Amendment to the UFA Citizen Petition under the Seafood HACCP Transition Guidance (August 24, 2001).

April 3, 2002
(resubmitted with certification statement)

March 18, 2002
(original submission date)

Submitted to the:

Dockets Management Branch
Food and Drug Administration
Room 1061
5360 Fishers Lane
Rockville, Maryland 20852

Submitted by the:

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April 3, 2002

Dockets Management Branch
Food and Drug Administration
Room 1061
5360 Fishers Lane
Rockville, Maryland 20852

On March 18, 2002, an amendment to the UFA Citizen Petition under the Seafood HACCP Transition Guidance submitted on August 24, 2001, was sent to your office. The March 18 amendment was submitted for consideration based on interaction with the agency, which led to narrowing the scope of the original petition.

This revised amendment (April 3, 2002) is submitted today in response to a request from the Dockets Management Branch to include a statement about environmental and economic impacts and a certification statement. No other changes were made to the content of the petition.

Please confirm receipt of this petition. We look forward to the agency's comments and decision on our petition.

Sincerely,

Brooks H. Takenaka

Brooks Takenaka
Assistant General Manager
United Fishing Agency

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Certification:

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes pertinent information and views relevant to the Hawaii pelagic fishery and United Fishing Agency setting and practices on which this petition relies. Further, the undersigned does not believe that environmental or economic impacts are necessary considerations for the intent and purpose of the petition at this time.

Brooks H Takenaka

Brooks Takenaka, Assistant General Manager

1. Action requested.

This petition is submitted by the United Fishing Agency (UFA) to the Food and Drug Administration, Office of Seafood (FDA) for the purpose of requesting the FDA to consider exercising enforcement discretion on certain matters under the seafood HACCP regulations pending their scientific resolution.

2. Statement of grounds.

UFA is facing continued difficulty applying current FDA recommendations for primary processors on how to control potential histamine accumulation in susceptible fish on fishing vessels at sea. After careful review of the FDA guidance, UFA was unable to see how its suppliers, specifically Hawaii longline and troll fishermen could comply. Not all

Hawaii fishermen supplying UFA are able to meet the recommended fish handling goals (time and temperature limits) as they are currently written. This is what led the company to develop and adopt an alternative system for histamine hazard controls on fishing vessels (Kaneko, 2000). UFA believes there is sufficient evidence that, while some of the fishing and fish handling practices that typify Hawaii's fishery do not meet the FDA recommended Critical Limits, these practices provide an equivalent level of histamine control. Research is proposed to strengthen the scientific justification for the industry's position regarding the safety of current fishing and fish handling practices aimed at histamine hazard control. UFA submits this petition on the grounds that,

- The FDA Fish and Fishery Products Hazards and Controls Guide ("the Guide") presents guidance not binding regulations (FDA, 2001).

- Current guidance on Critical Limits for fish handling (time and temperature control) by fishermen does not account for all Hawaii fishing methods or ocean environmental conditions.

- Current guidance on Harvest Vessel Records for handling large tuna appears to be incompatible with guidance for receiving large tuna (> 20 lb) by primary processors.

3. Context of this Amendment.

UFA submitted a petition for Transitional Policy on August 24, 2001 to the FDA through the San Francisco District Office. The petition was submitted as a result of UFA's continued difficulty in applying either of FDA's two alternative approaches to histamine controls on fishing vessels (Histamine Testing and Harvest Vessel Records approaches). UFA is a fresh fish auction company, providing auctioning services on a commission basis to the majority of commercial fishermen of Hawaii.

The petition was prepared at the advice of an FDA official after UFA was inspected in July 2001. The petition described UFA's situation and explained the fishing and marketing practices that led the company to develop and implement its own alternative histamine control approach for fishing vessels. The petition included the rationale and main body of research that supported the UFA hazard analysis and reliance on sensory evaluation as a histamine control procedure for this unique fishery and marketing setting. The petition also presented two research and training proposals that had been prepared and submitted to USDA and NOAA. These were proposals to provide additional research support to validate the UFA hazard analysis and HACCP Plan and to conduct a training program in histamine hazard controls for Hawaii fishermen.

The first notification from the agency acknowledging receipt of the petition was on February 11, 2002 in a Warning Letter issued to UFA, citing deficiencies in UFA's HACCP Plan for controlling histamine on fishing vessels. At that time, the original petition was said to be under review and a decision had not been made.

Soon after the Warning Letter was received, UFA's Assistant General Manager, Brooks Takenaka and UFA's consultant Dr. John Kaneko held a conference call (February 25, 2002) with Don Kraemer and Walter Staruskewicz of the FDA Office of Seafood specifically to discuss the status of the petition. As a result of that conversation UFA agreed to prepare this Amendment and to narrow the focus of the petition to challenging

the key Critical Limits provided as guidance by the FDA because they are believed to be overly restrictive for Hawaii pelagic longline fishing vessels harvesting histamine-forming fish species. UFA is in the process of adopting the Harvest Records Approach with modified Critical Limits. The rationale for the application of these modified limits is described in detail in this petition.

4. Difficulties meeting FDA guidelines for on-board handling of histamine-forming fish.

4.1 FDA Guide presents guidance not binding requirements.
The following is based on "Guidance for Industry, Seafood HACCP Transition Guidance" (FDA, 1999).

- Under the FDA HACCP regulation, companies are responsible for conducting hazard analyses and developing appropriate and effective HACCP Plans to control food safety hazards that are deemed "reasonably likely to occur".

- The FDA describes the guidance contained in the Hazards Guide as recommendations and not binding, or prescriptive requirements.

- Processors may rely on hazard analyses that differ from those in the Guide as long as they are scientifically valid for their particular circumstances.

- Processors may also control hazards in other ways if those alternatives are scientifically defensible.

4.2 Current guidance on Harvest Vessel Records does not account for all Hawaii fishing methods or conditions.

Hawaii's pelagic fishing industry is comprised of four basic types of fishing gear (trolling, handline, pole & line and longline). These fisheries share important characteristics. They are all hook and line fisheries, mostly chill and store fish in ice, and they deliver and market fresh fish through UFA's display auction where buyers have a chance to judge the quality of each fish. UFA believes that each fishing method has distinct features that must be considered in determining the likelihood of histamine formation and defining safe handling parameters. The Critical Limits for fish handling at sea (as written in the Guide) provide good general guidance but may be unnecessarily restrictive when applied to some of the Hawaii fisheries.

Local experience and research results indicate that some of these handling guidelines can be modified to accommodate the way in which fishing operations are actually carried out in Hawaii and at the same time continue to effectively minimize the risk of elevated histamine concentration in the landings.

4.2.1 *FDA guidance.*

The FDA guidance recommends that primary processors such as UFA require fishermen to provide harvest records that document monitoring procedures and compliance with the following set of Critical Limits (Table 1). Harvest Records must show that,

Table 1. Critical Limits for on-board fish handling of histamine-forming fish.

Generally	**1. Fish are iced in ≤ 12 hours (after death)** or, 2. Fish placed in RSW or brine ≤ 40 °F in ≤ 12 hours (after death) or, 3. Fish placed in RSW or brine ≤ 50 °F in ≤ 9 hours (after death)
When ambient temp ≥ 83 °F	**4. Fish placed in ice ≤ 6 hours (after death) or** 5. Fish placed in RSW or brine ≤ 40 °F in ≤ 6 hours (after death)
Large tuna (> 20 lb.)	**6. Fish internal temp to ≤ 50 °F in ≤ 6 hours (after death)** or, 7. Eviscerated fish iced in ≤ 6 hours (after death) or, 8. Eviscerated fish in RSW or brine ≤ 40 °F in ≤ 6 hours (after death)

(Source: based on FDA Fish and Fisheries Products Hazards Guidance: 3rd ed, June 2001)

4.2.2 *Interpretation.*

- When fish (other than tuna > 20 lb round weight) are exposed to ambient temperatures (water and air) of < 83 °F, fishermen must place fish in ice in ≤ 12 hours after death.

- When ambient temperatures ≥ 83 °F, the time allowed is cut in half and fishermen must ice fish in ≤ 6 hours after death.

- When large tuna (> 20 lb) are caught and kept whole, fishermen must document that the internal fish temperature is ≤ 50 °F in ≤ 6 hours (after death) regardless of ambient temperature. This represents a significant reduction in time allowed and very different monitoring requirements.

4.2.3 *Difficulties complying with these recommendations are related to,*

- how the guidance addresses the relationship between time and temperature and histamine formation.
- how the various fishing gears in Hawaii actually catch fish
- the interpretation of and impact of ambient air and water temperatures
- the inability to determine time of death on longline gear
- the special restrictions placed on large tuna (> 20 lb)

4.2.4 *Histamine formation is time and temperature dependent.*

The formation of histamine in susceptible fish is related to bacterial growth and the decarboxylation of the amino acid, histidine. Both processes are dependent on enzymes. All enzymes are temperature dependent. The growth of bacteria, the production of histidine decarboxylase by the bacteria and the activity of this enzyme are all temperature dependent processes. As such, the accumulation of histamine is related not only on the temperature, but the time (duration) that fish are held at the various temperatures.

Enzyme kinetic curves are used to describe the characteristics of enzyme systems in terms of how reaction rates relate to temperature. Enzyme rates change along a characteristic curve with temperature. Enzyme activity is essentially arrested at freezer temperatures and low at lower temperatures. Rates increase to reach a maximum velocity at an optimum temperature and then begin to decline and finally stop when enzymes (proteins) become denatured (cooked).

Critical Limits for histamine control describe the necessary time and temperature of handling conditions from the time the fish dies until it is finally consumed. The Guide presents good general guidance but does not account for the range of handling conditions that may also effectively control histamine.

The guidance recommends that histamine-forming fish should be placed in ice in ≤ 6 hours (after death) if the ambient temperatures are ≥ 83 °F. This indicates that at temperatures < 83 °F the predicted rate of bacterial growth, enzyme production and histamine production would be controlled by this upper temperature limit as long as the fish are iced and chilling begins no longer than 12 hours after death. However, at temperatures ≥ 83 °F the time and temperature allowed before icing is reduced to just 6 hours and yet it is highly unlikely that the rate of histamine production doubles between 82.9 and 83.0 °F. The limit of 6 hours must have been based on a significantly higher upper temperature limit than 83 °F.

The Guide also makes specific recommendations for large tuna. Fishermen that catch tuna > 20 lb must document that the internal temp is ≤ 50 °F in ≤ 6 hours (after death). This recommendation does not consider the ambient temperature the fish are exposed if they die on the line. Large tuna held at high initial temperature may need to be chilled to ≤ 50 °F in ≤ 6 hours. This is particularly true for purse seine-caught tuna in the tropics, where fish may be held dead in the warm surface water (86-88 °F) during brailing for several hours, before chilling begins. In purse seine operations in the Western Tropical Pacific the initial body temperature of fish often exceeds 90 °F.

However, large tuna that are caught on deep set longline gear in the Hawaii fishery are held in significantly cooler water (< 65 °F) and the time required to bring these fish to ≤ 50 °F to control histamine might be safely extended beyond 6 hours.

Research is needed to determine safe fish handling parameters for Hawaii's longline tuna fishery, as well as for the troll and handline fisheries.

4.2.5 *Hawaii troll and handline vessels.*

Hawaii trollers and handliners retrieve fish while they are still alive. For these two gear types, the time of death can be determined. Hawaii trollers and handliners use ice (alone) or ice brine (followed by ice) to chill and store fish on-board. However, when trollers and handliners catch large tuna (> 20 lb) they have difficulty documenting that fish are chilled to an internal temperature of ≤ 50 °F in ≤ 6 hours. UFA believes that the recommendation specific for large tuna is impractical and is too restrictive when applied in the context of the fishing conditions that characterize the Hawaii fishery.

4.2.5.1 On-board fish handling.

From a practical standpoint, once tuna (or any other fish) are placed into ice, UFA believes it is best to leave the fish in the ice to allow for rapid chilling and not use thermometers to monitor fish temperatures in the fish hold or box. This is because the thermometer creates an entry for bacteria deep inside the muscle facilitating bacterial contamination and possibly promoting histamine formation. UFA believes it is better to

quickly ice the fish and ensure that the fish is properly iced throughout the fishing trip similar to what is recommended for all other histamine-forming fish besides tuna > 20 lb.

4.2.5.2 Chilling rates and fish size.

One important variable affecting chilling rates is fish size. The heat mass contained in a 210 lb yellowfin is certainly greater than a 21 lb yellowfin with the same internal body temperature and yet fishermen would be required to chill both these fish to ≤ 50 °F in ≤ 6 hours. Fishermen handling smaller sized tuna should be able to achieve this cooling rate, but they would understandably have difficulties when handling very large tuna. UFA believes that fishermen should focus on ensuring that chilling continues steadily until the fish is < 40 °F. Fish should be properly iced thereafter. Exactly how quickly fish must be chilled to < 40 °F is not known in all situations. Perhaps there are other critical time and temperature parameters such as time to ≤ 70 °F in combination with time to < 40 °F that are equally important in controlling histamine formation.

4.2.5.3 Initial fish internal temperature.

Another important variable is the activity of the fish prior to death. Tuna that struggle on the line in the surface waters have elevated body temperatures. The initial body temperature of troll and handline-caught tuna can exceed 90 °F. Live fish caught on longline gear have considerably lower internal temperatures and therefore do not pose as great a potential for histamine formation.

4.2.5.4 Large troll-caught blue marlin.

Troll-caught blue marlins are currently held to the same Critical Limits for time and temperature as other fish (besides larger tuna > 20 lb). Chilling large blue marlin is a challenge. Trollers routinely catch fish over 300 lb and fish in excess of 800 lb are also landed. These large fish can take well over 24 hours to be chilled to < 40 °F. UFA believes that time and temperature limits recommended in the Guide may be overly restrictive when applied to large blue marlin. Research is needed to determine if the Critical Limits for blue marlin can be modified and still ensure histamine control.

4.2.6 *Hawaii longline vessels.*

Hawaii longliners retrieve a mixture of live and dead fish. For the fish that die on the line, the time of death cannot be known. This has implications because FDA guidance is based on key time and temperature targets that begin after the fish dies.

4.2.6.1 Ambient temperature at the hooking depth.

Harvest Vessel Records require measurements of air and sea surface water temperature (SST) with Critical Limits impacted when temperatures are ≥ 83° F. However, the SST has little relevance to the temperature of the water that longline fish are actually exposed to. This is in sharp contrast to tuna purse seine fishing, especially in the Western Tropical Pacific, where during the brailing process, dead fish are held in the seine at the sea surface where temperatures are the highest in the water column.

Hawaii tuna longliners target bigeye tuna that are found in deep water layers where water temperature is significantly cooler than at the surface. Most bigeye are caught at

depths greater than 200 meters (646 ft) where water temperature is 53 to 57 °F (Boggs, 1992). Newly proposed regulations for the Hawaii longline fishery are aimed at requiring deep sets to avoid sea turtle interactions, where the shallowest hooks allowed are 50 meters (164 ft) below the surface. In the fishing grounds accessible to the Hawaii fleet, this layer of water is about 65 °F. Using these estimates and knowledge of fishing practices, we would predict that even if fish die on longline gear, they are held in water with temperatures less than 65 °F and chilling would begin immediately after death.

4.2.6.2 Histamine accumulation in live versus dead fish on retrieval.

Research results indicate that the mean internal temperature of Hawaii longline-caught fish retrieved alive was 79.5 °F (Kaneko, 2000). Fish retrieved after dying on the line had a mean internal temperature of 69.1 °F indicating that chilling had begun in the water. These fish were monitored for time and temperature on-board and sampled for histamine at the end of the trip. The mean histamine concentrations (Table 2) for live and dead fish (a mix of histamine forming fish species) were 3.0 ppm and 2.1 ppm respectively with a maximum of 8.8 ppm found in a striped marlin, still well below the defect action level (50 ppm). The mean histamine concentrations of live and dead tuna were not significantly different and both were well below the defect action limit. The mean histamine concentrations for the tuna species retrieved after dying on the line (bigeye, yellowfin and albacore) ranged from 2.1 to 2.4 ppm with a maximum concentration of 5.3 ppm. While the total elapsed time dead fish were held on the line could not be determined, information on the duration of the longline set was collected and evaluated. Based on this information, it does not appear that longline-caught fish that die on the line in Hawaii's fishery pose a significantly greater risk for elevated histamine than those retrieved alive because of the ambient seawater temperatures in which the fish die.

Table 2. Comparison of the histamine concentration of longline-caught fish retrieved alive and dead. (Kaneko, 2000)

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)
(*ppm = mg/100g X 10)

4.2.6.3 Total duration of the longline set.

The Hawaii Longline Association (personal communication Feb 27, 2002) reports that the standard operating procedure for Hawaii longliners is to start setting gear in the early morning and finish setting in about 4 hours. The line is then "soaked" for about 6 hours

and then hauling begins. Hauling the line can take 6 to10 hours. This amounts to a range of 16 to 20 hours total time per set.

Twenty-one (21) commercial Hawaii longline sets were monitored (Kaneko, 2000) to characterize the schedule of setting that typifies the Hawaii-style of longline fishing. The time from when the first hook was set until the last hook was retrieved was monitored. The mean total set duration was 18 hours (SD 1 hour 14 minutes), the minimum was 16 hours 7 minutes and the maximum was about 20 hours 30 minutes.

UFA believes that it is highly unlikely that a fish will take the first hook deployed at the same time it is set. It is even more unlikely that the fish will die immediately after being hooked. It has been shown that bigeye tuna do not generally take hooks until after the gear has finally settled, which takes about 30 minutes. Research by NMFS scientists (Boggs, 1992) determined that over 50% of the longline-caught fish in Hawaii's fishery are retrieved alive. Bigeye tuna and striped marlin were shown to survive up to 6 to 9 hours after being hooked. The shortest time between hooking and the retrieval of a dead bigeye tuna or striped marlin was 2 to 3 hours.

By taking a maximum total set duration of 20 hours and 30 minutes, subtracting 30 minutes for the first hook to settle, and if that first hook was taken by a fish, subtracting an additional 2 hours before it might die after being hooked, we calculate that the maximum time a fish might be dead on the line to be approximately 18 hours. Based on the mean set duration, the time a fish could be dead on the line would be approximately 15.5 hours. Considering that these fish would be held in water less than 65 °F, UFA believes that this may constitute safe handling for histamine forming fish when followed by proper icing and storage.

4.2.6.4 Evidence that Hawaii-style longline set parameters are safe.

The landings of forty-two (42) different Hawaii longline trips were sampled for histamine (Kaneko, 2000). Two hundred seventy-six (276) fish displayed for sale were sampled from the UFA auction floor. Each individual fish had passed sensory examination. The longline sets that produced these fish were representative of the Hawaii-style of longline fishing and set duration parameters described above. None of the fish including (68) bigeye, (77) yellowfin, (39) albacore, (30) striped marlin, (30) blue marlin and (32) mahimahi tested for histamine exceeded the histamine defect action limit. With the adoption of Harvest Vessel Records and additional research, the relationship between the longline setting parameters and histamine accumulation can be further verified.

4.2.7 Proposed Critical Limit.

UFA proposes to use a Critical Limit of $\leq$ 20 hours for the total longline set duration for the Hawaii longline fleet. This limit is proposed because this is within the documented maximum set time that produced safe fish in the Hawaii longline fishery. This information is to be recorded by the fishermen on Harvest Vessel Records along with the time the fish are brought on-board, when they are placed into the ice (standard practice is within 30 minutes) followed by daily ice checks during chilling and storage throughout the trip.

4.3 Current guidance on Harvest Records appears to be incompatible with Receiving requirements for primary processors receiving large tuna (> 20 lb).

UFA has adopted recommended Critical Limits at the receiving step for monitoring the internal temperature of histamine-forming fish. At receiving,

- Fish ≥ 24 hrs after death must have internal temperature ≤ 40 °F.
- Fish ≥ 12 hrs and ≤ 24 hrs after death must have internal temperature ≤ 50 °F.
- Fish < 12 hrs after death must have internal temperatures that "demonstrate appropriate chilling methods" (FDA, 2001).

UFA has also adopted the Harvest Vessel Records Approach to controlling histamine. A problem arises when fishermen catch large tuna > 20 lb if the Critical Limit for chilling the fish to an internal temperature of ≤ 50 °F in ≤ 6 hours of death is applied. While this strict time and temperature guidance is placed on fishermen at sea, it is greatly relaxed when they deliver the same tuna to the primary processor. At receiving, it is recommended that the primary processor apply the Critical Limit that ensures fish are ≤ 50 °F in ≥12 but ≤ 24 hours of death, a considerable discrepancy. UFA believes that the FDA temperature guidance for receiving fish by primary processors (first receivers) is more appropriate than the specific recommendations for handling large tuna (> 20 lb) at sea.

5. The Proposed Research.

UFA is supporting research to investigate practical parameters that can be used by Hawaii's fishermen to ensure histamine control on fishing vessels. The proposal titled *"Verification of a HACCP-based system for Histamine Controls for the Fresh Tuna Industry"* was submitted to the NOAA Saltonstall-Kennedy Fisheries Research Program on May 7, 2001 (Appendix A). This project has been funded by NOAA and supported by UFA, the Hawaii Longline Association and the Western Pacific Regional Fishery Management Council. The overall goal of the project is to verify the efficacy of on-board fish handling procedures used by Hawaii longline and trolling vessels in controlling histamine accumulation in susceptible fish species.
UFA believes that the initial fish handling period at sea is the most important phase in the prevention of histamine formation. Quickly chilling the fish is extremely important to prevent histamine formation at high temperatures. Defining fish handling Critical Limits that anticipate and cover the range of fishing methods and environmental conditions found in all fisheries is an extremely difficult challenge. Recognizing and understanding that the various circumstances found in the variety of fisheries relate to the rates of histamine formation, accumulation, food safety risk and control measures requires further study.

UFA is now aware that FDA is pursuing studies to simulate abusive fish handling practices by exposing fish to extremes of time and temperature abuse. The aim of these studies is to identify how histamine forms under extreme conditions with a focus on histamine formation at high temperatures.

UFA is supporting the NOAA/SK research project to focus on the characterization and verification of the fishing and on-board fish handling practices that are actually used by Hawaii longliners and trollers and their effectiveness in controlling histamine. The

Harvest Vessel records required by UFA from fishing vessels are being used to control the likelihood of high temperature abuse and histamine formation. The project goal is to demonstrate the efficacy of fish handling parameters other than those currently recommended by FDA that provide an equivalent level of histamine control.

5.1 Status of the study.

The NOAA/SK research project has been approved and a start date of April 1, 2002 is expected pending the completion of contract negotiations with NOAA. The negotiations over the research protocol between the principal investigator (PI) and NOAA occurred prior to the UFA Warning Letter and the constructive dialogue that followed between UFA and the FDA concerning the original UFA petition. However, UFA believes that within the proposed research scope, the important questions raised in this amended petition can be evaluated.

Only slight modifications are anticipated to the overall research plan to facilitate the research needed to support this petition. These should be acceptable to NOAA. The PI is negotiating with another research team studying longline methods for assistance with some of the on-board work for the project. A fisheries researcher contracted by the University of Hawaii (UH) will be able to record important longline set data, place time and temperature loggers into fish and possibly assist with hook timers. Taking advantage of this opportunity, it is anticipated that 40 loggers per longline trip will be deployed to monitor more fish per trip than originally planned for the first 2 to 3 trips. The remaining research will be conducted as planned with the cooperation of fishermen, so that the project stays within budget.

5.2 What specific questions will be addressed by this research?

5.2.1 *Does the Critical Limit of ≤ 20 hours for the total duration for longline sets in the Hawaii fishery provide effective histamine control?*

The total longline set duration (first hook set, last hook retrieved) will be recorded. Time-depth-recorders (TDRs) will be attached to the line to determine the water depth and temperature when available (from the cooperating UH researcher). The research plan calls for studying a total of 240 mixed histamine-forming fish, including bigeye tuna, yellowfin tuna, albacore tuna, blue marlin, mahimahi and escolar. Fish will be tagged, the time of retrieval recorded and waterproof time/temperature loggers will be placed to record internal temperature during chilling and storage. At the end of the trip, these fish will be identified, the loggers retrieved and muscle samples will be collected for histamine analysis. Fish internal temperature must be below 40 °F before muscle samples are collected. Samples will be frozen and submitted to the laboratory for histamine testing using AOAC fluorometric method (AOAC, 1995 Official method 977.13 for histamine in seafood). The correlation between histamine concentration and total set duration will be determined.

5.2.2 *Within the Critical Limit of ≤ 20 hours for the total set duration, are fish that die on the line a greater risk for elevated histamine than those that are retrieved alive?*

The highest risk fish should be fish that have been held dead on the line for the longest period. Cooperating fishermen (and the UH fisheries researcher) will be asked to tag fish from the last two baskets of gear hauled in longline sets, identify fish by set number

and whether it was dead or alive on retrieval. Vessel records will be used to confirm the total set duration. Muscle samples will be collected at receiving and fish temperature must be below 40 °F. Samples will be frozen and sent to the laboratory for histamine testing. Histamine analysis will be performed and the initial body temperature, time to 50 °F and 40 °F will be determined. Using this approach, it is anticipated that approximately 120 live fish and 120 dead fish will be monitored and analyzed to determine the relationship with histamine accumulation. The mean and maximum histamine concentrations of dead and live fish will be compared.

5.2.3 *Can the Critical Limit of ≤ 50 °F in ≤ 6 hours of death, and/or the Critical Limit of ≤ 40 °F in ≤ 24 hours of death be extended for large tuna (> 20 lb) and still provide effective histamine control?*

The project does not have the opportunity to request that fishermen intentionally temperature abuse large tuna at sea. However, we can predict that troll-caught, larger yellowfin tuna (>100 lb) would have the most difficulty meeting the FDA guidance because they are surface caught, die after a struggle on the line, have elevated initial body temperatures and because of their size, represent a greater total required temperature drop.

Troll fishermen are required to record the time they catch fish and put them into the ice (Harvest Vessel Records). Cooperating fishermen will be trained to place temperature loggers into twenty (20) large yellowfin tuna (> 100 lb). At the time of delivery to UFA, the fish weight will be recorded and the loggers will be retrieved. Muscle samples for histamine testing will be collected after the fish are finally chilled to < 40 °F. Muscle samples will be frozen and sent to the laboratory for analysis. Time from death to 50 °F and 40 °F will be determined and compared with histamine concentration.

Cooperating longline fishermen (and the UH fisheries researcher) will also be asked to deploy time and temperature loggers into twenty (20) larger yellowfin tuna (> 100 lb) retrieved alive. Longline vessel records will indicate when the fish were caught and placed into the ice along with daily ice checks. At the end of the trip, the fish weight and receiving temperature will be recorded, muscle samples collected for histamine analysis (if < 40 °F) and temperature loggers retrieved. Time from death to 50 °F and 40 °F will be determined and compared with histamine concentration. A comparison will be made between longline and troll caught fish.

5.2.4 *Can the Critical Limit of ≤ 50 °F in ≤ 12 hours of death and/or the Critical Limit of ≤ 40 °F in ≤ 24 hours of death be extended for large Pacific blue marlin and still provide effective histamine control?*

The project does not have the opportunity to request that fishermen intentionally temperature abuse large blue marlin at sea. We can predict that large troll-caught, blue marlin (> 200 lb) would have difficulty meeting the FDA guidance because they are surface caught, die after a struggle on the line, have elevated initial body temperatures and because of their size represent a greater heat mass.

Troll fishermen are required to record (Harvest Vessel Records) the time they catch fish and put them into the ice. They will be trained to place temperature loggers into twenty (20) large blue marlin (> 200 lb). At the time of delivery to UFA, the fish weight will be

recorded. Marlins will be chilled until the internal temperature drops below 40 °F. The loggers will be retrieved and muscle samples for histamine testing will be collected. Time from death to 50 °F and 40 °F will be determined and compared with histamine concentration.

Cooperating longline fishermen (and the UH fisheries researcher) will also be asked to deploy time and temperature loggers into twenty (20) large blue marlin (> 200 lb) that are retrieved alive. Longline vessel records will indicate when the fish were caught and placed into the ice, along with daily ice checks. At the end of the trip, the fish weight will be recorded, muscle samples collected for histamine analysis and temperature loggers will be retrieved. Time from death to 50 °F and 40 °F will be determined and compared with histamine concentration.

6. What UFA proposes to do in conjunction with the proposed research plan.

- Apply the Harvest Vessel Records Approach.
- Apply the modified Critical Limit of ≤ 20 hours total for longline set duration.
- Apply the Critical Limit of placing all histamine-forming fish into ice ≤ 12 hours of death to all fish (including large tuna > 20 lb) unless there is significant exposure to ambient temperatures ≥ 83 °F for over 30 minutes.
- At receiving, continue to apply the recommended Critical Limit guidance.

  Fish ≥ 24 hrs after death must have internal temperature ≤ 40 °F.
  Fish ≥ 12 hrs and ≤ 24 hrs after death must have internal temperature ≤ 50°F.
  Fish < 12 hrs after death must have internal temperatures that "demonstrate appropriate chilling methods".

- Monitor Hawaii Department of Health Epidemiological reports for the number of histamine cases or incidents during the study period.
- Conduct verification procedures of the Harvest Vessel Records Approach including random sampling and testing of large tuna > 20 lb.
- Conduct the proposed research to further verify the effectiveness of the Critical Limit for Hawaii style longline sets (≤ 20 hours total set duration).
- Conduct the proposed research to further evaluate the relationship between time and temperature parameters and histamine formation in large blue marlin with an emphasis on troll-caught fish.
- At the end of the research project, complete the analysis and present findings to FDA for decision on whether to allow the Hawaii fishery to continue to apply the modified Critical Limit for longline sets and possibly adopt a new Critical Limit specific for blue marlin.

7. Time Line.

The research project was designed to be an 18-month project with the bulk of the fieldwork completed within the first 12 months. Progress reports to NOAA are planned at 6 and 12 months and pertinent sections can be copied to FDA. The data analysis and final report will be completed within 18 months of the start date. If possible, time for data analysis and report preparation will be compressed.

8. Conclusion.

As described in the December 1999 FDA Guidance for Industry, Seafood HACCP Transition Guidance, the agency will take into consideration the methodology of the study, scientific merit of the conclusions and the consistency of the recommended actions with agency policy. When considering the scientific merit, the agency will ultimately make the judgment on whether the information can be integrated into the FDA Guide ("its own guidelines").

The intent of UFA is not to change the FDA Guide, but to be allowed to practice the principles of HACCP, conduct research to verify its own hazard analysis and justify its approach to histamine controls. UFA believes that the Guide provides good general guidance and that each company and fishery setting should take its own initiative to conduct the necessary research to justify their own approaches and situations when a variance from FDA guidelines is necessary.

The modified Critical Limits being evaluated through this research apply to the Hawaii Fishing methods and fishery setting. Hawaii boats make deep sets during the day and haul at night when temperature on deck is cooler. Other longline fleets (i.e. Chinese and Taiwanese) are known to use longline gear in an entirely different manner than the Hawaii fleet. These vessels set gear at night and retrieve during the day. They also tend to make shallow sets in the warmer water layers. For this style of longline fishing, a modified Critical Limit for the total set duration of $\leq$ 20 hours might not be appropriate. The issue is not simply what gear is used, but where and how it is used.

UFA is very serious about protecting its suppliers, buyers and markets and maintaining Hawaii's reputation in the market as one of the few sources of high quality fresh tuna and related pelagic fish. UFA is not seeking a change in the Guide, but enforcement discretion allowing UFA to follow HACCP principles, conduct research and apply customized practical Critical Limits and monitoring procedures.

9. References.

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APPENDIX A

Statement of Work

NOAA/SK Project: Verification of a HACCP system for the Control of Histamine for the Fresh Tuna Industry

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.

Project Responsibilities

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.

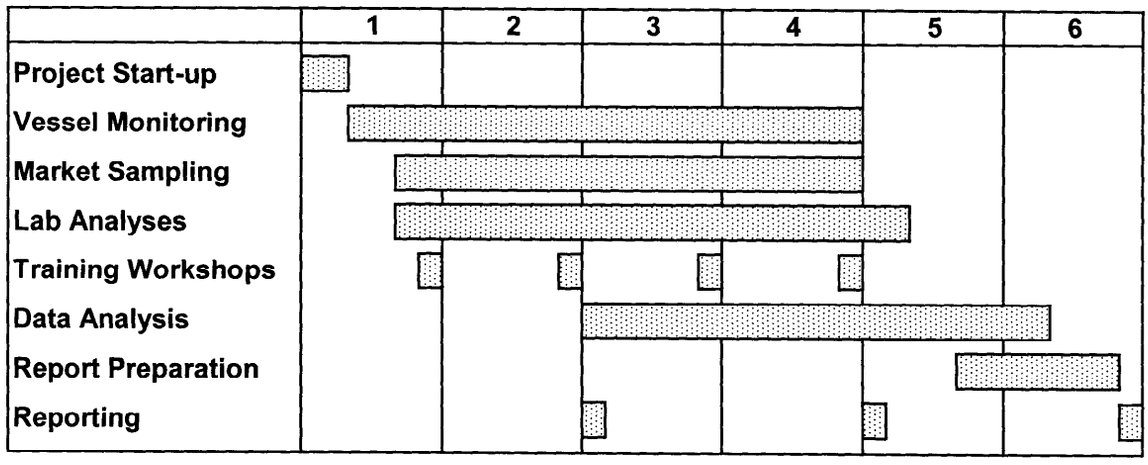
Third Quarter
- 60 mixed pelagics monitored on longline vessels and sampled.
- 5 blue marlin monitored and sampled on trolling vessels.
- 60 mixed pelagics sampled from the market and tested.
- Third training workshop completed.

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.

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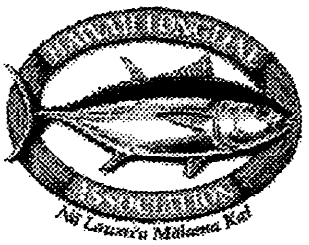

117 Ahui Street, Honolulu, Hawaii 96813

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 C 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 Simonds

Kitty M. Simonds
Executive Director

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