accelerated greatly. By hour 12, the temperature differential between the two fish was almost eliminated. This temperature profile suggests that longline crews may want to carefully reconsider the time they wait before repacking fish in the ice. Repacking after a shorter waiting period would help to maintain optimum heat transfer and overall chilling rates. The advantages of a shorter waiting period should be weighed against the possibility that a second re-packing might become necessary. The cooling efficiency of an ice slurry over ice alone is potentially significant in terms of fish quality and food safety because it is an extremely effective method of heat transfer during the critical handling period when fish are >70° F.

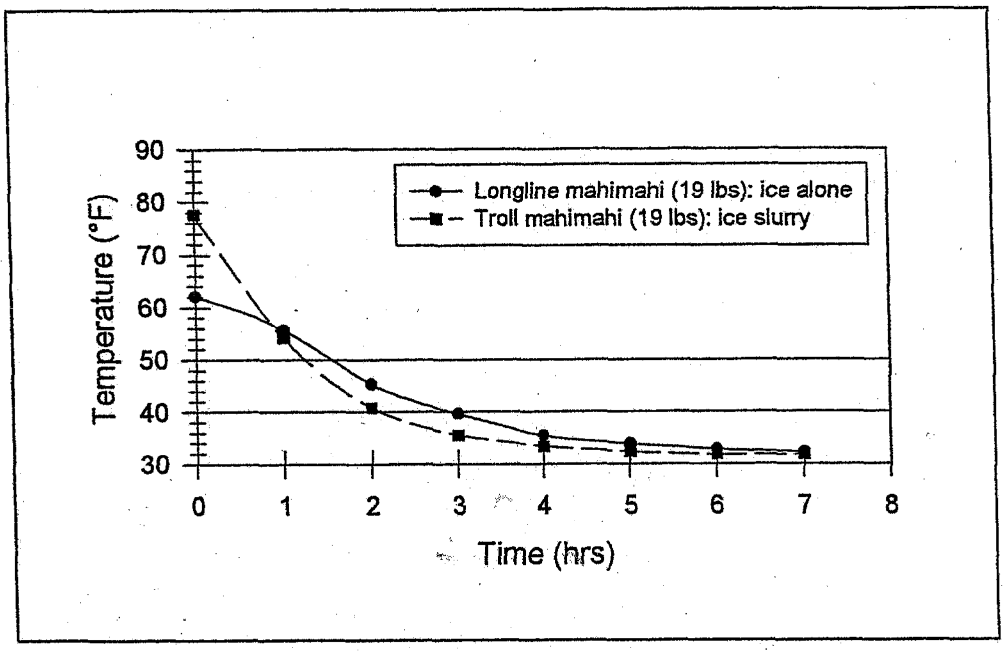

Figure 6. Fish Temperature Profiles comparing chilling rates for individual mahimahi (19 lbs each) caught by longline and troll gear, chilled by ice alone and ice slurry. The troll fish was alive and the longline fish was dead upon retrieval.

The difference between chilling methods on mahimahi of similar size is illustrated in Figure 6. The troll-caught mahimahi was landed alive and chilled in an ice slurry, had an initial core temperature of 79° F and yet after 1 hour, was cooler than the longline mahimahi stored in ice. Note that both mahimahi were chilled at relatively fast rates compared to the tuna in Figure 5. Body size (weight) accounts for much of this difference. However, the body conformation also impacts the heat transfer rates. Mahimahi are compressed laterally and have a greater surface area for heat exchange, while tuna are more rounded in cross-section and are anatomically evolved for heat retention.

What were the vessel standard operating procedures for post-harvest fish handling?

Vessel standard operating procedures for post-harvest fish handling were observed and monitored for fish brought aboard alive and dead. The parameters monitored included fish weight, initial core temperature, deck time, time to 50° F, time to 40° F, temperature at 6 hours (after boarding), temperature at 24 hours (after boarding), the total fish hold time, and at the end of the trip the quality grade and corresponding histamine concentration. Post-harvest handling data were summarized for each species group and for all fish combined (Table 9a and 9b). The means of each parameter were compared across fish species groups.

Table 9a. Verification of post-harvest fish handling during longline fishing sets: fish weight, initial core temperature, deck time, time to 50° F and time to 40° F.

FISH	WEIGHT (lb.) ($p < 0.0001$)			INITIAL CORE TEMP (°F) ($p = 0.9188$)			DECKTIME (Min) ($p = 0.286$)			TIME TO 50°F (min.) ($p < 0.0001$)			TIME TO 40°F (min.) ($p < 0.0001$)		
	n	mean	SD	n	mean	SD	n	mean	SD	n	mean	SD	n	mean	SD
BE	19	94.2	38.7	19	74.7	7.7	19	18.2	5.6	19	397	236.8	19	851	327.4
YF	15	81.4	12.2	15	74.8	7.0	15	15.9	5.4	12	352	142.8	12	786	113.8
AL	20	60.0	10.6	20	73.3	8.4	20	15.1	11.2	20	168	145.6	20	512	238.3
SM	15	66.5	17.7	15	75.8	5.8	15	14.0	5.9	14	218	100.9	14	410	160.7
BM	1	369.0		1	74.0		1	30.0		1	855		1	1435	
MM	10	28.2	7.8	10	76.1	6.4	10	18.6	10.5	9	179	45.9	9	313	80.1
ALL	80	73.2	44.6	80	74.8	7.1	80	16.4	8.2	75	275	195.7	75	611	312.8

(Abbreviations: BE = bigeye tuna, YF = yellowfin tuna, AL = albacore tuna, SM = striped marlin, BM = Pacific blue marlin, MM = mahimahi)

Table 9b. Verification of post-harvest fish handling during longline fishing sets: fish temperature after 6 and 24 hours, quality grades (No. 1-5), total fish hold time and histamine concentration.

FISH	TEMP AT 6 HR (°F) ($p < 0.0001$)			TEMP AT 24 HR (°F) ($p < 0.0001$)			GRADE ($p = 0.0132$)			FISH HOLD TIME (min.) ($p = 0.0032$)			HISTAMINE (mg/100g) ($p = 0.2806$)		
	n	mean	SD	n	mean	SD	n	mean	SD	n	mean	SD	n	mean	SD
BE	19	51.2	6.8	19	35.6	3.6	19	2.1	0.8	19	13085	7733.6	19	0.35	0.22
YF	12	50.2	4.7	12	33.5	0.7	12	2.4	0.7	12	17502	5885.5	12	0.25	0.15
AL	20	44.0	5.8	20	32.4	0.7	20	1.9	0.3	20	10651	4789.9	20	0.21	0.15
SM	14	42.6	4.7	14	31.5	0.5	14	1.6	0.5	14	9507	4609.4	14	0.21	0.22
BM	1	65.2		1	40.1		1	2.0		1	21727		1	0.14	
MM	9	38.4	3.5	9	31.4	0.3	9	2.1	0.3	9	17110	7463.9	9	0.30	0.26
ALL	75	46.2	7.3	75	33.2	2.6	75	2.0	0.6	75	13073	6746.0	75	0.26	0.20

(Abbreviations: BE = bigeye tuna, YF = yellowfin tuna, AL = albacore tuna, SM = striped marlin, BM = Pacific blue marlin, MM = mahimahi)

The mean fish weights were significantly different across species. This is only a reflection of the inherent differences between the fish species. However, fish weight was expected to have an effect on heat transfer rates reflected by differences in time and temperature parameters.

The mean initial core temperatures did not differ across the species and all species groups essentially began the on-board chilling process at similar starting temperatures. No difference was found in the mean deck time across species indicating that fishers tend to apply standard procedures in pre-processing fish before placing them in the fish hold.

Significant differences were found in the time and temperature parameters indicating that the differences in fish weight and physical differences in conformation between species has an effect on total heat load and heat transfer rates.

The total fish hold time differed significantly across species. The means ranged from a low of 6.6 days for striped marlin to a high of 15 days for the blue marlin. Fish hold time was compared to determine if the length of the time the fish was in the ice might have an effect on histamine accumulation.

After unloading, the fish were graded for quality and muscle samples were collected for histamine analysis. The mean quality grades differed significantly across species, however, no odor rejects (Grade 5) fish were found among these fish. Histamine concentration did not differ across species and the average histamine concentration for all of the fish in this sample set was 0.26 mg/100g (range 0.02 – 0.88 mg/100g, SD = 0.2mg/100g), well within the FDA defect action limit of 5 mg/100g. No histamine rejects were found within this sample set.

The post-harvest handling procedures and performance in temperature control documented during the 21 longline sets monitored during the project are considered representative of the Hawaii longline fleet that targets tuna. Those vessels that target swordfish tend to take longer trips and with the extended fish hold times, are known to produce high as well as low quality fish.

Did fish size make a difference?

Fish size logically makes a difference in chilling rates. The mean chilling rates reported in Tables 9a and 9b were ranked for comparison to illustrate the relationship between fish size (round weight) and chilling rates, where significant differences occurred between species (Table 10). The blue marlin was the largest group by weight followed by bigeye, yellowfin, striped marlin, albacore and mahimahi. If chilling rates are directly influenced by fish size, then similar species rankings should be expected for these time and temperature parameters.

Table 10. Comparison of pelagic fish ranked by mean fish size (weight) and chilling rates.

Weight	Initial Core Temp	Time to 50° F	Time to 40° F	Temp at 6 hours	Temp at 24 hours
BM (large)		BM (long)	BM (long)	BM (high)	BM (high)
BE ↓	No	BE ↓	BE ↓	BE ↓	BE ↓
YF ↓	statistical	YF ↓	YF ↓	YF ↓	YF ↓
SM ↓	Difference	SM ↓	AL ↓	AL ↓	AL ↓
AL ↓	(P>0.05)	MM ↓	SM ↓	SM ↓	SM ↓
MM(small)		AL (short)	MM(short)	MM (low)	MM (low)

(Abbreviations: BE = bigeye tuna, YF = yellowfin tuna, AL = albacore tuna, SM = striped marlin, BM = Pacific blue marlin, MM = mahimahi)

The initial core body temperatures of these fish were not significantly different and ranged from 73.3 to 76.1° F (Table 9a). Ranking the time and temperature parameter means by species reveals that the blue marlin with the greatest size also had the slowest chilling rate followed by bigeye and yellowfin tuna respectively. The last three fish in each category varied in order with mahimahi being the smallest fish by weight and having the fastest chill rate to 40° F and the lowest temperatures after 6 and 24 hours. This is also an indication of the size or weight factor. Heat transfer in mahimahi may also be influenced by other anatomical differences (body conformation, thickness of skin, fat content, etc.). Albacore had the fastest time to 50° F presumably because this species also had the lowest initial core temperature (73.3° F).

Results Obj. 4. Verify the relationship between post-harvest fish handling procedures and histamine accumulation.

Were the FDA fish handling guidelines met?

Yes for fish that are brought aboard alive. Uncertain for fish that died on the line. The on-board handling time and temperature parameters were evaluated in Objective 3. On average, all three fleets (troll, handline and longline) were capable of chilling fish within the guidelines offered by FDA, once the fish were brought on-board. Table 11 summarizes the critical information presented in Tables 9a and 9b from both dead and live longline fish. The uncertainty of the time of death for fish that are retrieved dead makes the calculation of exact chilling rates impossible. However, once fish were brought on-board, chilling rates from the time of boarding were determined accurately. Disregarding the additional time dead fish spend on the line, on average, all species groups caught by longline gear met the 50° F and 40° F guidelines. Mahimahi, striped marlin and albacore met the 50° F guideline, bigeye and yellowfin were close to meeting the guideline and the blue marlin was far from meeting this time and temperature goal. The FDA (1998) recognizes that if fish are well handled on-board the harvest vessel, that fish may be able to safely withstand somewhat more exposure to elevated temperatures during the post-harvest period. This indicates a certain amount of flexibility in adhering to the handling guidelines.

Table 11. Histamine concentration and compliance with FDA guidelines for pelagic fish caught by longline (retrieved alive and dead).

Fish	**Were the FDA handling Guidelines met?**		**Were fish below the FDA histamine DAL?**
	temp <50° F w/in 6 hrs.	temp <40° F w/in 24 hrs.	Histamine <5mg/100g
Bigeye tuna	No, but close	Yes	Yes
Yellowfin tuna	No, but close	Yes	Yes
Albacore tuna	Yes	Yes	Yes
Striped marlin	Yes	Yes	Yes
Blue marlin	No	Yes	Yes
Mahimahi	Yes	Yes	Yes
All fish (mean)	Yes	Yes	Yes

Did the post-harvest handling procedures adequately control histamine?

Yes. All samples collected from fish (alive and dead) with known on-board temperature histories fell within acceptable limits for histamine. The mean histamine concentration was 0.26 mg/100g (range = 0.02 - 0.88 mg/100g, SD = 0.20). The conclusion is that the on-board handling methods observed and documented on Hawaii longliners are capable of adequately controlling histamine accumulation.

The group of longline fish was divided into fish that died and those that survived until being brought on-board. A comparison was made to determine if the mean histamine concentration differed between fish retrieved alive and those that died on the line. The results displayed in Table 12 indicate that there is no significant difference (P>0.2). This finding reduces the uncertainty about the adequacy of the current practices in preventing histamine accumulation in Hawaii longline fish that die on the line.

Table 12. Comparison of the histamine concentration of longline-caught fish retrieved alive and dead.

Fish	Histamine (mg/100g) Live fish at retrieval					Histamine (mg/100g) Dead fish at retrieval					Prob.
	N	mean	SD	min	max	N	mean	SD	min	max	
BE	14	0.38	0.23	0.04	0.72	5	0.24	0.19	0.02	0.53	P>0.5
YF	6	0.29	0.16	0.02	0.52	6	0.21	0.11	0.02	0.31	P>0.5
AL	10	0.18	0.13	0.02	0.39	10	0.23	0.17	0.02	0.53	P>0.5
SM	4	0.21	0.16	0.05	0.36	10	0.21	0.25	0.02	0.88	P>0.2
BM	0					1	0.14				
MM	7	0.33	0.28	0.02	0.74	2			0.05	0.26	
ALL	41	0.30	0.21	0.02	0.74	34	0.21	0.18	0.02	0.88	P>0.5

(Abbreviations: BE = bigeye tuna, YF = yellowfin tuna, AL = albacore tuna, SM = striped marlin, BM = Pacific blue marlin, MM = mahimahi)

The laboratory maintained strict QA/QC procedures using histamine-spiked samples during each batch of fish run for histamine analysis. The average percentage recovery was 95.7% (range 89.2 - 109.0%, SD = 4.20%). The QA/QC for histamine analysis was deemed to be adequate and the histamine results are considered reliable.

Results Obj. 5. Determine the importance of fish quality grades and odors of decomposition as indicators of histamine concentration.

In addition to the fish sampled with known on-board temperature histories from studies in Objectives 3 and 4, fish were also sampled at the 2 fish auctions to represent fish delivered by the primary producer to the primary processor in the Hawaii fresh fish market. Fish were sampled from 42 commercial longline trips, 45 trolling trips and 32 handline trips. Fish were sampled between July 1998 and October 1999 during all four quarters of the year. This collection period encompassed the summer peak of fishing activity by all three gear types as well as the winter months when bigeye tuna are more prevalent.

The entire market sample set is displayed in Table 13. A total of 583 mixed pelagic fish were sampled, weighed, graded for quality and subjected to sensory evaluation for odors of decomposition and analyzed for histamine concentration. The sampling protocol attempted to collect equal numbers of fish in the 5 quality grades (Grades 1 – 4 and Grade 5 or "odor rejects"). Of the total, 119 fish were graded as odor rejects due to the presence of odors of decomposition detected by sensory examination.

Table 13. Histamine concentrations of commercial pelagic fish landed in Hawaii fresh fish market by gear type, fish species, weight, quality grade and sensory evaluation.

Gear type with common names	Round weight (lbs)				Grade 1 Histamine (mg/100 g)					Grade 2 Histamine (mg/100 g)					Grade 3 Histamine (mg/100 g)					Grade 4 Histamine (mg/100 g)					Reject Histamine (mg/100 g)				
Longline	N	Mean	Min	Max	N	Mean ±	SD	Min	Max	N	Mean ±	SD	Min	Max	N	Mean ±	SD	Min	Max	N	Mean ±	SD	Min	Max	N	Mean ±	SD	Min	Max
Bigeye tuna	96	102	39	210	17	0.30	0.29	0.02	1.18	17	0.24	0.16	0.02	0.59	18	0.45	0.86	0.02	3.92	16	0.20	0.14	0.02	0.46	28	10.27	36.71	0.02	196.00
Yellowfin tuna	90	95	31	150	17	0.36	0.27	0.02	0.84	23	0.37	0.26	0.02	1.14	23	0.30	0.24	0.02	1.00	14	0.54	0.54	0.10	2.27	13	19.56	47.59	0.02	179.00
Albacore tuna	54	54	29	74	19	0.12	0.14	0.02	0.50	20	0.20	0.15	0.02	0.53											15	3.13	4.85	0.02	15.90
Striped marlin	40	69	31	126	15	0.35	0.40	0.02	1.63	15	0.16	0.13	0.02	0.42											10	0.29	0.44	0.02	1.54
Pacific blue marlin	30	179	99	429	15	0.29	0.49	0.02	2.02	15	0.33	0.44	0.02	1.72															
Mahimahi	86	19	5	45						31	0.32	0.51	0.02	2.91	1	0.69									53	0.39	0.93	0.02	5.74
Handline																													
Bigeye tuna	4	51	31	107						4	0.48	0.19	0.21	0.70															
Yellowfin tuna	65	111	43	188						48	0.25	0.28	0.02	1.20	17	0.14	0.13	0.02	0.41										
Albacore tuna	43	51	36	67						43	0.19	0.16	0.00	0.78															
Troll																													
Yellowfin tuna	35	124	84	171						17	0.39	0.37	0.02	1.30	18	0.16	0.19	0.02	0.63										
Pacific blue marlin	24	246	103	599	18	0.14	0.21	0.02	0.72	6	0.11	0.11	0.02	0.33															
Mahimahi	17	18	8	34	17	0.20	0.25	0.02	0.92																				
All gear types																													
Bigeye tuna	100	100	31	150	17	0.30	0.29	0.02	1.18	21	0.28	0.19	0.02	0.70	18	0.45	0.86	0.02	3.92	16	0.20	0.14	0.02	0.46	28	10.27	36.71	0.02	196.00
Yellowfin tuna	190	106	31	188	17	0.36	0.27	0.02	0.84	88	0.31	0.30	0.02	1.30	58	0.21	0.21	0.02	1.00	14	0.54	0.54	0.10	2.27	13	19.56	47.59	0.02	179.00
Albacore tuna	97	53	29	74	19	0.12	0.14	0.02	0.50	63	0.19	0.15	0.00	0.78											15	3.13	4.85	0.02	15.90
Striped marlin	40	69	31	126	15	0.35	0.40	0.02	1.63	15	0.16	0.13	0.02	0.42											10	0.29	0.44	0.02	1.54
Pacific blue marlin	54	208	99	599	33	0.21	0.37	0.02	2.02	21	0.27	0.39	0.02	1.72															
Mahimahi	102	19	5	45	17	0.20	0.25	0.02	0.92	31	0.32	0.51	0.02	2.91	1	0.69									53	0.39	0.93	0.02	5.74

A comparison of fish weight, grade and histamine was made between species for all gears combined (Table 14) in the market sample. The 6 fish species in the market sample differed statistically by weight (P<0.0001) as expected. Blue marlin was the largest species, followed by yellowfin, bigeye, striped marlin, albacore and mahimahi.

Table 14. Comparison of weight, grade and histamine concentration between pelagic fish species for all gears.

Fish	N	Weight (lb) (P<0.0001)		Grade (No.1-5) (P<0.0001)		Histamine (mg/100g) (P=0.259)	
		mean	SD	mean	SD	mean	SD
BE	100	100	44.0	3.17	1.47	3.10	20.04
YF	190	106	32.2	2.57	0.99	1.62	13.40
AL	97	53	10.8	2.27	1.24	0.63	2.20
SM	40	69	23.7	2.38	1.60	0.26	0.35
BM	54	208	128.6	1.39	0.49	0.23	0.38
MM	102	19	8.6	3.40	1.71	0.34	0.74

(Abbreviations: BE = bigeye tuna, YF = yellowfin tuna, AL = albacore tuna, SM = striped marlin, BM = Pacific blue marlin, MM = mahimahi)

The 6 fish species differed in average quality grades (P<0.0001) with Grade 1 being the highest quality and Grade 5 being a reject. Blue marlin had the highest average quality score (1.39) followed by albacore (2.27), striped marlin (2.38), yellowfin (2.57), bigeye (3.17) and mahimahi (3.40) the lowest quality score in the market sample collected. It should be stressed that this is merely an analysis of the quality of the fish in the market sample set that was designed to compare across grades and is not a reflection of the typical catch make-up and fish quality available in the Hawaii market.

The comparison of histamine concentration in the market sample set by fish species for all fishing gears was not significant (p = 0.259). This is due to the wide variance in histamine values in the odor reject category (Grade 5).

Does fish quality grading and sensory evaluation effectively screen out fish with high histamine risk?

Yes. Every fish that contained histamine greater than 5 mg/100g fell into the category of odor rejects (Grade 5) made up of fish rejected due to inferior quality and odors of decomposition. The conclusion is that standard fish quality grading and screening fish for odors of decomposition is effective in eliminating fish with high histamine content.

In another study, sensory evaluation was shown to be highly correlated with histamine concentration in studies of histamine formation and decomposition at elevated temperature in mahimahi in Hawaii (Baranowski, et al, 1990).

Was there any evidence of histamine accumulation in the fish that passed sensory evaluation?

Yes. Four (4) out of the 464 fish of Grade 1 through Grade 4 had histamine concentrations above 2.0 mg/100g but none exceeded 4.0 mg/100g. These fish had all passed sensory evaluation. One (1) blue marlin (Grade 1, 2.02 mg/100g), 1 bigeye tuna

(Grade 3, 3.92 mg/100g), 1 mahimahi (Grade 2, 2.91 mg/100g) and 1 yellowfin (Grade 4, 2.27 mg/100g) were found. Fish that exceed 2.0 mg/100g histamine raise questions about inadequate on-board fish handling. Assuming that problems with handling these muscle samples between collection and histamine analysis did not occur to account for the elevated histamine, we conclude that the occasional fish can be found with more than 2.0 mg/100g histamine after passing sensory evaluation. However, these fish were still within legal and safe limits for sale and consumption.

Clearly, these few fish if improperly handled as they pass through the subsequent processing and marketing channels may have resulted in further histamine accumulation. However, with the FDA HACCP program, all histamine forming fish should be kept below 40° F at all times to control histamine. The potential problem increases after these fish leave the jurisdiction of FDA HACCP and into the hands of retailers, restaurants and consumers. In order to control histamine in these outlying groups, education and training in proper fish handling is greatly needed.

Is there a statistical difference between Grades 1, 2, 3, 4 and odor rejects?

The histamine concentration of longline fish was compared by quality grade and by species (Table 15). Only the bigeye and yellowfin tuna had sufficient numbers of fish from each of the 5 quality grade categories. The longliners in Hawaii do not generally produce the full range of quality grades for all species of fish. Grade 4 and odor rejects are relatively uncommon. Longliners do not produce the high quality, Grade 1 mahimahi that are only available from trollers making day trips. Grades 1 and 2 predominate in albacore, striped marlin and blue marlin in longline catches, while Grades 3 and 4 and odor rejects in these species are uncommon. During the market sampling, no blue marlin odor rejects were detected.

A comparison was made of histamine concentration between quality grades within species for longline-caught fish. Significant differences were found for albacore (P=0.0022) and yellowfin (P=0.0245)(Table 15).

Table 15. Comparison of histamine concentration for longline caught fish by species and quality grade.

Fish	Probability	Grade 1 Histamine (mg/100g)			Grade 2 Histamine (mg/100g)			Grade 3 Histamine (mg/100g)			Grade 4 Histamine (mg/100g)			Rejects Histamine (mg/100g)		
		n	mean	SD	n	mean	SD	n	mean	SD	n	mean	SD	n	mean	SD
BE	0.3214	17	0.304	0.302	17	0.236	0.167	18	0.449	0.881	16	0.201	0.145	28	10.271	37.387
YF	0.0245	17	0.359	0.275	23	0.365	0.262	23	0.298	0.243	14	0.541	0.561	13	19.561	49.532
AL	0.0022	19	0.125	0.139	20	0.199	0.157							15	3.13	5.019
SM	0.3559	15	0.346	0.419	15	0.161	0.137							10	0.291	0.461
BM	0.8268	15	0.291	0.505	15	0.329	0.452									
MM	0.8682				31	0.323	0.519	1	0.690					53	0.388	0.942
ALL	0.0346	83	0.279	0.344	121	0.279	0.345	42	0.372	0.601	30	0.359	0.426	119	5.416	24.790

(Abbreviations: BE = bigeye tuna, YF = yellowfin tuna, AL = albacore tuna, SM = striped marlin, BM = Pacific blue marlin, MM = mahimahi)

Comparisons of mean histamine concentrations between grades within each species were made. In the albacore group, odor rejects had a greater average histamine (3.13 mg/100g) and differed from both Grade 1 (0.13 mg/100g, P= 0.0017) and Grade 2 (0.20 mg 100g, P=0.002) (Table 16). Within the yellowfin group, odor rejects had a mean histamine concentration of 19.56 mg/100g and differed from Grade 1 (P=0.0063), Grade 2 (P=0.0038), Grade 3 (P=0.0037) and Grade 4 (P=0.0095). Grades 1 through 4 however, were not significantly different from each other.

Table 16. Comparison and ranking of mean histamine concentrations by grade for longline caught fish (Reject = Grade 5).

Fish	Grade vs. Grade comparison	Probability	Rank of Means	Histamine (mg/100g)
Albacore	Grade 1 vs. Reject	0.0017	Reject	3.13
	Grade 2 vs. Reject	0.002	Grade 2	0.20
			Grade 1	0.13
Yellowfin	Grade 1 vs. Reject	0.0063	Reject	19.56
	Grade 2 vs. Reject	0.0038	Grade 4	0.54
	Grade 3 vs. Reject	0.0037	Grade 2	0.37
	Grade 4 vs. Reject	0.0095	Grade 1	0.36
			Grade 3	0.30
All species	Grade 1 vs. Reject	0.013	Reject	5.15
	Grade 2 vs. Reject	0.006	Grade 3	0.37
	Grade 3 vs. Reject	0.052	Grade 4	0.35
	Grade 4 vs. Reject	0.087	Grade 2	0.28
			Grade 1	0.28

When all species were considered, comparisons of the mean histamine concentrations of odor rejects and the other quality grades were significant except for Grade 4.

By combining the Grades 1 through 4, the mean histamine concentrations of acceptable quality fish and odor rejects were compared (Table 17). In this way, the odors of decomposition were evaluated as indicators of histamine risk. Bigeye and yellowfin tuna were the two species with sufficient numbers of Grades 1 through 4 and odor rejects (Grade 5) needed to make the following comparison. For both bigeye and yellowfin tuna, odor rejects had significantly higher mean histamine concentrations than fish without odors of decomposition (Grades 1 - 4 combined). The mean histamine concentration for all of the acceptable quality bigeye and yellowfin (Grades 1 – 4) was 0.30 and 0.37 mg/100g respectively, well below the defect action level. By contrast, bigeye and yellowfin odor rejects had mean histamine concentrations of 10.27 and 19.56 mg/100g respectively, far exceeding the defect action limit.

Table 17. Comparison of histamine between grade 1 through 4 combined and odor rejects (Grade 5) longline caught bigeye (BE) and yellowfin tuna (YF).

Fish	Probability	Grades 1 to 4 combined. histamine (mg/100g)			Grade 5 (odor rejects) Histamine (mg/100g)		
		N	mean	SD	N	mean	SD
BE	0.0292	68	0.30	0.48	28	10.27	37.38
YF	0.0007	77	0.37	0.33	13	19.56	49.53

(Abbreviations: BE = bigeye tuna, YF = yellowfin tuna)

What can be said about the odor reject category?

Table 18 displays the numbers and percentages of the odor rejects separated by species, that had histamine levels of 0 - 1.99, 2.00 – 4.99 and >5.00 mg/100g. These values were used because of the regulatory implications. The defect action level for histamine in seafood is 5 mg/100g. Histamine concentration between 2.00 and 4.99 mg/100g although acceptable, is cause for concern because it indicates marginal post-harvest handling. Fish with less than 1.99 mg/100gm are acceptable for sale.

A total of 119 fish rejected from the market due to odors of decomposition (Grade 5) were sampled during the study in order to achieve close to equal numbers of fish to represent each of the 5 grade categories in the market sample.

All of the histamine rejects found in the study were initially rejected for decomposition. There were only 14 fish found that exceeded the histamine defect action limit (5mg/100g) amounting to only 11.7% of the 119 odor rejects. The majority (85%) of the decomposed fish had low and acceptable levels of histamine (<1.99mg/100g). Only 4 fish (3.3%) were found with histamine concentrations between 2.00 and 4.99 mg/100g.

Table 18. Histamine concentrations of longline odor rejects.

Fish	Odor Rejects N	Histamine <1.99mg/100g N (%)	2 - 4.99mg/100g N (%)	>5mg/100g N (%)
Bigeye	28	22 (78.5%)	1 (3.6%)	5 (17.9%)
Yellowfin	13	8 (61.5%)	1 (7.7%)	4 (30.8%)
Albacore	15	10 (66.6%)	1 (6.6%)	4 (26.6%)
Striped Marlin	10	10 (100%)		
Blue Marlin	0			
Mahimahi	53	51 (96.2%)	1 (1.9%)	1 (1.9%)
TOTAL	119	101 (85%)	4 (3.3%)	14 (11.7%)

Five (5) of the bigeye tuna odor rejects (17.9%) contained histamine levels above 5 mg/100g. Four (4) of the yellowfin odor rejects (30.8%) were also histamine rejects. There were 4 albacore histamine rejects (26.6%) among the 15 albacore odor rejects. The striped marlin odor rejects were all within acceptable limits for histamine. No blue marlin odor rejects were found during the market sampling. Only 1 mahimahi histamine reject (1.9%) was found among the 53 mahimahi odor rejects. This finding is of great interest in that mahimahi is one of the two most commonly implicated species in cases of histamine poisoning in Hawaii. It may be that the domestically produced mahimahi reported to cause histamine poisoning in Hawaii are not landed by longline vessels. More thorough epidemiological reporting and investigations would be required to answer this question.

What was the source of the odor rejects and high histamine fish?

All of the odor rejects were from longline sets and none were found in the landings of Hawaii trollers and handliners during the study. The lack of rejects from trollers and handliners is likely due to the short period to time between death and delivery to the primary processor. Evaluating the histamine accumulation that may occur after delivery to the market was not one of the objectives of this study.

Longline trips in Hawaii can be categorized by target species into tuna and swordfish trips. Fishing trips targeting swordfish and tuna differ in primary target species, some of histamine accumulation and standard industry practices, specific to the Hawaii pelagic fishery.

The Hawaii VSOP Approach for histamine control.

The VSOP (vessel standard operating procedures) for post-harvest fish handling at sea is designed for Hawaii's fresh tuna fishery and integrates the FDA fish handling guidelines and new information generated during on-board research in this study. The VSOP details the minimum handling parameters required for the control of histamine accumulation in histamine-forming fish species (Figure 7). The guidelines recommended by FDA of chilling fish to below 50° F within 6 hours and to below 40° F within 24 hours of boarding are used in the VSOP. Results of this study demonstrated that on average, Hawaii longline, handline and trolling vessels are capable of meeting these guidelines once the fish are brought aboard and adequately controlling histamine accumulation.

The primary processor requires some form of verification that vessel crews adhere to the VSOP during fishing trips. Primary processor should prepare VSOP documents that can be signed by the vessel owner and captain to be kept on file for each vessel, as a pre-requisite of purchasing or marketing agreements. The VSOP on file with the primary processor should be renewed annually. A letter of assurance (LOA) should be signed and submitted each time the vessel delivers fish to the market as a written guarantee of compliance with the VSOP (Figure 8) and the HACCP Plan of the receiving company.

In addition, the adequacy of the icing in the hold should be checked at the time of unloading. The amount of ice at the beginning of the trip should be reported. The time the first and last fish were boarded is also very important information. Internal fish temperatures should be recorded for 3 fish per ton at the time the fish are delivered. All fish that are over 24 hours out of the water should be below 40° F. Fish out of the water between 6 and 24 hours should be less than 50° F at receiving. Fish out of the water less than 6 hours can be received at above 50° F as long as the icing is adequate.

It has been demonstrated that odors of decomposition are reliable indicators of fish with high histamine concentration in the Hawaii fresh tuna industry. As a vital part of the VSOP approach, individual fish should under go quality grading and sensory evaluation to screen out fish with odors of decomposition at the time of delivery. This standard industry practice in Hawaii is now incorporated into a practical HACCP approach. Quality grading and sensory evaluation are conducted by the HACCP manager or scale master, again by the auctioneer and finally by the individual buyers at the point of purchase. This redundancy of quality and sensory checks ensures that decomposed, along with high histamine-risk fish are effectively culled from the market. Decomposed fish should be rejected on an individual fish basis and have no impact on the rest of the fish in the load as in the lot sampling methods.

Hawaii's two display auctions adopted a VSOP system soon after the FDA HACCP program became effective in December of 1997 (Kaneko, 1997a,b,c). Cooperation from fishers has been exemplary to date. The VSOP has focused attention to on-board handling details, increasing the awareness of fishers to their responsibility in providing high quality and safe fish to the market. The VSOP approach integrated in-depth knowledge of standard industry practices with available scientific understanding of histamine formation and the principles of HACCP. The current study was proposed and conducted to provide scientific validation of the efficacy of the Hawaii VSOP system for controlling histamine accumulation in tuna and associated pelagic fish.

Figure 7. Vessel Standard Operating Procedure (VSOP) document.

COMPANY X, Inc.
VSOP
(Vessel Standard Operating Procedures)
On-board Fish Handling for Histamine Control

Fishing Vessel: ________________________

Owner: (print)________________ (sign)________________ (date ________)

Captain: (print)________________ (sign)________________ (date________)

This is to verify that the following standard operating procedures for on-board fish handling are practiced on this vessel and that any significant deviation from these practices will be noted and the receiver notified prior to unloading. This VSOP is submitted in cooperation with the receiver's HACCP Program designed especially for the prevention of histamine accumulation in susceptible fish species.

Fishing Method: longline / handline / troll

Refrigeration Method: ice slurry / ice alone / ice with refrigerated fish hold / RSW

Sanitation:

The fish holds are cleaned and sanitized after each trip using a dilute chlorine bleach solution (specifically, sodium hypochlorite solution of 100 ppm). Clean, new ice made from potable water is loaded into the fish hold at the start of each fishing trip. Fish holds are not used to store fuel. Fish holds are kept free of chemicals and lubricants used on-board the vessel.

Fish Handling Method:

Fish are handled carefully, kept clean and chilled rapidly in order to prevent the potential formation of histamine in susceptible fish species.

Fish are landed individually by hook and line, gaffed and immediately stunned with a club and bled using gill and tail cuts. The fish is rinsed with clean seawater and placed immediately into ice or ice slurry. Fish may be kept whole, gilled and gutted or headed and gutted. This process takes no more than 15 minutes from the time of boarding.

Fish are chilled to an internal temperature of 50°F within 6 hours of boarding. Fish temperatures are brought down to < 40° F within a total of 24 hours of boarding. Fish are kept properly iced during storage on-board the vessel to maintain fish temperature <40°F until unloading.

Figure 8. Letter of Assurance (LOA) of compliance with VSOP.

COMPANY X, INC.
VESSEL HACCP RECORD

Letter of Assurance (LOA)

This certifies that the fish delivered to COMPANY X from the described fishing trip were handled in accordance with the current signed VSOP (vessel standard operating procedures) document on file at COMPANY X. This information is provided as a component of the COMPANY X VSOP program for compliance with US FDA HACCP regulations (21 CFR Part 123).

Vessel Name: ____________________

Fishing Method: (circle one) (longline / handline / troll)

Captain: (print)__________________(sign)________________(date)________

Trip details:

Date trip started:	__________	Time departed:	__________
Date first fish caught:	__________	Time fish caught:	__________
Date last fish caught:	__________	Time fish caught:	__________
Date of unloading:	__________	Time started:	__________

Last fish caught: ( ) dead for more than 24 hours at delivery
(check one) ( ) dead for 12 to 24 hours at delivery
( ) dead for less than 12 hours at delivery

Cooling Methods:

Tons or lbs. of ice at start of trip: __________

Icemaker capacity: __________/day

Refrigerated hold? (circle) (yes / no)

Tons or pounds of fish: __________ total estimate

*To be completed by COMPANY X:

Icing adequate at time of unloading? (yes / no)

VSOP on file at COMPANY X? (yes / no)

Signature of COMPANY X staff: ________________________

The VSOP system designed for the Hawaii fresh tuna industry is tailored to the unique industry setting and fishery. The VSOP system currently in place is effective only because of the special relationship between the fleets and the market through the 2 fish auctions that receive the majority of the commercial fish landings in the state. The Hawaii fish auction system is unique in the US and allows each fish to be displayed, closely evaluated for quality and odors of decomposition and sold on an individual fish basis. An important feature is that buyers have no obligation to bid on or purchase fish and must take the full responsibility to evaluate the fish that they buy for quality and relative safety indicators. The auction system rewards high quality with higher prices and links the interests of fishers with the auctions directly. Fishers recognize the direct relationship between proper handling, fish quality and monetary returns to the vessel. This emphasis on higher quality at the same time promotes the control of histamine. The VSOP system helps the auctions to encourage fishers to practice proper on-board fish handling methods that are known to prevent the accumulation of histamine.

Precautions about the application of the VSOP system.

The VSOP system is supported by the results of the studies designed and conducted to evaluate the specific industry and environmental conditions in Hawaii. Extrapolation of this information to other fisheries is not acceptable. The principles of HACCP require hazard analysis to be conducted for each operation and industry sector as the first step in developing a HACCP program.

To illustrate this point, the same information and VSOP approach to controlling histamine cannot be applied to frozen tuna products. This is especially true for carbon monoxide or filtered wood smoke treated frozen tuna. This is because the important characteristics of fresh tuna grades (muscle color and clarity) are altered in frozen tuna unless they are frozen to ultra-low temperatures (-50° F). Carbon monoxide treatment of tuna creates an unnatural and unusually stabile red muscle color that does not have the normal characteristics of fresh untreated tuna. The use of carbon monoxide eliminates the ability to accurately judge the true product quality and therefore product safety. Most importantly, the use of carbon monoxide to treat tuna alters the odor characteristics of the product. This makes the critical step of sensory evaluation uncertain and unreliable in screening out fish with high histamine risk. This is in sharp contrast to the demonstrated efficacy of sensory evaluation in culling high histamine-risk fish in landings of chilled, untreated tuna and associated pelagic fish species in Hawaii.

Results Obj. 7. Communication of results to the FDA Office of Seafood.

Copies of the final report will be submitted to the FDA Office of Seafood. Dr. George Hoskin, Director for Science and Technology in the Office of Seafood served as the primary point of contact. He will distribute the report copies to specialists at the FDA.

B. If significant problems developed which resulted in less than satisfactory results, they should be addressed.

No significant problems occurred. However, during the study, vessel-based research was conducted on-board commercial trollers, handliners and longliners. During the initial trips on trollers and handliners, the post-harvest fish handling methods were documented and it was determined that the cooling method used (ice slurry) was more efficient than the method used on longliners (ice alone). The catch rates on trollers and handliners also proved to be much lower than expected and data collection from these two fleets was inefficient. The decision was made to focus more attention on the longline fleet that produces the bulk of the commercial fish landings in Hawaii and could be studied in multiple productive longline sets more reliably than on troll or handline trips.

C. Description of need, if any, for additional work.

Follow-up work should focus on prevention of histamine problems in the fresh tuna industry. Additional work recommended includes:

- Monitor the efficacy of the VSOP system for controlling histamine risk by reviewing epidemiological data and auction company records. Assist State of Hawaii Department of Health investigators in thorough investigations of incidents of histamine poisoning.
- Prepare training materials on seafood safety, quality and proper handling for commercial fishers, fish auctions, fish processors, and retail and restaurant staff. Should be translated into Korean, Vietnamese, Chinese, Samoan and Filipino.
- Use reject data to target training and education efforts for vessels with quality, seafood safety and on-board handling problems. The appropriate training materials should be distributed to the vessel owner and captain each time the vessel delivers decomposed fish in a continuing effort to improve the safety, quality and value of fish landed in Hawaii.
- Work with fishers to develop alternative on-board fish handling and marketing strategies to reduce the likelihood of delivering decomposed fish, improve the economic viability of the vessel and reduce the histamine risk in the market.
- Conduct practical training workshops for commercial fishers on seafood quality, safety, VSOP and HACCP compliance. This might be incorporated as a requirement of the VSOP system for vessels supplying fish to the first receiver.
- Conduct practical training workshops for fish auctions, processors, wholesalers and distributors on seafood handling, seafood safety and the VSOP system for histamine control.
- Conduct practical training workshops for retailers and restaurant staff on proper seafood handling and seafood safety.
- Conduct practical training workshops for recreational and subsistence fishers about seafood safety and proper fish handling in an effort to reduce histamine poisoning from non-commercial channels.
- Conduct practical training workshops for FDA Inspectors on fresh tuna quality and the VSOP system to ensure a working understanding of industry practices, seafood safety controls and HACCP compliance.
- Investigate the source, fishing methods and cause of the high histamine risk in imported mahimahi. Considering how rapidly properly handled mahimahi can be chilled, the handling on-board fishing vessels supplying the US market with imported mahimahi must be grossly inadequate. Investigate practical methods for detecting high histamine concentration in frozen product.

- Further evaluate the relative risk of histamine accumulation in the Pacific blue marlin as this species is the largest and most difficult to properly chill. Develop practical measures to improve the chilling rates on small trolling vessels for properly handling large fish.

- Continue to study histamine accumulation, quality shelf life and the relative safety of fresh fish landed by troll, handline and longline vessels as they are processed and distributed through the market channels. The present study only focused on the histamine risk at the time of delivery from the vessels to the first receiver.

VII. Evaluation:

A. Describe:

1. Were the goals and objectives attained? How? If not why?

Objective 1. Evaluate epidemiological data on histamine poisoning in Hawaii.

Yes. Ten (10) years of epidemiological data on reported cases of histamine poisoning in Hawaii were reviewed and summarized. These data indicate that tuna and mahimahi are the most frequently implicated fish species. This information is helpful in identifying the other less common species implicated.

Objective 2. Develop Fleet on-board handling profiles (trollers, handliners and longliners).

Yes. Fleet profiles were written for the troll, handline and longline fleets. Fishing and fish handling practices were evaluated and summarized based on observations at sea, interviews with fishers and literature review.

Objective 3. Verify the post-harvest fish handling procedures.

Yes. On-board fish handling practices were observed and monitored during commercial fishing trips by the project researchers. Vessels representative of the three fishing gear types participated and provided an opportunity for verifying the fish handling procedures. Temperature loggers proved to be valuable in recording time and internal body temperature from the time the fish were brought aboard until they were unloaded at the end of the trip.

Objective 4. Verify the relationship between post-harvest fish handling procedures and histamine accumulation.

Yes. The same fish monitored at sea with the temperature loggers were also sampled for histamine at the time of unloading. This allowed for histamine analysis of fish with known time and temperature histories. This allowed for the verification of fish handling procedures in terms of controlling histamine accumulation.

Objective 5. Determine the importance of fish quality grades and odors of decomposition as indicators of histamine concentration.

Yes. Fish were sampled from the two fish auctions in Hawaii. Each fish was graded for quality and odors of decomposition. It was determined that within the 583 fish sampled, a total of 14 high histamine fish were effectively isolated and culled from the market by using quality grading and sensory evaluation. Odors of decomposition were demonstrated to be practical and useful in culling fish with high histamine risk.

Objective 6. Develop a HACCP-based strategy for the control of histamine for the fresh tuna industry.

Yes. The VSOP strategy for controlling histamine in fresh tuna and associated species in Hawaii's fishery was developed to integrate industry practices and knowledge with the principles of HACCP and the best available scientific knowledge. The current project served to strengthen the understanding of the histamine risk in the Hawaii fishery and how our major fleets are able to control histamine accumulation. The VSOP system draws from the Vessel Records Approach presented by the FDA. It links fishers with the primary processors in a system of mutual responsibility to produce safe fish and to ensure that safe fish are sold into the market. The auction system adds an additional safeguard in that auction buyers are representatives of the secondary processors and have the opportunity during the display auction to carefully judge quality and safety of the fish they purchase. There is no obligation to buy.

Objective 7. Communication of results to the FDA Office of Seafood.

Yes. Draft copies of this report were sent to Dr. George Hoskin, Director of Science and Technology at the FDA Office of Seafood. He distributed copies to professional staff for comment. Detailed comments on the draft were received from Robert Samuels of the FDA Program and Enforcement Branch. The comments were considered and many of them were helpful in strengthening this final draft. The FDA Office of Seafood will receive copies of the final report. It is anticipated that the discussion with the FDA about the validity of the Hawaii VSOP system for controlling histamine in fish will include detailed evaluation of the findings of this project. It is hoped that this research funded by NOAA through the Saltonstall-Kennedy Fisheries Research Program will contribute to the sustainability of the Hawaii fresh tuna industry by streamlining food safety assurance efforts, marrying effective industry practices with the science of histamine controls and the principles of HACCP.

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PART 4: CRITICAL REVIEW OF FDA POSITION ON PARASITE HAZARDS IN TUNA

THE WHOLESOMENESS OF RAW TUNA:

ARE PARASITES A PUBLIC HEALTH HAZARD?

A Position Paper prepared in response to

the Proposed FDA HACCP Program for Seafood

Prepared for the Ocean Resources Branch of

the Department of Business, Economic Development and Tourism

State of Hawaii

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May 11, 1994

The Wholesomeness of Raw Tuna: Are Parasites a Public Health Hazard?

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Executive Summary

The following is a summary of the findings and recommendations of the Position Paper prepared for DBEDT, Ocean Resources Branch, State of Hawaii, by John Kaneko M.S., D.V.M., Seafood Quality Specialist, and Mr. Paul Bartram, Seafood and Fisheries Development Specialist, both of PacMar, Inc., Honolulu, Hawaii. These comments are submitted to the FDA in response to the request for comments on two FDA Documents, a) Fish and Fishery Products Hazards and Control Guide (FDA, 1994)b) Proposal to establish procedures for the safe processing and importing of fish and fishery products. 21CFR Parts 123 and 1240 [Docket Nos. 90N-0199 and 93N-0195]

ISSUE: The newly proposed FDA HACCP regulations for seafood call for freezing fish that are intended to be eaten raw or undercooked in order to eliminate parasite hazards. These regulations which include the large tuna species, are not supported by the best available scientific evidence, nor are they compatible with the principles of HACCP.

IMPACT: The regulation will destroy the fresh tuna industry in Hawaii and the rest of the U.S., forcing many fishermen, processors and others out of business by favoring foreign competitors.

RECOMMENDATIONS:

1. Adhere to the FDA approach to establishing a HACCP system for seafood which is;
    - to be focused on likely hazards
    - to be based on the best scientific information available and
    - not to be a "zero risk" system.
2. List these tuna species separately in the FDA guidelines for the HACCP program. Tuna make up the bulk of fish eaten raw or undercooked in the U.S., including,
    - yellowfin tuna <u>Thunnus albacares</u> - bluefin tuna (Northern) <u>Thunnus thynnus</u>
    - bigeye tuna <u>Thunnus obsesus</u> - bluefin tuna (Southern) <u>Thunnus maccoyii</u>
3. Recognize that these 4 species of tuna have not been associated with cases of parasitism supported by,
    - The best available scientific information in the U.S. and Japan, the world's largest consumer of raw tuna.
    - Parasitological and epidemiological surveys that support that these tuna do not harbor harmful parasites in the edible portions (muscle).
4. Recognize that the potential for parasite hazards in these species of tuna is negligible. Therefore, parasite hazards should not be assigned to these species in the FDA guidelines.
5. To reduce parasite hazards from the consumption of raw fish, focus efforts on Education and Training of consumers, recreational fishers, industry and public health personnel about the actual risks involved with eating raw or undercooked fish and,
    - apply preventative measures on a species-specific basis
    - exercise species avoidance
    - support parasite research

The Wholesomeness of Raw Tuna: Are Parasites a Public Health Hazard?

1. Purpose

This document is presented in response to the FDA request for comments on the newly proposed HACCP program and regulations pertaining to the seafood industry. The comments are meant to be constructive and represent the concern of the fresh tuna producers, processors, distributors and importers in Hawaii. The focus of this document is on the implications of the FDA HACCP program's position on parasite hazards in raw fish and specifically, the implications for the fresh tuna industry in the U.S.A. The following will be addressed.

- Review the implications of the proposed FDA HACCP program and its position on parasites on the fresh tuna industry.
- Develop a case for the wholesomeness of fresh tuna in regards to parasites by reviewing the scientific literature.
- Request FDA reconsideration and modification of the proposed regulations.
- Make recommendations for how to best control parasite hazards in raw fish.

2. Overview

Within its Retail Food Protection Manual and the Food Code, FDA recommends that all fish intended to be consumed raw should be frozen to eliminate parasite hazards. Within the new HACCP program, this same recommendation appears and again notes that "all species that are intended for raw or marinated consumption and that have known parasite danger should be treated as suggested in Option 4." (FDA, 1994a, p. 82).

The principal objective of this position paper is to have fresh tuna, specifically, yellowfin tuna (Thunnus albacares), bigeye tuna (T. obesus) and bluefin tuna (T. thynnus and T. maccoyii) exempted from freezing requirements when eaten raw or undercooked (rare).

It is the opinion of the fresh tuna industry in Hawaii, the State of Hawaii Department of Business, Economic Development and Tourism (Ocean Resources Branch), The Hawaii Seafood Promotion Committee and the Western Pacific Regional Fisheries Management Council Executive Director that the FDA position on parasites in raw fish is in need of reconsideration and can be easily modified to keep in line with the purpose and objective of the HACCP program being proposed.

2.1 The Fresh Tuna Market

The two dominant global markets for fresh tuna are the U.S. and Japan. The end products, the markets and fisheries for fresh tuna are virtually unrelated to the canned tuna industry. The U.S. and Japan fresh tuna markets differ in the primary use of the product, the prices paid and the dominant species.

The U.S. market for fresh tuna is supplied primarily with longline caught yellowfin tuna, with limited amounts of bigeye and bluefin entering the market. Japan is the dominant market for fresh tuna and consumes fresh yellowfin, bigeye, and northern and southern bluefin. The bluefin tuna is highly prized in Japan reflected by the extremely high prices paid for these fish. Consequently, little of the high quality bluefin produced in the U.S. remains in the U.S. market. The bigeye is second in preference in Japan and only limited amounts of the high quality bigeye remain in the U.S. market. Consequently, the overwhelming majority of the fresh tuna consumed in the U.S. is yellowfin. The exception is Hawaii, especially during the winter and spring months, when the consumer has access to fresh bigeye tuna produced by local fishermen.

When the U.S. consumer orders grilled tuna steak in the restaurant, yellowfin is normally served. Lightly grilled yellowfin (raw in the center) has become very popular in recent years. When consumers order sashimi in a Japanese restaurant in the U.S. they again are normally served fresh yellowfin. In the U.S. market, the term "sashimi" is virtually synonymous with raw tuna, while this Japanese word is a more general term for exquisitely fresh, high quality, raw seafood of a wide variety. "Sushi" is another Japanese term for a variety of cooked and raw seafood products prepared with seasoned rice. Fresh tuna is the principal raw fish used in sushi bars where it is known as "maguro". In the U.S. most of the maguro available is fresh yellowfin.

There have been approximately 50 reported cases of human Anisakiasis (roundworm parasites) from raw fish in the U.S. to date. Many of these cases have involved people who do not have a tradition of eating sashimi and have experimented with raw fish prepared in the home. Simply eating an uncooked piece of fish does not constitute the preparation of sashimi. Nor does the swallowing of live bait minnows by fishermen (Gunby, 1982) as several cases in Maryland have been misrepresented by Wittner et. al. (1982) in an article in the New England Journal of Medicine. This is only one example of how the misuse of terminology in the literature and the press has helped to create a situation where the wholesomeness of raw tuna is questioned without justification. It also brings to light the need for educating the consumers, industry and public health personnel about the actual risk involved in eating raw fish, what types of fish can be safely eaten raw, and which species should be avoided.

2.2 Impact of freezing on the fresh tuna industry.

Much of the fresh tuna in the U.S. market is of the high quality required for raw and undercooked preparations. Lightly grilled tuna (rare) steaks are popular for the same reason many people prefer beef steaks grilled rare. Conventional freezing cannot preserve the high quality (color, texture, taste) required by this market. The ultra-low temperature freezing technology (-60 C) needed to preserve "sashimi" quality is considerably more expensive than conventional freezers. The special freezers also must be on-board the fishing vessels and throughout the entire distribution system in order to produce a sashimi quality frozen tuna. The distant water tuna fleets of Japan, Korea and Taiwan have this capability. U.S. tuna vessels do not.

A detailed economic impact analysis is beyond the scope of this document, however, the general impacts are obvious. U.S. tuna vessels, processors and distributors are not equipped to handle ultra-low temperature tuna. Freezing requirements for tuna would not only have an enormous negative economic impact on our U.S. fishermen, they would also increase the price of high quality tuna in the market. Ultimately, with higher prices in the U.S., foreign imports of high quality frozen tuna would become economically feasible, favoring foreign producers (Japan, Korea and Taiwan) at the expense of the U.S. fishermen. A freezing requirement applied to fresh tuna would tend to cripple or even kill the U.S. fresh tuna industry.

3. FDA Position on Parasite Hazards

3.1 FDA Retail Food Protection Program Information Manual

The information laid out in the Retail Food Protection Program Information Manual on parasite hazards is comprehensive and well meaning. However, the interpretation and conclusions drawn from the information contained in this document are in need of reconsideration. The logic of this document is as follows.

- People eat many types of raw and marinated fish dishes.
- Many different species of fish are eaten raw.
- Certain fish species harbor parasites of public health significance.
- Therefore, do not eat any fish raw unless it has been frozen to kill harmful parasites.

The flaw in this logic is that it fails to take into account that not all species of fish traditionally eaten raw harbor parasites that are harmful to consumers. The recommendation takes a blanket approach and treats all species of fish as equally harmful. This is an erroneous conclusion. This overly conservative approach is again evidenced by the FDA's Seafood Safety Task Force (FDA, 1989) conclusion that,

> "...as for any raw flesh food such as steak tartare, tuna may pose a hazard due to the possible presence of parasites....".

This position is not supported by scientific evidence in the case of the large tuna species. In contrast, as the author states, beef is known to harbor larvae of the beef tapeworm, Taenia saginata which can cause cysticercosis in man, a serious zoonotic disease. The FDA position on freezing tuna is also curiously conservative considering that there is no similar freezing requirement for beef which is commonly eaten fresh and rare (undercooked) and absolutely raw in the case of steak tartare in the U.S. The freezing requirement which is to be placed on raw fish, tends to treat fish differently from beef and pork. In the case of pork, through education and consumer awareness, cases of trichinosis in the U.S., another serious parasitic disease, have been greatly reduced without the need for a freezing requirement.

Just as there are fish species that should never be eaten raw because of real parasite hazards (such as salmon), there are certain fish such as the large tuna species which are free of hazardous parasites and are wholesome to eat raw.

3.2 FDA Approach to HACCP

The establishment of a HACCP program for the seafood industry is an enormous undertaking. It is important to industry as well as the consumer. The seafood industry supports a mandatory seafood inspection program. It should be created to provide reasonable protection of the public from real hazards, while not placing unreasonable burden on the industry. There should be some guidelines to create a sensible system. Such a system has been proposed by FDA, although some "fine tuning" of the systems' inconsistencies is still required.

Among the seven key principles for the establishment of a sensible HACCP program will be:

The identification of <u>likely hazards</u> in a given product.

a) should be made within the limits of existing scientific knowledge (FDA, 1994b, p.18)

b) should include preventive controls that take into account the unique characteristics of seafood products (FDA, 1994b, p.21)

4. Analysis of FDA Position on Parasites

The proposed HACCP program essentially adapts the FDA Retail Food Protection recommendation that <u>all</u> fish intended to be eaten raw, should be frozen to eliminate parasite hazards. In keeping with the agency's own guidelines, this regulation, as it is applied to the large tuna species, is neither,

a) based on the key principle that the HACCP program address <u>likely hazards</u>,

b) based on <u>scientific evidence</u> or

c) accounting for the <u>unique characteristics</u> of seafood products

It is for these reasons that we are requesting the reconsideration of the FDA approach to parasite hazards in fish, and in particular, the large tuna species.

4.1 Should freezing be required for all fish intended to be eaten raw or undercooked?

"HACCP is not a zero risk system...." and yet the freezing requirement appears to be based on the concept of complete removal of risk. "Hazards that involve low risk and that are not likely to occur need not be considered for purposes of HACCP" (FDA, 1994b, p 16).

Freezing regulations will be costly to the industry and not easily enforced. In the case of fresh tuna, the freezing requirements are not warranted. The Raw Fish Steering Committee of the Model Seafood Surveillance Project (MSSP, 1990) stated that recommendations for freezing should be based on the identification of those species that present substantial public health risk from parasites. This recommendation is clearly consistent with the key principles used to establish the FDA HACCP program. The large tuna species clearly do not present such a risk.

The National Academy of Sciences study on Seafood Safety (NAS,1991) reported that the Hawaii Seafood Industry and the State regulatory personnel recommend that the FDA freezing recommendation be reconsidered and rejected. Risk from parasites is limited to a small number of species and regulations requiring preventative measures (freezing) should be species specific.

The NAS study (1991) also came to the conclusion that "the very low frequency of reported disease due to these agents (parasites) does not justify using public resources specifically to identify parasites in seafood". Likewise, regulations which require industry to freeze and verify freezing all fish intended to be eaten raw or undercooked are not justifiable.

4.2 Species specific nature of the hazard

In reviewing the literature, it becomes apparent that the reported cases of parasitism due to raw fish in the U.S. are,

a) limited in total number of cases,

b) limited to relatively few host species of fish and

c) do not involve the large tuna species

According to the FDA (1987), the principal parasites of concern from fish in the U.S. are tapeworms and roundworms. There are many general reviews of fish parasites of public health importance which support this conclusion (Oshima, 1987; Bryan, 1986; Olson, 1986). Of particular concern are the anisakid roundworms which cause anisakiasis in man (Sakanari and McKerrow, 1989). The debate over the parasite hazard in fresh tuna revolves around the <u>alleged</u> presence of anisakid larvae in tuna muscle. There is no evidence that tuna harbor tapeworm larvae of public health concern and the following discussion will focus on Anisakiasis.

When reviewing the scientific literature to determine the species of fish implicated in cases of anisakiasis in the U.S., it is noteworthy that most cases have been caused by the consumption of raw salmon (Oncorhynchus spp) and Pacific rockfish (Sebastes spp) (Deardorff, 1991; McKerrow et. al. 1988). Also included in the transmission of anisakiasis in the U.S. are cod (Gadus spp), herring (Clupea spp), halibut (Hippoglosus stenolepsis), mackerel (Scomber spp) and squid (Todarodes spp). It is important to note that the large tuna species have not been positively implicated in any of the U.S. reported cases to date. This is the basis of requesting reconsideration of a freezing requirement which would include the large tuna species.

4.3 Definition of "tuna"

The current FDA definition of "tuna" appears to be based on the group of species which can be canned and labeled as tuna. This term is related to the taxonomic classification of the Tribe Thunnini of the Family Scombridae (Joseph, 1988). This same definition is being carried into the new FDA HACCP program (FDA, 1994a, p.34). The common use of the term "tuna" is ill defined (Klawe, 1977) and the definition appearing in the FDA guidelines (1994a) is inadequate.

The use of "tuna" for canned product continues to be acceptable. However, when the same term "tuna" is used in regards to the fresh tuna industry in the U.S. and the global market, it has an entirely different meaning. The global market and fishery for fresh tuna is focused on relatively few species. These include:

Bluefin Tuna, Northern	Thunnus thynnus
Bluefin Tuna, Southern	Thunnus maccoyii
Bigeye Tuna	Thunnus obesus
Yellowfin Tuna	Thunnus albacares

For the purposes of the FDA HACCP list of market names, may we suggest that these 4 species of tuna be broken down into 3 categories by common names, bluefin, bigeye and yellowfin tuna. For the purposes of further discussion, the term "large tuna" species will be used to describe these four species only.

In reviewing the species list in the FDA guide (1994a), other much less important species are given special consideration and listed separately. Consider the "shark" category. There is a generic shark category which includes 11 genera of sharks. In addition to this, there are seven (7) other shark categories which identify individual genera to reflect the market names in common usage of these shark species. This same treatment of the "tuna" category is therefore justified. The tuna group includes individual species which alone are vastly more important in terms of volume and market value than all of the shark genera put together. It is for this reason, we request the similar treatment of the tuna group that is presently given to the shark group. This will help to accurately assign hazards to the various species of tuna where appropriate. This species specific approach is in keeping with the objective to consider the unique characteristics of seafood products when designing the HACCP system.

reported that of the 5657 cases of anisakiasis which occurred on Kyushu Island, Japan between 1964 and 1988, none of the cases were caused by the large tuna species (personal comm., 1990). He also states that the people of Kyushu eat more raw tuna than anywhere else in Japan, and probably the world. Based on this evidence and other surveys, Dr. Kagei feels that the large tuna species are safe to eat fresh and raw.

As might be expected, the consumer in Japan is at risk from parasites because of the traditional and popularity of eating raw fish. Parasitological and epidemiological surveys have shown that cases of anisakiasis in Japan are mostly (over 80%) due to eating raw mackerel and squid and not from the large tuna species (Oshima, 1972; Kagei, 1990).

Oshima (1972), in an extensive parasitological survey of marine fishes in Japan, found that none of the large tuna species were found to harbor hazardous parasite larvae in the edible portion (muscle). Similarly, Kagei (1971) reports that the large tuna species, bluefin and yellowfin, do not harbor anisakid larvae in the muscle and are therefore safe to eat raw.

Oshima (1987) concluded that because bluefin and bigeye tuna do not harbor anisakid larvae in the edible muscle, that these species should be considered safe to eat fresh and raw. Oshima did not mention yellowfin, however all parasitological data indicate that yellowfin can also be considered wholesome and free of parasite hazards when eaten raw.

The only reference in the literature which at first appears to implicate tuna as a cause of anisakiasis in Japan was written by Asaishi et.al. (1989). This report contains a table which lists tuna as one of the variety of marine products which cause anisakiasis. This table, which is scantily described in the text, does not identify the species which are included under the term "tuna". As described earlier, the definition of "tuna" is not fixed and at times can include 5 different genera of scombrid fishes. Similarly, the term "flatfish" is used for the principal variety of fish causing anisakiasis but represents many different species of fish. Again, it is important that researchers make the effort to identify fish to species and refrain from using ill-defined, common names in scientific articles.

Personal communication with Dr. Asaishi (1994) has clarified how the table in question was generated and what it actually represents. The table was generated through interviews with patients suffering from anisakiasis. Patients were merely asked if they ate any of the seafood items listed in the table. None of the patients in this survey claimed to have eaten only tuna. All respondents who reported eating tuna also ate other items on the list. Neither the patients or the author knew what species of tuna was eaten. In conclusion, Dr. Asaishi believes that the large tuna species are safe to eat raw and do not cause anisakiasis.

To illustrate why this is so important, we need to take a careful look at a recent article which again incorrectly implicates tuna as a source of infection by Anisakis. Adams et.al. (1994) produced a composite table that utilizes data from different references. This table uses the term "tuna" and equates it with the Japanese term "maguro" which includes bluefin, bigeye and yellowfin. The source of the information on tuna is the report by Asaishi (1989) which after further clarification, clearly does not identify the three large species of tuna as the cause of anisakiasis. The linkage between the large tuna and anisakiasis remains unsubstantiated.

4.5.3 Iranian study

Of particular interest in the literature is a study of parasites in market fish in Iran (Eslami and Moyhayer, 1977). This study has been the source of considerable confusion over the wholesomeness of the large tuna species. In this survey, the researchers found that 75 of the 100 "tuna fish" sampled contained anisakid larvae. Fifteen of these fish were found with larvae in the edible muscle. The "tuna fish" in this study were identified as Euthynnus spp. which is a genus not included as one of the large tuna species group. In the U.S., Euthynnus spp. are insignificant market fish. Again, the researchers did not identify the host or the parasite to species. As such, this study is of little relevance to the debate over the wholesomeness of the large tuna species.

5. Conclusion

The large tuna species including yellowfin, bigeye and bluefin are wholesome and safe to eat fresh and raw. There is no scientific evidence that these species of tuna harbor potentially harmful parasites. There is no evidence that these species have caused a single case of parasitism in the U.S. or in Japan, the world's largest consumer of raw tuna.

For these reasons, it is recommended that mandatory freezing requirements for raw tuna (yellowfin, bigeye and bluefin) be rejected. It is recommended that the newly proposed HACCP system for seafood in the U.S. contain a modified version of the mandatory freezing requirement.

The preventative measure of freezing fish intended for raw consumption should only apply to species with demonstrated and likely parasite hazards. Fish that are safe to eat raw should be identified and specifically exempted from freezing requirements.

6. Recommendations

6.1 Education and Training

We recommend that the best way to prevent cases of parasitism from fish is through efforts to make consumers and industry personnel aware of the health risks from eating raw or undercooked seafood. Just as public health education has reduced the amount of trichinosis from pork and salmonellosis from poultry, similar efforts can help to control the limited amount of parasitism occurring from eating raw fish.

For those consumers who choose to eat raw fish, efforts should also be made to educate them about which species of fish are considered safe or low risk when eaten fresh and raw.

6.2 Apply species-specific freezing regulations

Freezing regulations should only be applied to those seafood products that pose significant threat to public health because of parasite hazards. The FDA guidelines should only list known and likely hazards. This list is to be used by the industry HACCP plans and needs to be accurate and based on the best scientific information available.

6.3 The definition of tuna should be revised to accomodate the fresh tuna industry.

For the purposes of the new regulations, tuna should be redefined and identify bluefin, bigeye and yellowfin as separate species from those normally found in canned tuna products.

7. Specific Comments of FDA Documents

- Fish and Fishery Products Hazards and Controls Guide
- Proposal to establish procedures for the safe processing and importing of fish and fishery products. [Docket Nos. 90N-0199 and 93N-0195]

7.1 Fish and Fishery Products Hazards and Controls Guide

7.1.1 Please add the following.

Section II, Table 1. Vertebrate Hazards and Controls List, Page 34.

MARKET NAMES	SCIENTIFIC NAMES	SAFETY	NON-SAFETY HAZARDS
TUNA, YELLOWFIN	Thunnus albacares	6	4, 5, 8
TUNA, BIGEYE	Thunnus obesus	6	4, 5, 8
TUNA, BLUEFIN	Thunnus thynnus Thunnus maccoyii	6	4, 5, 8

7.1.2 Please modify the following.

TUNA,	Allothunnus fallai	6, 8	4, 5, 8
	Auxis spp	6, 8	4, 5, 8
	Euthynnus spp	6, 8	4, 5, 8
	Katsuwonas pelamis	6	4, 5, 8
	Thunnus spp	6	4, 5, 8
	Thunnus obesus	6	4, 5, 8

7.1.3 Please add the following.

SPECIES-RELATED HAZARD AND CONTROL #8, Page 82, end of paragraph 4.

"Species which do not have known parasite danger (such as the yellowfin, bigeye and bluefin tuna) are exempt from the treatment suggested in Option 4. The large tuna species do not have known parasite danger and are considered safe to eat fresh and raw."

7.1.4 Please modify the first sentence to read....

SPECIES-RELATED HAZARD AND CONTROL #8, OPTION 4, Page 86

"Where the firm markets fish known to have parasite hazard to firms that produce seafood intended to be eaten raw, undercooked, cold smoked or marinated, the following applies."

*Note: The reason why this should be changed is that it is not necessary to single out the sushi restaurant when other types of restaurants prepare ceviche, lox and lightly grilled fish, etc.

7.2 Proposal to establish procedures for the safe processing and importing of fish and fishery products. [Docket Nos. 90N-0199 and 93N-0195]

7.2.1 Please modify table as follows.

Table 1, Page 116.

HAZARDS	Reported cases (annual)	Upper-bound (annual)	Estimated (annual)
Anisakiasis	5	10	5

*Note: "Anasakis" is a spelling error of the genus. Anisakiasis is the more accurate term which includes infection by the other genera of anisakid parasites of concern.

*Note: the total number of cases ever reported in the U.S. is approximately 50 beginning in the early 1970's. Fifty cases over 20 years does not add up to an estimate of 100 cases per year. The estimates should be adjusted to reflect the actual risk. Recommend much lower numbers.

7.2.2 Please modify the table as follows.

Table 2, Page 117.
*Note: "Anisakiasis" should replace the incorrectly spelled, Anasakis.

*Note: Again, the estimates again are questionable. Total number of cases ever reported is closer to 50.

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F.D.A., (1994b) Proposal for establishment procedures for the safe processing and importing of fish and fishery products 21 CFR Parts 123 and 1240 [Docket Nos. 90N-0199 and 93N-0195]. U.S.F.D.A.

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F.D.A., (1987) Food Preparation- Raw, Marinated or partially Cooked Fishery Products. Part 6-Inspection, Chapter 01-Code Interpretations, Number 2-403 (8/21/87), Center of Food Safety and Applied Nutrition, Retail Food Protection Branch. U.S.F.D.A.

Statement of Work

(May 7, 2001)

Title: **Verification of a HACCP System for the Control of Histamine for the Fresh Tuna Industry.**

Project Goals and Objectives:

The specific program funding priority addressed by the proposed project is II-B. *Optimum utilization of harvested resources under federal jurisdiction.* The goal of this project is to verify the efficacy of on-board fish handling procedures used by Hawaii longline and trolling vessels in controlling the human health hazard caused by histamine accumulation in fish.

Context of the Proposal

The NOAA/SK Program funded the study *"Development of a HACCP-based Strategy for the Control of Histamine for the Fresh Tuna Industry"* completed in July, 2000. The project resulted in several significant findings. It documented the fish handling practices and capabilities of Hawaii's longline, handline and troll fleets. It documented the relationship between histamine concentration and decomposition in fish as a practical means of minimizing histamine risk. The project also helped to support the application of scientifically derived information and industry knowledge on histamine risk and controls. However, since the end of the project, the Food and Drug Administration (FDA) Office of Seafood has stepped up its efforts to focus on histamine control in the U.S. industry. Compliance with FDA recommendations for HACCP (*Hazard Analysis Critical Control Point*) controls for histamine remains a serious industry issue. The following proposal addresses the verification of some of the significant findings of the previous study and builds on this foundation to help the fresh tuna industry in the U.S. remain viable, to produce safe seafood products and meet its obligations to comply with the principals of HACCP.

Identification of the Problem

Histamine poisoning is the most important food safety problem facing the Hawaii longline and trolling fleets. Many of the fish species caught by these pelagic fisheries are susceptible to accumulating toxic levels of histamine (and other related biogenic amines) when mishandled in the post-harvest period. These include tuna and mahimahi, some of the most important U.S. market species that are produced by Hawaii, other domestic fisheries and supplied by fisheries overseas.

The initial fish handling period at sea is the most important phase in the prevention of histamine formation. Efforts are needed to ensure that vessel captains and crew understand what causes histamine to form and how proper on-board fish handling can prevent histamine accumulation. After the fish dies, its natural defenses against bacteria breakdown. For many of the pelagic fish species, the body temperature at the time the fish are brought aboard starts out relatively high and within the range that promotes rapid bacterial growth. Quickly chilling fish to below 40° F is extremely important to limit bacterial growth. Rapid chilling also limits the amount of *histidine decarboxylase* enzyme produced by certain species of bacteria. This enzyme is responsible for converting the naturally occurring amino acid, *histidine*, into the toxin, histamine. Quickly reducing the fish temperature is required to limit the amount of time the fish is held within the favorable temperature range for bacterial growth, enzyme production, enzyme activity and rapid histamine accumulation.

The FDA considers the control of histamine to be one of the priority issues in its nationwide mandatory HACCP-based seafood inspection program. A recent U.S. General Accounting Organization (GAO, 2001) questions the efficacy of the FDA HACCP program for seafood in the U.S. The FDA responded by announcing a mid-course correction and is focusing on priority high-risk seafood safety problems including histamine controls.

The FDA announced its mandatory seafood inspection program in December 1995 (FDA, 1995) and it became effective in December 1997. Since then, the Hawaii tuna fisheries have been scrutinized over the adequacy of process controls aimed at preventing the accumulation of histamine. The FDA recommends two different approaches to histamine controls. One approach requires detailed harvesting and fish handling data collected at sea by fishing vessel crews and the other relies on random sampling and histamine testing of the catch by the first receivers (processors). The sampling and testing approach is routinely applied in the tuna canning industry that receives large volumes of frozen tuna from purse seiners, longliners and bait boats. However, neither approach is suitable for practical application to Hawaii's lower volume hook and line fisheries, specialized marketing system (display auction) and emphasis on high quality, fresh product.

The FDA recommends that in order for fishermen to control histamine, susceptible fish must be chilled to below 50° F within 6 hours of death and to below 40° F within 24 hours of death (FDA, 1998). While these may be good goals for fish handling, there is evidence that they may be excessively restrictive for the Hawaii fishery, the different fish species and the range of fish sizes harvested.

A series of research efforts have been conducted in Hawaii to arrive at a practical and effective HACCP-based system, appropriate for the fishery. Kaneko and Bartram (1994) critiqued the original FDA HACCP Program Proposal on behalf of the State of Hawaii and the local seafood industry. Histamine controls were identified as a potential problem at that time. To assist the Hawaii seafood companies and fishing industry, Kaneko (1997) drafted a generic model HACCP Plan for the typical fresh fish wholesaling operation in Hawaii, again with state support. Later, a HACCP-based system for the control of histamine by fishing vessels was developed and evaluated by Kaneko (2000) with NOAA (National Oceanographic and Atmospheric Administration) Saltonstall Kennedy Program funding.

Rationale of the Proposed Project

The FDA continues to question the efficacy of the Hawaii system for control of histamine, which is based on the establishment of a set of vessel standard operating procedures (VSOP) and the use of sensory evaluation of fish for odors of decomposition. At this writing, the agency is not fully satisfied with the VSOP system that has been in place in Hawaii's two (2) fish auctions since late 1997.

The NOAA study (Kaneko, 2000) demonstrated the capability of Hawaii longliners, handliners and trollers for meeting FDA fish handling guidelines (for fish retrieved alive), histamine control and the value of odors of decomposition for culling fish with high histamine content from the market. However, additional efforts and data are needed to further verify the effectiveness of standardized on-board fish handling procedures (VSOP) in controlling the accumulation of histamine. This project is proposed to help the fishery avoid adopting an impractical, costly, time consuming and possibly ineffective system of random end product sampling and testing for histamine.

The histamine hazard analysis specific to the Hawaiian fishing vessels and local seafood industry, and the development of the HACCP-based approach were conducted using a science-based approach. Utilization of this approach will continue during the further verification of the efficacy of the HACCP approach. To be effective, any HACCP control system for histamine ultimately relies on training fishers about effective preventative measures. To close this information gap, training workshops for vessel operators are necessary to communicate the program findings, explain the important role fishers play in seafood safety and HACCP, and promote the safe fish handling practices.

Sensory evaluation for odors of decomposition was shown to be an effective tool for screening out fish (tuna, marlin and mahimahi) with high histamine concentration in market sampling in Hawaii (Kaneko, 2000). This finding is important as supporting evidence of the efficacy of the HACCP approach that integrates scientific knowledge with industry knowledge and practices. The finding that odors of decomposition may be useful and practical indicators of histamine risk is so controversial that it warrants additional work for verification.

Recently, concerns have been raised about the food safety of escolar (*Lepidocybium flavobrunneum*), one of the market species caught in pelagic longline fishing operations. This may be in part due to the common confusion between escolar and a similar species of fish known as the oil fish or scour fish (*Ruvettus pretiosus*). The oil fish is known to contain a mild toxin (*gempylotoxin*) that causes diarrhea (FDA, 1998). It is suspected that part of the apparent toxicity of the oil fish (and possibly the escolar) might be due to elevated histamine concentration. Escolar and oil fish were not sampled during the market study conducted by Kaneko (2000) and should be evaluated.

Project Objectives

To expand the database needed to verify that the standard operating procedures for fish handling (VSOP) by Hawaii's hook and line fishing vessels are effective in controlling the accumulation of histamine.

To determine whether odors of decomposition are effective indicators for culling mixed pelagic fish (including *escolar*) with high histamine concentration from the market.

To conduct training workshops for vessel operators to ensure understanding of the histamine risk, preventative measures and the important supportive role for HACCP control systems.

Specific objectives include:

- Greatly increase the database (from 75 to over 300 fish temperature profiles) characterizing the fish handling procedures on-board longliners and trollers in terms of fish chilling rates and storage temperatures.
- Determine the resulting histamine concentration of fish with known on-board time and temperature histories.
- Determine the relationship between on-board handling procedures, chilling rates and histamine concentration of fish at the time of delivery.
- Determine the relationship between the presence of odors of decomposition and histamine concentration in bigeye, yellowfin and albacore tuna, blue marlin, mahimahi and escolar from market and vessel samples.
- Conduct training workshops for vessel operators to transfer knowledge of histamine formation, risk and prevention to ensure compliance of HACCP programs.

Project Impacts:

Anticipated Impact

The successful verification of the efficacy of the on-board fish handling procedures in controlling histamine production and accumulation in fish delivered by the Hawaii longline and trolling vessels will directly impact the viability of the fleet to produce fresh tuna for the Hawaii seafood market. The verification of fish handling and evaluation procedures as a science-based method to comply with FDA HACCP regulations for the control of histamine risk is critical to the industry. Successful verification could result in improved efficiency of inspection, processing and marketing, and significantly decrease the risk of histamine poisoning and ensure a safer seafood supply for consumers.

Dissemination of Findings

NOAA Publication

Industry Publications

Presentation of Results to Industry

Evaluation of the Project:

If the findings of the proposed project verify the effectiveness of the HACCP control system for histamine, the practical evaluation of the project will ultimately be made by the FDA Office of Seafood and its inspectors.

Need for Government Financial Assistance:

The project is proposed in response to a change in the government regulatory environment facing the U.S. fishing and seafood industry. The FDA HACCP-based Seafood Inspection Program continues into a new implementation phase. Histamine controls have been identified as a top national priority. The fresh tuna industry in Hawaii and the fragmented domestic hook and line tuna fishing industry are poorly organized to be able to address these issues effectively without government support.

Government efforts are providing training to the seafood processing sector on how to design and implement suitable HACCP programs. However, the development of specific strategies for individual companies and industry sectors, remains the responsibility of industry (Spiller, 1997). The financial assistance is requested in order to help keep U.S. tuna fisheries and the processing and marketing sector competitive while producing seafood products of ever increasing safety, quality and value.

An individual company is unlikely to be able to bare the costs of developing the proposed strategy and system. A single company could not hope to recoup the costs by keeping the information proprietary. Lastly, the regulators are likely to be more receptive to the verification of the Hawaii HACCP approach if conducted by a competent third party rather than based on information and studies conducted by individual companies on their own behalf. For these reasons, the funding support is requested.

Federal Activities Affected

The proposed project will support the implementation of a federal regulation (Federal Register as 21 CFR Parts 123 and 1240, Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products) impacting the fishing and seafood processing sectors.

Project Statement of Work:

Project Design: Objectives and Methods

Objective: Verify-board fish handling procedures for controlling histamine accumulation.

The proposed 18-month study will document the on-board temperature profiles of mixed pelagic fish and link this information with histamine analysis results. This will help to determine what time and temperature parameters are effective in controlling histamine accumulation in the Hawaii pelagic longline and troll fisheries.

Details of the fish harvesting methods will be recorded. Fish temperature profiles during the on-board handling period will be recorded using temperature loggers (*Onset Computer Corporation, Stowaway® TidBit XT*). Five (5) longline vessels fishing for tuna will be selected from the active longline fleet operating out of Honolulu for each of the first four quarters. For each longline vessel trip, twelve (12) temperature loggers will be issued to the vessel to be placed into the fish being monitored as described by Kaneko (2000). The vessel captain and crew will receive hands-on training on how to record the essential fish harvesting data, to properly insert the temperature loggers to record deep core muscle temperature and how to clearly identify fish containing temperature loggers.

Commercial trolling vessels operating out of Oahu will be selected to monitor on-board time and temperature histories for blue marlin. Efforts will be made to accumulate 20 temperature histories for blue marlin caught by trollers in addition to those collected on longliners. A special emphasis is being placed on blue marlin because of the challenge associated with chilling large fish. Attempts will be made to collect the 20 temperature histories based on seasonal peak in catch rate and sampling may not be spread evenly over the four sampling quarters.

The vessel crew will receive a set of temperature loggers along with data cards to complete for each fish monitored. Data collected will include, the date and number of the longline set (or trolling trip), logger number, the time the set began, when the line hauling started, the time the fish was boarded, how long it sat on the deck before being placed in the ice and whether the fish was alive or dead when retrieved. Each fish monitored will be identified clearly by attaching a bright colored plastic flagging ribbon around the caudal peduncle and one through the isthmus between the gill cavities. Longline crews will be instructed to deploy all of the loggers in the first two sets of the trip if possible. The sampling schedule will attempt to monitor 2 bigeye tuna and 2 yellowfin tuna above 80 lbs round weight, 2 albacore above 50 lbs round weight, 2 blue marlin above 150 lbs round weight, 2 mahimahi above 20 lbs round weight and 2 escolar above 10 lbs round weight per trip. Trolling crews will be instructed to monitor only blue marlin over 150 lbs.

At the end of the fishing trips, the vessels will be unloaded and the catch delivered to the Honolulu Fish Auction. The auction staff will notify the project team when the vessel will be unloaded. Fish with temperature loggers will be identified during unloading and the loggers will be retrieved. The fish will be weighed, identified by species, graded for quality and evaluated for odors of decomposition. After this initial evaluation, a muscle sample for histamine analysis will be collected from the dorsal muscle mass, just posterior to the cleithrum. This is the standard sampling location because it is the area most likely to develop histamine (Baranowski, et al., 1990). Samples will be placed into plastic freezer bags, labeled, kept buried in ice, then frozen and delivered to the laboratory for histamine analysis. The Food Quality Laboratory of Honolulu will analyze the samples using the standard AOAC fluorometric method (AOAC 1995, Official Method 977.13 for histamine in seafood) for histamine analysis and QA/QC procedures. The Food Quality Laboratory will be utilized for the analyses as a sole source because this laboratory was previously selected (three competitive bids) as the most suitable laboratory for the SK project (NOAA award number NA86FD0067)(Kaneko, 2000). If a bidding process is required by the agency, three competitive bids will be obtained and the most appropriate laboratory will be selected.

Time and temperature data will be downloaded from the loggers and maintained in a computer database. Analysis of the fish handling data will determine the initial status of the fish (live or dead), the initial core body temperature, critical performance targets of time to below 50° F and time to below 40° F and storage temperature for the duration of the trip. The total time from boarding to collection of the muscle sample will be determined for each fish monitored. These data will be compared against the FDA recommendation that histamine susceptible fish be chilled to below 50° F within 6 hours of death and to below 40° F within 24 hours of death in order to adequately control histamine accumulation.

The relationship between histamine concentration and fish quality grade and odors of decomposition will be determined by species. Fish histamine concentration will also be compared with time and temperature parameters (time to <50° F and <40° F). The relationship between total storage time and histamine accumulation will be evaluated.

Two (2) interim progress reports and a final report will be prepared to present the findings along with analysis of the relationship between documented fish handling practices and histamine accumulation. The results and implications will be presented in the context of verifying the Hawaii VSOP system for histamine controls.

Objective: Verify the relationship between odors of decomposition and histamine production and risk

In addition to the 260 mixed pelagic fish monitored at sea on longliners and trollers described above, 240 more mixed pelagic fish will be sampled from fresh fish landings at the Honolulu fish auction. Included in this sample will be forty (40) escolar. Sampling will be spread out over the first 4 quarters of the project. Market sampling, quality grading, sensory evaluation for odors of decomposition and histamine analysis will be conducted in order to verify that quality and sensory indicators can help to prevent fish containing high concentrations of histamine from entering the market.

Objective: Conduct training workshops for vessel operators

Workshops will be conducted near shore-based operations for the vessel personnel. A total of 4 workshops is anticipated, two for trollers and two for longliners. The contents of the workshops will include details on histamine production, and the best practices contained in the HACCP program to prevent histamine production and accumulation. Feedback on study testing efforts and vessel assistance will also be included.

<u>Project Responsibilities</u>

Principal Investigator: John Kaneko MS, DVM, PacMar, Inc.

Responsible for the overall management of the project. Coordinate vessel work, market sampling, data analysis and reporting. Coordinate laboratory analyses and selection of laboratory (if bidding is needed). Plan and conduct training workshops. Primary point of contact for NOAA/SK Program Officer.

Co- Principal Investigator: Jon Bell PhD, PacMar, Inc.

Responsible for co-managing the project, participate in vessel work, market sampling, data management and analysis and reporting. Plan and conduct training workshops.

Statistician: Wayne Toma MS

Responsible for statistical analysis.

Financial Management: Thanh Lo Sananikone, PacMar, Inc.
(*not billing to the project)

Major Products (Deliverables)

A project report containing the following:

- Assessment of histamine production and risk, and understanding of compliance with HACCP program and practices to prevent histamine hazard by vessel operators in Hawaii's fresh tuna industry.

- Determination of efficacy of sensory evaluation methods to identify odors of decomposition and histamine hazard in delivered fish.

A strengthened database and hazard analysis for histamine in Hawaii's pelagic fisheries to utilize as the basis for policy discussions with FDA Office of Seafood.

Training workshops for vessel operators.

Project Milestones (based on 18-month contract, 3 months per quarter)

First Quarter
- Start-up phase, purchase equipment and supplies.
- 60 mixed pelagics monitored on longline vessels and sampled.
- 5 blue marlin monitored and sampled on trolling vessels.
- 60 mixed pelagics sampled from the market and tested.
- Training workshop developed and first workshop completed.

Second Quarter
- 60 mixed pelagics monitored on longline vessels and sampled.
- 5 blue marlin monitored and sampled on trolling vessels.
- 60 mixed pelagics sampled from the market and tested.
- Second training workshop completed.
- First interim progress report due.

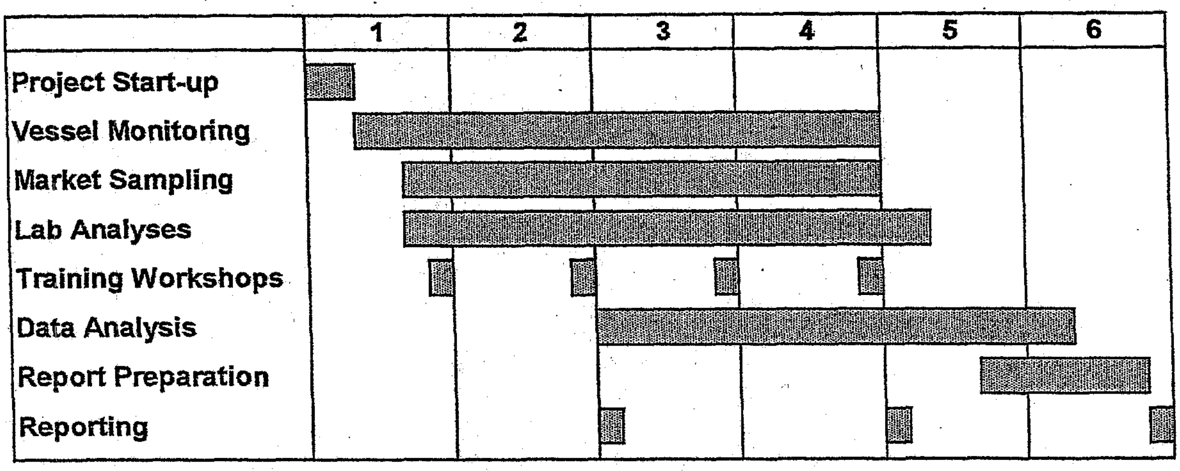
Third Quarter
- 60 mixed pelagics monitored on longline vessels and sampled.
- 5 blue marlin monitored and sampled on trolling vessels.
- 60 mixed pelagics sampled from the market and tested.
- Third training workshop completed.

Fourth Quarter
- 60 mixed pelagics monitored on longline vessels and sampled.
- 5 blue marlin monitored and sampled on trolling vessels.
- 60 mixed pelagics sampled from the market and tested.
- Fourth training workshop completed.
- Second interim progress report due.

Fifth Quarter
- Finalize histamine analysis.
- Analysis of handling, sensory, and histamine data and interactions.

Sixth Quarter
- Finalize data analysis
- Prepare final report
- Final report in the form of a manuscript for publication.

Milestone Chart*



*Project duration: 18 months (6 quarters, 3 months/quarter)

Participation by Other Persons or Groups:

Wendy Minor, Food Quality Laboratory, Inc. (*if permitted to continue with laboratory services) will conduct the histamine analyses for the project.

Nelson Aberilla, HACCP Manager, United Fishing Agency will help with vessel monitoring, retrieving loggers and collecting muscle samples.

Sean Martin, President of the Hawaii Longline Association will assist the project by identifying longline vessels to cooperate with on-board fish monitoring. Will also help recruit participants for training workshops and advise the investigators on vessel operating procedures.

Project Management:

Principal Investigator:	John Kaneko MS, DVM, PacMar, Inc.
Co- Principal Investigator:	Jon Bell Ph.D., PacMar, Inc.
Statistician:	Wayne Toma

References:

AOAC. 1995. *Histamine in Seafood: Fluorometric method.* Sec 35.1.32, Method 977.13. In Official Methods of Analysis of AOAC International, 16th ed., P.A. Cunniff (Ed.), 16–17. AOAC International, Gaithersberg, MD.

Baranowski, J.D., H.A. Frank, P.A. Brust, M. Chongsiriwatana and R.J. Premarante. 1990. Decomposition and Histamine Content in Mahimahi (*Coryphaena hippurus*). J. Food Protection 53(3): 217-222.

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Kaneko, J.J. 1997. *The Development and Practical Application of a Generic HACCP Model for the Hawaii Seafood Industry.* Prepared for the Dept. of Business, Economic Development and Tourism, State of Hawaii.

Kaneko, J.J. 2000. *Development of a HACCP-based Strategy for the Control of Histamine in the Fresh Tuna Industry.* Project Report NOAA Award No. NA86FD0067. 48 p.

Spiller, P. (1997) *The New U.S. FDA HACCP Program. In: Fish Inspection, Quality Control and HACCP.* R.E. Martin, R.L. Collete and J.W. Slavin (eds.) p. 427- 436.

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EDUCATION: D.V.M. (Veterinary Medicine, Univ. of Florida, Gainesville, Florida, 1987)
M.S. (Animal Sciences, University of Hawaii, Manoa, 1983)
B.S. (Fisheries, Humboldt State University, Arcata, California, 1980)

TRAINING:

Certified HACCP Trainer, Assoc. of Food and Drug Officials, Certificate No. 0064-050698-10232 Salt Lake City, Utah, 1998

HACCP Training Certificate No. HACCP HNL 12 - 16-96-0005. AFDO course, Honolulu, Hawaii, 1996

Sanitation Control Procedures (SCP) Trainer. Assoc. of Food and Drug Officials, Certificate No. 9014-082100-98705, Honolulu, Hawaii. 2000

EMPLOYMENT RECORD:

PacMar, Inc. (Pacific Management Resources), Honolulu, Hawaii, USA (Apr.1992 to present).

Director of Projects. Responsible for project coordination and development for *PacMar*, an international, diversified agricultural development consulting firm. Specific areas of concentration include fisheries and seafood industry development. Provides technical advisory services in the areas of seafood safety issues, HACCP program development and implementation for seafood businesses. Special research effort in histamine control and HACCP systems for the fresh tuna industry. Designs and conducts practical training for fishers and seafood processors on quality improvement, seafood safety and HACCP. Proposal preparation, technical writing, consultant recruiting and backstopping of projects from home office. Pertinent project experience includes,

Seafood HACCP Specialist (Nov 1997 to present). Designed and implemented HACCP Programs for seafood companies in Hawaii, California, Vietnam, Saipan, and Indonesia. These clients include seafood producers, processors and manufacturers of fresh and frozen tuna, surimi-based fish cake products, dried tuna, dried and frozen squid, frozen shrimp, frozen shark fillets and an assortment of marinated fish products. Clients include fisher/processors, processors, importers and exporters.

Tuna Quality Specialist (July 1996 to present). Designed, organized and conducted a series of training workshops for tuna purse seine fishermen on issues of vessel refrigeration and tuna quality and safety. Workshops trained personnel from 8 US tuna purse seiners American Samoa and 10 tuna purse seiners fishing in Ecuador. Client is the world's largest tuna canning company.

Seafood HACCP Specialist (June 1998 to June 2000). PI for *"The Development of a HACCP-based strategy for the control of histamine for the fresh tuna industry"*, an investigation of histamine formation in tuna and other susceptible pelagic fish. The project documented standard fish handling procedures, verified temperature profiles for fish on-board and conducted histamine analysis of muscle samples. NOAA/NMFS Saltonstall/Kennedy Fisheries Research Program.

Seafood HACCP Specialist and Trainer (Sep. 1998 to Nov. 1998). Prepared and conducted a series of training short courses for Seafood Quality Control personnel from *JICA (Japan International Cooperation Agency)* member countries from Asia, Latin America, Africa and the Middle East. Training was conducted at the *JICA Kanagawa International Fisheries Training Center* and at the *JICA headquarters* in Tokyo, Japan.

Seafood HACCP Specialist and Trainer (Sept. 1997 to Nov. 1997). Designed the Hawaii Seafood HACCP Model for use by the seafood industry in Hawaii. Practical workshops on implementation of the Model were conducted for over 50 seafood companies in Hawaii. State of Hawaii, Dept. of Business and Economic Development.

Seafood Quality Specialist (Apr. 1994 - May 1994). Prepared a position paper on behalf of the State of Hawaii and the Hawaii Seafood Industry addressing critical elements of the newly proposed US FDA Seafood Regulations based on HACCP (hazard analysis critical control point). State of Hawaii, Dept. of Business and Economic Development.

Hawaii Seafood Products, Inc., Honolulu, Hawaii USA (Apr. 1988 to Apr. 1992)

Vice President for Research and Development and Quality Control Supervisor. Vice President and partner in one of Hawaii's largest fresh seafood import and export businesses. Responsible for staff training in product handling, fresh tuna grading, quality control and plant sanitation. Wrote the company operations manual that served as a training tool for the staff.

Hawaii Seafood Industry Representative (1988- 1990). Served as Hawaii seafood industry representative on the National Steering Committee (for Raw Fish) for the *"Model Seafood Surveillance Program,"* a federally mandated program to develop a plan for the establishment of a mandatory seafood inspection service for the U.S. based on HACCP concepts. This committee consisted of National Marine Fisheries Service, the National Fisheries Institute and other seafood industry members from across the nation.

(Employment prior to 1988 available on request).

RELEVENT PUBLICATIONS

Kaneko, J.J. 2000. *Development of a HACCP-based strategy for the control of histamine for the fresh tuna industry.* Final Report to NOAA. Award No. NA86FD0067 pp. 47.
Kaneko, J.J. 1999. *Development of a Methyl Mercury Profile for the Central North Pacific Broadbill Swordfish Fishery.* Final Rept NOAA. Award No. NA66FD0057 pp 19.
Kaneko, J.J. 1997. *The Development and Practical Application of a Generic HACCP Model for the Hawaii Seafood Industry.* State of Hawaii, Dept. of Business and Economic Development.

JON WILLIAM BELL

PacMar, Inc., 3615 Harding Avenue, Suite 408
Honolulu, HI 96816 ph: (808) 735 – 2602

EDUCATION:

Ph.D. in Food Science, North Carolina State University, December 2000.
M. S. in Food Science, University of California at Davis. July 1989.
Peace Corps Fisheries Training, University of Oklahoma. June 1984.
B. S. in Food Science, University of California at Davis. December 1983.

EXPERIENCE:
FOOD INDUSTRY

Food Scientist, PacMar, Inc., Honolulu, HI (5/01 – present)

- Projects involve food safety training and workshops for the seafood industry and process development and improvement research for canned tuna industry.

Post-Doctoral Research Scientist, Dept. Food Science, NCSU, Raleigh, NC. (1/01 – 4/01)

- Continued work on liquid mass transfer and retention in skipjack tuna muscle.

Graduate Research Assistant, USDA National Needs Fellowship, Dept. Food Science, North Carolina State University, Raleigh, NC. (1/97 – 12/00)

- Ph.D. research involves investigating cannery processing effects of cooking, retorting, and expression on moisture transport mechanisms in tuna muscle.
- Minor in Biological and Agricultural Engineering.

Manager, Procurement R & D, StarKist Seafood, Newport, KY. (10/94 - 12/96)

- Development of an R & D program for the Tuna Procurement department: quality research, process development, and extension and training program components in fish handling, cannery integration, capture technology and fleet benchmarking, and fisheries biology areas.

Seafood Technologist, Seafood Quality Specialist, San Diego, CA (10/92 - 9/94)

- Direction of contract research to design, develop, and implement a raw tuna handling and quality program for a global tuna company: relational database design and analysis of capture and cannery quality inputs, design and implementation of at-sea research protocols, and analysis of U.S. tuna fleet fishing activity and capture rates.
- HACCP Certification, NMFS, Bell, CA, April 1993

Yield Improvement Superintendent, StarKist Seafood, American Samoa. (6/90 - 6/92)

- Manager of the Yield Improvement Program in the cannery production department: program budget; production scheduling, reporting, and process control; daily supervision of 50 program personnel; and coordination of process improvement and development projects.
- Chairperson of the plant-based Heinz TQM Product Quality Improvement Team; QES, TQM training.

Quality Control Supervisor, Simplot Aquaculture, Caldwell, ID. (7/89 - 6/90)

- Implementation of the quality assurance program in a state-of-the-art processing plant for an integrated tilapia culture facility: development of the QC laboratory, HACCP, and plant sanitation programs; direction of quality investigations and shelflife studies.

INTERNATIONAL

Fisheries Extension Agent, Peace Corps, Bakel, Senegal. (8/84 - 9/86)

- Direction and management of the village-based agricultural cooperative pond culture program in the Senegal River basin; pond management training; start-up of project hatchery and research station; and brood stock procurement. Designed and implemented the first successful cage culture program on the Senegal River.

EXTENSION ACTIVITIES:

Skipjack tuna handling on-board purse seiners and fish quality loss. Training presentation to fishermen's groups, Manta, Ecuador, July, 1996.

On-board handling, albacore tuna quality, and cannery reject criteria. Training presentation to Tuna fishermen and buyers, Capetown, South Africa, April, 1996.

On-board handling and albacore tuna quality. Training presentation to fishermen's group and buyers, Auckland and Nelson, New Zealand, December, 1995.

Relationships between vessel handling and cannery quality parameters. Training presentation at Charlie's Challenge: StarKist Suppliers Meeting, Cabo San Lucas, Mexico, January 1996; Miami, FL, January 1995.

Tilapia growth and pond management. Training workshops for agricultural cooperatives, Bakel region, Senegal, 1985 – 1986.

PUBLICATIONS:

Bell, J.W., B.E., Farkas, S.A. Hale, T.C. Lanier. Effects of Retorting and Storage on Liquid Mass Transfer in Canned Skipjack (*Katsuwonas pelamis*) Muscle. J. Food Processing and Preservation. Submitted.

Bell, J.W., B.E. Farkas, S.A. Hale, T.C. Lanier. Effect of Thermal Treatment on Moisture Transport during Steam Cooking of Skipjack Tuna (*Katsuwonas pelamis*). Journal Food Science. 66(2).

Price, R.J., E.F. Melvin, J.W. Bell. 1992. Postmortem Changes in Blast, Brine and Brine-Coil Frozen Albacore. Journal Aquatic Food Products Technology 1(1): 67-84.

Price, R.J., E.F. Melvin, J.W. Bell. 1991. Postmortem Changes in Chilled Round, Bled and Dressed Albacore. Journal Food Science 56(2): 318-321.

117 Ahui Street, Honolulu, Hawaii 96813

May 2, 2001

John Kaneko MS, DVM
Project Director
PacMar, Inc.
3615 Harding Avenue, Suite 409
Honolulu, Hawaii 96816

Re: Letter of Support for the Proposal: *Verification of a HACCP system to control histamine in the fresh tuna industry.*

Dear Dr. Kaneko,

HLA recognizes the importance of efforts to verify how the standard practices on-board fishing vessels and the auction marketing system act to control histamine problems in the Hawaii tuna fishery. The proposed project is needed to help document the relative food safety risks and effective histamine control measures. This is the type of project that SK/NOAA funding should support.

HLA will help the project by recruiting vessels for participation in the vessel research and in the training workshops.

Sincerely,

Sean Martin
President
Hawaii Longline Association

UNITED FISHING AGENCY, LTD.

117 AHUI STREET

HONOLULU, HAWAII 96813

TEL: (808) 536-2148 • FAX: (808) 526-0137

May 2, 2001

John Kaneko
Project Director
PacMar, Inc.
3615 Harding Avenue, Suite 409
Honolulu, Hawaii 96816

Re: Letter of Support for the Proposal: *Verification of a HACCP system to control histamine in the fresh tuna industry.*

Dear John,

UFA supports the proposed project that will help to further define our fisheries and operating procedures in Hawaii and demonstrate the effectiveness of practical control measures for histamine. This is extremely important in light of the FDA HACCP program efforts to control histamine in seafood.

UFA will assist the project by facilitating fish sampling, recruiting participation from fishermen in vessel related research and the training workshops.

Sincerely,

Frank Goto
General Manager
United Fishing Agency

WESTERN
PACIFIC
REGIONAL
FISHERY
MANAGEMENT
COUNCIL

May 1, 2001

John Kaneko MS, DVM
Project Director
PacMar, Inc.
3615 Harding Avenue, Suite 409
Honolulu, Hawaii 96816

Re: Letter of Support for the Proposal: *Verification of a HACCP system to control histamine in the fresh tuna industry.*

Dear Dr. Kaneko,

The proposal for NOAA/SK funding addresses an important issue facing our pelagic fisheries in the Western Pacific Region. The verification of the HACCP system for controlling histamine is important in that the overwhelming majority of our fishing and seafood industry constituents are impacted by inspection regulations dealing with this important food safety problem.

Efforts to verify industry practices and the practical histamine control measures in place in Hawaii are important to keeping our fisheries viable and competitive in the changing regulatory environment.

WESPAC supports the proposed project and believes it is compatible with the objectives and purpose of NOAA/SK fisheries research funding. WESPAC supports the project concept and will assist in advertising and recruiting participation in training workshops.

Sincerely,

Kitty M. Simonds
Executive Director

1164 BISHOP STREET • SUITE 1405 • HONOLULU • HAWAII 96813 USA • TELEPHONE (808) 541-1974 • FAX (808) 526-0824

TRAINING PROGRAM DEVELOPMENT TO STRENGTHEN SEAFOOD HACCP SYSTEMS (HISTAMINE)

Principal Investigator: Aurora Saulo Hodgson, University of Hawaii at Manoa
Subcontractor Project Director: J. John Kaneko, Pacific Management Resources, Inc. (PacMar, Inc.)
Subcontractor Associates: Jon W. Bell and Robert Nakamura, Pacific Management Resources, Inc.

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TRAINING PROGRAM DEVELOPMENT TO STRENGTHEN SEAFOOD HACCP SYSTEMS (HISTAMINE)

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Subcontractor Project Director: J. John Kaneko, Pacific Management Resources, Inc. (PacMar, Inc.)
Subcontractor Associates: Jon W. Bell and Robert Nakamura, Pacific Management Resources, Inc.

PROJECT SUMMARY

The proposal aims to develop a practical certification training program on preventive measures needed to control histamine (scombroid) poisoning. Although project focus is on commercial and non-commercial fishers in Hawaii, the program and materials can be used to improve the safety of domestic seafood. The proposal is highly relevant to the purpose of the *National Food Safety Initiative* because the program can effectively communicate principles and methods for prevention of histamine, a food safety hazard.

Histamine poisoning is one of the most common seafood-borne illnesses in the U.S. today (NAS, 1991). It is caused by the ingestion of fish, such as tuna and mahimahi, containing high levels of histamine and related biogenic amines. Results of our previous studies (Kaneko, 2000) indicate that preventive measures at sea immediately post-harvest offer the greatest potential to assure histamine control. But this most critical period for histamine control occurs *before* seafood products enter the HACCP systems of primary processors. Results further indicate that understanding the formation of histamine and its control measures at sea can result in improved product quality, higher value, safer seafood, more effective HACCP controls, and improved economic viability of fishing operations, including recreational and subsistence communities. By integrating applied research, instruction, and extension with stakeholder input and knowledge, a practical and effective certification training program will be developed, revised, and conducted through a series of workshops for the hard-to-reach recreational, subsistence, and commercial fishing sectors to explain the formation of histamine and the control measures at sea that can effectively control histamine.

TRAINING PROGRAM DEVELOPMENT TO STRENGTHEN SEAFOOD HACCP SYSTEMS (HISTAMINE)

PROJECT DESCRIPTION

INTRODUCTION

The proposal presents a multi-functional approach that integrates applied research, education, and extension to promote food safety through the application of HACCP (hazard analysis critical control point) principles through education and training of the hardest- to- reach segment of the food production system, the fishers at sea. Although fishers control the most critical stage of the safe food handling sequence and can make the greatest impact on ensuring the control of histamine in susceptible fish species, fishing vessels currently fall outside HACCP inspection programs. The proposal aims to improve the effectiveness of HACCP controls for histamine in fresh tuna and related pelagic fish by addressing this sector of the fishing industry.

Project Goal: Long-term

The HACCP approach to food safety is focused on hazards that are "*reasonably likely to occur*" based on scientific evidence and can be controlled through prevention. Considerable effort has been placed on developing HACCP training programs for processors that fall under USDA and FDA oversight. While the processing sectors are striving to implement effective HACCP Plans, supporting efforts are needed to include and inform the primary producers and the end-product users that fall outside the scope of HACCP.

The emphasis on prevention of food safety hazards is becoming widely accepted over systems that rely on end-product sampling and testing. Understanding how food safety hazards occur is the key to prevention. Integrating applied research, appropriate training materials and effective extension or outreach programs is critical in supporting the implementation of effective HACCP plans. Involving food production stakeholders in the development of training and outreach programs is equally important in providing appropriate, practical, and effective communication of HACCP principles and preventive measures.

The long-term goal of this proposal is to develop a practical and effective certification training program with materials that will be designed, tested, refined, and disseminated to improve the understanding of a food safety hazard, histamine (and related biogenic amines), how they occur, how they are prevented, and how HACCP works. Specifically for the high-risk, hard-to-reach audiences, the fishers at sea, the project goal will be achieved by coordinating and integrating applied research, instruction, extension, and stakeholder input and knowledge.

Summary of Past Experience and Knowledge Substantiating the Need for the Project

National

At the national level, the U.S. seafood industry has been under HACCP regulation since December 1997. Efforts to prepare the industry for the new FDA inspection program involved the development of HACCP training materials through the Seafood HACCP Alliance with universities, FDA, and AFDO (Association of Food And Drug Officials) inputs. The certification training program presents seafood processors and importers with the basic HACCP concept, how to conduct a hazard analysis, and design, implement, and verify an effective HACCP Plan.

The primary audience of these training sessions, however, has been processors, and inspection programs began at processing facilities. For some important food safety issues, effective preventive measures ***must*** take place before raw materials even arrive at the processing facilities. Recent foodborne illness cases have dramatically shifted the focus of training to the foodhandlers at the earlier part of the food chain, such as farmers, growers, and harvesters. Ironically, it is the same group of foodhandlers who are not used to such training and are therefore, more difficult to reach and to convince of the relevance of education to the safety of the food they produce and ultimately, their livelihood. To seemingly complicate matters, documentation and validation of diligent and consistent practice of GMPs and sanitation control procedures at this stage of foodhandling as assurance to the delivery of safe foods are now also being required by many processors. It is therefore not surprising that many post-harvest and pre-processing foodhandlers are feeling targeted by regulators and processors.

- AFDO seafood HACCP training programs
  The Association of Food and Drug Officials (AFDO) operates a HACCP training and Train-the-Trainer certificate programs. The Seafood HACCP Alliance conducts the training courses along with a growing number of AFDO certified HACCP trainers. Drs. Hodgson and Kaneko are both AFDO certified HACCP trainers and have been involved in numerous HACCP trainings for industry members in Hawaii and overseas.

- Development of Model Scombrotoxin Control Procedures for commercial Atlantic Fish Species, George Flick (Food Science & Technology Department, Virginia Polytechnic Institute, Blacksburg, VA), start date of 10/1/00 for 36 months (on-going)
  Another CSREES-funded project began on 10/1/00 to evaluate the greatest hazards for food poisoning from harvest through retailing by studying histamine formation in various Atlantic fish tissues. That project will develop Model HACCP procedures. The subcontractor Project Director, Dr. J. Kaneko (1997), has previously developed a generic Model Seafood HACCP plan that is in use in Hawaii. Dr. Flick's project ***is distinct from our proposal***, which focuses on supporting HACCP Plans with training, education, and extension to the hard-to-reach fishers. In addition, this proposal is also unique by integrating stakeholder input and existing applied research findings specific to the Hawaii fishery and its industry setting with results that may be applicable to the fishing industry nationwide.

Hawaii

There has been extensive work performed in Hawaii on developing HACCP-based systems for controlling histamine in the fresh tuna industry, including the following:

- The Model Seafood Surveillance Project (MSSP) was a government-funded effort to develop a HACCP-based inspection system for the U.S. seafood industry. This was a collaborative effort among the National Fisheries Institute, industry, and the National Marine Fisheries Service. Dr. Kaneko, one of the key proposed project staff, served on one of the committees under MSSP between 1988-1990 to investigate ways in which HACCP could be effectively implemented in the fresh tuna industry.

- Kaneko, J.J. and P. Bartram. 1994. A Critical Review of the newly proposed FDA HACCP System for the Seafood Industry: The Hawaii Industry Perspective. Prepared for State of Hawaii, Department of Business, Economic Development, and Tourism (DBEDT) by PacMar, Inc., Honolulu, HI. 46 p.
  Based on previous experience, Dr. Kaneko was contracted in 1994 by the State of Hawaii to prepare a critique of the FDA proposal for seafood HACCP. This resulting position paper identified several issues of concern, made recommendations, and was presented to the FDA as industry input during the FDA comment period in formulating the HACCP program.

- Kaneko, J.J. 1997. The Development and Practical Application of a Generic HACCP Model for the Hawaii Seafood Industry. Prepared for State of Hawaii, DBEDT by PacMar, Inc., Honolulu, HI.
  To help the Hawaii industry develop HACCP plans required by the FDA HACCP Seafood Inspection Program, the State of Hawaii funded a project that generated a model HACCP plan based upon the typical Hawaii-based wholesaler and dealt with the common food safety hazards, histamine, and ciguatera fish poisoning. At least 50 companies received training using the model HACCP plan in formulating and customizing their individual company plans.

- Kaneko, J.J. 2000. The Development of a HACCP-based Strategy for the Control of Histamine for the Fresh Tuna Industry. NOAA Award No. NA86FD0067. PacMar, Inc., Honolulu, HI. 48 p.
  Recent research conducted in Hawaii focused on the development of a HACCP-based approach to the control of histamine in the fresh tuna industry. This study, supported by the National Oceanic and Atmospheric Administration (NOAA), evaluated the epidemiology of histamine poisoning in Hawaii, the fish handling practices aboard commercial fishing vessels, and the potentially valuable and practical method for screening out fish with high risk of toxic histamine concentrations. The study integrated local and industry knowledge, epidemiological data, and applied research to address a highly complex food safety issue. The study concluded that control measures for histamine based on sampling and testing would be ineffective and that the reporting of harvesting and on-board fish handling records would be impractical for fishers to collect on most vessels.

- Nakamura, R.M., J.S. Akamine, D.E. Coleman and S.N. Takashima. 1987. The management of yellowfin tuna in the handline fishing industry of Hawaii: A fish-handling handbook. Sea Grant Advisory Report UNIHI-SEA GRANT-AR-88-01. University of Hawaii, HI. 31 p.
  Dr. Nakamura conducted a research study focused on a small-boat tuna fishery and the prevention of a quality defect called the "burnt tuna syndrome". This defect results in some yellowfin tuna under conditions of temperature mishandling at sea and on shore during processing, storage, and distribution. The same guidelines for proper handling of yellowfin tuna are appropriate for the control of histamine production, the control of bacterial

decomposition, and the improved quality and market value of the catch. These recommendations promote seafood safety through the control of conditions that allow rapid histamine formation and accumulation.

On-going and Recent Work by Key Project Personnel

- Aurora S. Hodgson Food Technology Extension Specialist at the University of Hawaii, Cooperative Extension Service, Food Technology program just completed the development of a Train-the-Trainer certification program on the principles of basic food safety (Advisory Council on Food Protection Practices, 2000). This important program is being implemented to train trainers within companies to facilitate the strategic spread of the principles of food safety. The educational materials described in this proposal will be modeled after the University of Hawaii at Manoa work.

- John Kaneko, Project Director of PacMar Inc., Honolulu Hawaii, has just completed a NOAA-funded project that resulted in a detailed hazard analysis of the fresh tuna industry, investigated the relationship between on-board handling and histamine formation, and developed a HACCP-based approach to control histamine. Dr. Kaneko developed the Generic Seafood HACCP Model for the Hawaii Seafood Industry in 1997, sponsored by the State of Hawaii. He has also been involved in developing and conducting training programs for purse seine vessels in American Samoa, Puerto Rico and Ecuador on fish handling, quality improvement, and refrigeration.

- Robert Nakamura, Emeritus Professor of the University of Hawaii at Manoa and PacMar, Inc. Associate, conducted extensive research and training of fishers in proper fish handling to prevent burnt tuna syndrome. His team developed a valuable and practical training manual for fishers. He has also been involved in the development and implementation of training programs for purse seine vessels on fish handling, quality improvement and refrigeration.

- Jon Bell, Food Scientist, PacMar, Inc. Associate, has conducted training programs for fishers on quality improvement and on-board fish handling in South Africa, New Zealand, American Samoa, Puerto Rico and Ecuador. He has also conducted on-board research on fish quality, safety, and correlation between fish handling parameters and quality indicators.

Program Areas (Justification)

The proposal primarily addresses ***Program Area 111.H (Food Handler Education and Training for Commercial and Non-commercial audiences, including Food Handler Certification Training and Other Train-the-Trainer Programs)***. The end products are various educational materials for fishers, such as videotape and a simple, ready-to-use written manual that will be used in certification training programs. The proposal further addresses ***Program Area 111.G (Food Handler Education and Training for High-risk and Hard-to-reach Audiences)*** who are the fishers at sea and the recreational, and subsistence fishing communities. In addition, the proposal addresses ***Program Area 111.I (Hazard Analysis and Critical Control Points (HACCP) Model Development, Testing, and Implementation)*** using the generic HACCP model previously developed for the Hawaii Seafood Industry by the subcontractor (Kaneko, 1997). The proposal presents an opportunity to demonstrate an approach that builds on our previous applied research and incorporates practical training and extension efforts needed to support and enhance the effectiveness of a HACCP system for controlling a complex food safety problem, histamine in seafood.

The Food Safety Issue

The proposal addresses a fundamental and pervasive obstacle to the effectiveness of HACCP control systems, which is the lack of understanding of common and emerging food safety hazards by those who are implementing HACCP. As a result, HACCP programs are being treated by some as a paper exercise that holds no real benefit for the industry or the consumers.

The achievement of food safety through HACCP is dependent on food handlers being able to understand the potential hazards and effective control options to minimize risk. One weakness in the implementation and effectiveness of HACCP is the relative lack of efforts to elicit, understand, and incorporate industry input and knowledge into hazard analyses and HACCP plans. Local and traditional experience-based knowledge is often overlooked or ignored, neglecting the potential value in engaging industry members (stakeholders) and eliciting their insights (Kaneko et al 2000). If stakeholders themselves understand the potential hazards and realize that the control of the food safety problems is in their own personal and economic best interest, compliance will be increased even among hard-to-reach segments of food production systems. Although scientists and regulators may agree on HACCP principles and upper management may promise commitment to HACCP compliance, it is the food industry workers who perform day-to-day activities and routines of the lowest levels of labor within their companies and actually implement HACCP to make it work. These repetitive and routine tasks include many of the important steps that require critical decisions, such as basic sanitation practices, adhering to Good Manufacturing Practice (GMPs), and finally, HACCP monitoring and record-keeping. The workers performing these tasks are often the most difficult to reach and educate. It is important that all levels of staff and management within companies understand that each employee has a personal stake in ensuring food safety and optimizing product quality.

An important industry example of an effective HACCP control of a complex food safety issue that relies ultimately on practical training of hard-to-reach audiences is scombroid fish poisoning (also know as histamine poisoning). Histamine poisoning is one of the most common seafood-related illnesses in the U.S (NAS, 1991). The control of histamine poisoning is one of the top nationwide priorities facing the U.S. seafood industry and the FDA Office of Seafood, HACCP Inspection program (FDA, 2001).

Histamine poisoning is caused by the ingestion of fish muscle containing high concentrations of histamine and possibly additional biogenic amines generated through bacterial enzyme action on naturally occurring amino acids in susceptible species of fish. The fish species most commonly implicated in the U.S. include mahimahi (*Coryphaena hippurus*), tuna (primarily *Thunnus albacares*), and bluefish (*Pomatomus saltarix*). Tuna and mahimahi are extremely important market species and food fish in Hawaii, the Pacific, and across the continental U.S.

Histamine formation and accumulation is caused by time and temperature abuse of certain species of fish that contain naturally high levels of the free amino acid, histidine. When these fish are mishandled during the immediate post-harvest period, bacteria proliferate. If certain species of bacteria (in particular, *Morganella morganii*) are present, they are capable of producing the enzyme, histidine decarboxylase that converts histidine into the toxin, histamine. When consumers eat fish containing high histamine concentrations, they suffer pseudo-allergic reactions, including swelling and flushing of the face, hives, heart palpitations, and dizziness. Symptoms are self-limited and treatable with anti-histamines.

Fortunately histamine accumulation in fish is easily preventable through proper temperature control in the post-harvest period from the time fish is harvested and as it travels through the processing and distribution chains. The application of HACCP principles to the control of histamine in fish, however, is made particularly complex due to the wide variety of primary producers of susceptible fish species. These producers may be domestic or international, large-scale or small-scale fishing operations, and commercial, subsistence, or recreational fisheries. Each producer potentially impacts public health in the U.S.

Therefore, the critical and most effective opportunity for histamine control is immediately post-harvest, with the responsibility placed on fishing vessel crews during fishing operations. But this crucial period occurs on fishing vessels at sea and seafood HACCP programs currently place the first control on the first receiver, the primary processor. Thus, the most important phase of histamine control in the food production system occurs ***outside*** the regulatory system, well before the raw seafood enters the HACCP system of the processor.

There are currently two approaches available to the first receiver to control histamine in the fish they receive from fishing vessels. One approach implements a histamine sampling and testing program for incoming fish (FDA, 1998). Although this approach may be effective in screening gross mishandling of fish catches, it is highly unlikely to detect high histamine levels in a small number of individual fish during unloading, as is often the case (Kaneko, 2000). This sampling and histamine testing approach is not based on the HACCP philosophy that emphasizes monitoring of effective preventive measures rather than end-product testing. This approach is also ineffective in informing fishing vessel crews about the conditions that promote rapid histamine accumulation and how they can be easily controlled. If mishandling occurs at sea allowing bacterial growth and histidine decarboxylase formation, the succeeding HACCP controls are highly unlikely to be effective when applied later along the processing and distribution chain (FDA, 1998).

The second approach requires the primary processor to receive detailed harvesting records from fishing vessels delivering histamine-susceptible fish species (FDA, 1998). Although the recommended and highly detailed harvest monitoring records may be important, some of these recommendations are considered impractical to implement by fishers and may even jeopardize proper sanitation, adherence to GMPs, and producing safe products. When these requirements are perceived as unreasonable, unwarranted, and impractical, fishing vessel crews are likely to treat such harvest records as another paper exercise. As a result, there is no improvement in their understanding of the histamine problem or in the production of safer fisheries products.

Existing fishery management programs offer insights into the relationship of fishers and regulators. Tuna fishing operators are required to keep logbooks to document their fishing activities but not on-board fish handling. Although fishers meet their self-reporting obligation, fishers, scientists, and regulators question the accuracy of the data reported in logbooks. Consequently, federal observers are now deployed to collect similar data resulting in a redundant system. This reaction deteriorates the relationship among fishers, regulators, and scientists. If fishers, however, were engaged constructively by helping them understand the value of the data they report, the accuracy of the logbook reporting might be improved.

This proposal addresses an alternative approach that emphasizes training and outreach to fishing crews to improve their knowledge of histamine formation and their responsibilities in controlling the food safety issue. Histamine formation will be controlled only when fishers understand how proper time and temperature control at sea can improve fish quality, increase value and food safety of the catch, positively affect personal income, and maintain job security.

Magnitude of the Food Safety Issue

Seafood-related illnesses represented 56% of the reported outbreaks (two or more sick individuals) and 21% of all cases (a single ill person) in the U.S. caused by animal protein foods, meat, poultry, and fish between 1978 and 1987 (NAS, 1991). Of the seafood-related illnesses, scombroid fish poisoning and ciguatera fish poisoning (tropical reef fish) are estimated to have caused 62.5% of all seafood-related outbreaks and 28% of all reported cases. Hawaii, a state with a population of just over 1 million residents, reported 29% of the scombroid fish poisoning outbreaks and 23% of the U.S. cases reported to the Centers for Disease Control and Prevention between 1978 and 1987 (NAS, 1991).

Between 1989 and 1999, there were 188 outbreaks and 459 cases of histamine poisoning reported to the State of Hawaii Department of Health (Kaneko, 2000). Tuna (yellowfin and bigeye) represented 44% of the outbreaks and 25% of the number of reported cases. Mahimahi caused 24% of the outbreaks and 54% of the reported cases. These were the two dominant categories of fish causing histamine problems, with other fish species implicated at much lower frequencies.

Many cases of histamine poisoning may result from fish caught by recreational fishers, increasing the complexity of the problem. Recreational fishers in Hawaii are permitted to sell their catch with relative ease by maintaining commercial permits that allow them to recover operating expenses and income. The recreational or part-time commercial sectors represent a significant supply to consumers of fresh tuna and related species but are very difficult to reach and tend to fall outside the normal regulatory process. Recreationally caught fish, that do not enter commercial channels, have also been responsible for some reported cases of histamine poisoning and contributed to the overall concern about histamine poisoning in commercial fisheries products.

The National Academy of Sciences conducted an extensive study on seafood safety (NAS, 1991) that concluded that those at the greatest risk from seafood-related illness are: 1) consumers of raw molluscan shellfish, 2) sport anglers that consume their catch, 3) people who live in tropical islands, and 4) consumers of fresh and frozen mahimahi, tuna, and bluefish. Hawaii consumers and its important visitor population meet these qualifications and can therefore be described as at relatively high risk for histamine poisoning.

The NAS recommended that, to improve food safety, educational programs on natural seafood toxins be developed for recreational and subsistence fisheries. NAS also stressed the need for education materials to be made available to the fishing community, seafood industry, and public health workers. This proposal follows the NAS recommendation of an outreach approach that is extremely important in Hawaii and other tropical and subtropical locations amidst a growing concern about the origin of seafood imported into the US market.

Relevance to Stakeholder's Needs

The Hawaii Consumers and Tourism Industry

Hawaii consumers, the fishing and seafood industry, and its vitally important tourism industry impact perceptions of seafood safety. Pacific Rim cuisine and local fresh high quality seafood have become an increasingly important aspect of Hawaii's tourism product and visitor experience. Charter fishing is also an important segment of the tourism industry in Hawaii and is estimated to generate $14 million in charter revenue per year, with nearly 200 charter fishing vessels operating in Hawaii in 1997 (Hamilton, 1998). In addition, nearly 70% of the fish caught by the charter fleet is sold to primary processors and charter customers, crew, friends, and family consume a significant portion of the remaining catch. Thus, charter fleets also impact consumers through both commercial and non-commercial channels.

The Hawaii Fishing and Seafood Industry: Commercial, Non-commercial, Recreational, and Subsistence

Hawaii has the largest concentration of longline, handline, and trolling fishing vessels in the U.S. Ex-vessel value of the commercial pelagic fish landings in Hawaii, consisting primarily of histamine-susceptible fish, is estimated at $58 million (WPRFMC, 2000). The commercial fishing industry and seafood business make a significant contribution to the local economy, social, and cultural fabric of Hawaii's multi-ethnic population. The viability of the fishing industry requires the ability to control histamine and reach regulatory compliance. The recreational fleet in Hawaii is substantial and estimated in the thousands of vessels and fishers (Kaneko et. al., 2000). Accurate estimates of both recreational and subsistence fishers is especially difficult because fishers may shift utilization and sale of the catch depending on the catch volume, market conditions, need to recover expenses, and other factors. These two sectors of the pelagic fisheries have the potential for impacting public health through poor or ineffective fish handling and histamine accumulation. This proposal is intended to support industry and regulatory efforts to reach HACCP compliance, inform non-commercial sectors, and minimize histamine risk.

Objective 3. By the end of quarter 3-year 1, to have tested prototype training and outreach materials and program with stakeholder groups.

Objective 4. By the end of the second month of quarter 4-year 1, to have modified training materials with input from stakeholders.

Year 2

Objective 5. By the end of quarter 1-year 2, to have re-tested training materials with stakeholders.

Objective 6. By the end of quarter 3-year 2, to have finalized and produced training materials.

Objective 7. By the end of quarter 4-year 2, to have evaluated the finalized training materials for effectiveness.

Objective 8. By the end of quarter 4-year 2, to have incorporated training and certificate program into HACCP system.

Year 3

Objective 9. By the end of quarter 3-year 3, to have conducted training workshops for hard-to-reach individuals.

Objective 10. By the end of quarter 4-year 3, to have completed a final report on the project.

METHODS

Task 1 (Objective 1). By the end of quarter 1-year 1, to have compiled and summarized the best available scientific information on histamine formation and controls.

- Conduct literature search
- Compile and summarize pertinent scientific information on how histamine forms in fish, the relationship with fish handling procedures at sea, and how to best prevent its formation and accumulation.
- Summarize a list of best practices that can form the basis of recommended handling and information for training efforts.

Task 2 (Objective 2). By the end of quarter 2-year 1, to have designed prototype education and training materials (Train-the-Trainer certification course and stakeholder training)

- Define target audience(s) and engage key industry and community members to provide insight on the character of the target audience, potential restrictions on effective communication, and best approaches for effective training.
- Design training and educational materials integrating input from industry and community members. The training materials will be simple, graphics-filled materials that define histamine and related biogenic amines, how they occur, how they are prevented, and how HACCP works. An accompanying short videotape will be developed after the training materials have been finalized.
- Define course certification requirements.
- Finalize prototype training materials and certification training program.

Task 3 (Objective 3). By the end of quarter 3-year 1, to have tested prototype training and outreach materials and program with stakeholder groups

- Using the prototype training materials and program, conduct eight (8) training workshops within hard-to-reach segments of the stakeholder groups. These will likely include longline fishing vessel crews, commercial/charter trollers and handliners, and recreational fishing groups. Workshops for longliners, trollers and recreational fishers will be held on Oahu. Workshops for handliners will be held in Hilo, Hawaii, where this fishery is centered.
- Use an interactive approach for training and elicit input from trainees as well as the project team members on the effectiveness of the program and materials, and how they might be enhanced.
- Develop and use a survey instrument to collect meaningful evaluations, critiques, and recommendations from the range of stakeholders.
- Examine the results of the survey and prepare recommendations to incorporate in the next step.

Task 4 (Objective 4). By the end of the second month of quarter 4-year 1, to have modified training materials with input from stakeholders

- Compile and analyze stakeholder input generated by the workshop series.
- Incorporate their input to modify and enhance the training materials.

Task 5 (Objective 5). By the end of quarter 1-year 2, to have re-tested training materials with stakeholders.

- Conduct a second round of eight (8) training workshops for groups from commercial longlining, handline, troll fishing communities, and recreational fishers.
- Use an interactive approach for training and elicit input from trainees as well as the project team members on the effectiveness of the program and materials, and how they might be enhanced.
- Develop and use a survey instrument to collect meaningful evaluations, critiques, and recommendations from the range of stakeholders.
- Examine the results of the survey and prepare recommendations to incorporate in the next step.

Task 6 (Objective 6). By the end of quarter 3-year 2, to have finalized and produced training materials.

- Incorporate the second round of stakeholder inputs and finalize draft-training materials.
- Circulate training materials among project associates representing expertise in applied research, instruction, training, and extension for comments.
- Prepare final certification training program materials.
- Prepare the script for the accompanying short videotape.
- Select printer and videographer for the production of the final training materials.
- Produce final training materials.

Task 7 (Objective 7). By the end of quarter 4-year 2, to have evaluated the finalized training materials for effectiveness.

- Conduct four (4) training workshops using the improved training materials.
- Evaluate effectiveness of the materials by conducting practical examinations before and immediately following the training sessions.
- Develop and use a survey instrument to collect meaningful evaluations, critiques, and recommendations from the range of stakeholders.
- Examine the results of the survey and prepare recommendations to incorporate in the training sessions.

Task 8 (Objective 8). By the end of quarter 4-year 2, to have incorporated training and certificate program into HACCP system

- Select a company in Hawaii that receives fresh histamine-susceptible fish directly from fishing vessels and is willing to incorporate a training and certificate program into its HACCP System.
- Assist the integration of the training requirement and certificate program.
- Develop and use a survey instrument to collect meaningful evaluations, critiques, and recommendations from the range of stakeholders.
- Examine the results of the survey and prepare recommendations to incorporate in the training sessions.

Task 9 (Objective 9). By the end of quarter 3-year 3, to have conducted training workshops for hard-to-reach individuals.

- Conduct a series of thirty-five (35) training workshop for commercial longline, handline, troll, and recreational fishers. Workshops for commercial longline and troll fishermen will be held in Honolulu. Workshops for handliners will be conducted in Kona and Hilo where this fishery is concentrated. Workshops for recreational fishers will be conducted in Honolulu, Haleiwa, Waianae and Kaneohe on Oahu, Kona and Hilo on the Big Island.
- Develop and use a survey instrument to collect meaningful evaluations, critiques, and recommendations from the range of stakeholders.
- Examine the results of the survey and prepare recommendations to improve the training materials and program beyond the grant period.

Task 10 (Objective 10). By the end of quarter 4-year 3, to have completed a final report on the project

Following the CSREES guidelines, annual reports will be issued after each of the first two years and a final report will be completed at the end of the project life.

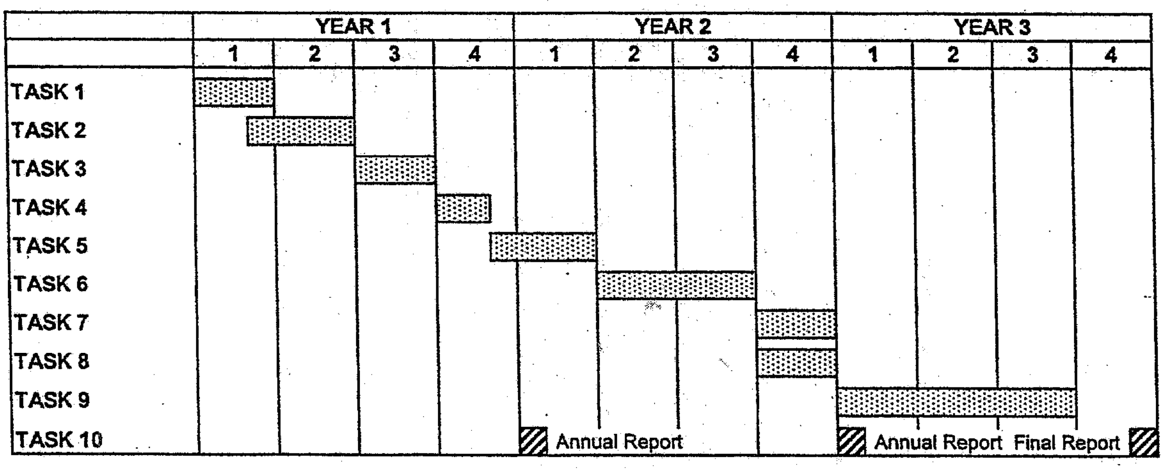
COOPERATION AND INSTITUTIONAL UNITS INVOLVED

The University of Hawaii at Manoa, Cooperative Extension Service, Food Technology program, is the lead entity for this project. In support, PacMar Inc., Honolulu, Hawaii will be the subcontractor to assist the University of Hawaii conduct this project. PacMar, Inc. is a private consulting and research firm that has been actively engaged in applied research in seafood safety, quality improvement in fishing operations, and HACCP applications for the seafood industry. PacMar, Inc. is the only firm in Hawaii to do such research work and with much success. The firm is well integrated in the Hawaii seafood and fishing industry and conducts practical training for fishers and for seafood processors. The PacMar team will serve as the conduit to the Hawaii fishing communities, many of which are diverse and hard-to-reach.

Key industry contacts in Hawaii will cooperate with the project team to advertise training sessions and recruit participation and input from fishers. These include the United Fishing Agency, which receives approximately 70% of all commercial fish landings in the state, and Hilo Suisan Company that receives a significant amount of fish landings on the Big Island of Hawaii. The Hawaii Longline Association is the industry organization that includes the majority of commercial longline vessels.

Additional support in arranging participation from fishers and in reviewing and commenting on the development of the training materials will be selected from the Hawaii Department of Health, Food and Drug Branch, the Western Pacific Regional Fisheries Management Council, and possibly the National Marine Fisheries Service Honolulu Laboratory.

PROJECT TIMETABLE



Task 1: Compile and summarize the best available scientific information on histamine formation and controls.
Task 2: Design prototype education and training materials.
Task 3: Test training and outreach materials and program with stakeholder groups.
Task 4: Modify training materials with input from stakeholders.
Task 5: Re-test training materials with stakeholders.
Task 6: Finalize and produce training materials.
Task 7: Evaluate the finalized training materials for effectiveness.
Task 8: Incorporate training and certificate program into HACCP system.
Task 9: Conduct training workshops for hard-to-reach individuals
Task 10: Annual and Final Report

EQUIPMENT AND FACILITIES

The cooperation and institutional units would provide all facilities for use or assignment to the project during the requested period of support involved. No potentially hazardous materials, procedures, situations, or activities, whether or not directly related to a particular phase of the effort, will be used for this project. All necessary precautions would be duly exercised.

REFERENCES

Advisory Council on Food Protection Practices. 2000. DO IT RIGHT! A Train-the-Trainer Course on Basic Food Safety. A 9-min videotape designed for entry-level foodhandlers and an accompanying written manual for the Trainer, with tip sheets, posters, and quizzes, designed as a certification course.

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APPENDICES TO PROJECT DESCRIPTION

Letters of commitment from collaborators and support from cooperating units are on pp. 57-60.