REPORT FOR THE 8/3/03 *Vibrio vulnificus* SUBCOMMITTEE MEETING

CHARGE 1

1a. Review completion of new work plan items assigned to the ISSC Executive Office at the July 17, 2002 Vv subcommittee meeting. – 60 minutes

- Review those work plan elements that were to have been completed since the July 2003 Vv subcommittee meeting. These items are as follows:

1b. Develop a website with specific Vv illness information. Modifying the existing website can do this or creating a new website that is specific to Vv illness information.

Discussion

The Executive Director reported that the website has been updated with Vv illness information. The Southeast Regional Office of FDA will send the Vv illness data to the Executive Office to be placed on the website and sent to the Vv subcommittee members. The Executive Director has asked for feedback on the website to determine if anything needs to be changed or added.

Recommendations

Not applicable

1. Develop and administer a survey to assess the current PHT processing capacity throughout the United States (ISSC Executive Office). The overall results of the survey will be reported at the 2003 Annual meeting.

Discussion

The PHT surveys results were presented the results are as follows:

PHT Summary Results – 22 Respondents from 3 States

(as of July 23, 2003)

State (No. of surveys)	Pounds shipped as Certified Dealer/No. of establishments responding	Percent Marketed for halfshell (no. of respondents)	Percent Harvested with refrigerated boat	PHT Processing (No. of Respondents)		
				No	Yes	Type
Alabama (6)	3,069,976 (2)	100 (1) 0 (5)	0 (5 plants responding)	X (5)	X (1)	IQF
Texas (5)	267,080 1 of 5 provided info on poundage	100 (1)	0 (4 plants responding)	X (4)		
Louisiana (12)	30,638,874 (6/10 responding 2/10 no poundage given)	25 Percent of 13,000,000 (1)	20		X (1)	IQF
		15 Percent of 66,000 (1)	0	X (1)		
		49 Percent of 10,922,871 (1)	10		X (1)	IQF Hydrostatic Pressure

		100 Percent No poundage given (1)	33	X (1)		
		No other information given (1)			X (1)	Ice Chilling
		2 Percent 150,003 (1)	80	X (1)		
		No other information given (4)		X (1)		
		No information given (1)		X (1)		
		90% (1) of 6.5 million				
		No information given (1)			X (1)	Mild Heat Pasteurization

Respondents:
Alabama – 6, Louisiana – 12
Texas – 5

Recommendations
After hearing about the administration of the survey and reviewing the survey results it was concluded that information was difficult to obtain and did not provide the level of detail desired. This was also true for the Florida PHT survey effort. Based upon these discussions the following motion was made:

MOTION: The Vibrio vulnificus subcommittee appoint a workgroup (Chair: Chris Nelson, David Heil and Don Kramer) to develop a better methodology by to gather data on PHT capacity and processing. The workgroup should also consider the capacity for treating Gulf oysters located outside of the Gulf States. These recommendations are to be presented to the Vv subcommittee at the early 2004 meeting.

Motion passed

2. Assure through FDA southeast regional office and CDC that the criteria being used to count illnesses were the same for both agencies and that the number we are using to track disease reduction are the proper numbers. Through the discussions of the report issues arose concerning the reporting criteria. Dr. John Painter from CDC will work with Marc Glatzer in reviewing the current disease reporting protocol and how cases of disease are counted as shellfish borne *Vibrio vulnificus* infections.

Discussion
John Painter and Marc Glatzer reported on their progress in reconciling the disease counting efforts of CDC and FDA. They stated that they are in agreement on the cases that have been counted as part of the baseline data and for years 2001 and 2002. The discussion then led to requesting Dr. Painter and Marc Glatzer to further develop the criteria for case counting, in writing, as part of the current FDA protocol document presented to the committee at the March 2003 meeting.

Recommendations
Based upon that conversation the following motion was made:

MOTION: Direct Marc Glatzer and Dr. John Painter to develop in writing the criteria that have been jointly agreed upon by FDA and CDC in the Vv illness reporting effort. This information will be added to the disease reporting protocol that was presented at the March 2003 Vv subcommittee meeting.

Motion passed

Discussion
There were also discussions concerning the reporting of Vv illnesses. Currently the illness information as FDA reports it may contain information that is required to be confidential under CDC requirements. Additionally, some information provided on shellfish dealers in these reports is not necessary for committee or conference purposes. Based upon these discussions the following motion was made:

Recommendations
MOTION: Direct FDA Southeast Regional Office (Marc Glatzer) to provide Vv illness data quarterly to the Vv subcommittee through the ISSC Executive Office. This illness data should be in tabular form including a case number other than the formal CDC case number, the general description of underlying health conditions by categories for the reported cases as a group. Additionally, the illness data concerning the city or county, patient information and shellfish dealer information should be left off the illness reporting data table to be sent to the Vv subcommittee.

Motion passed

3. Report on status of the letter that was approved as presented at the March 2003 Vv subcommittee meeting and was to be sent to the states to emphasize proper disease reporting.

Discussion
The disease reporting addendum form was discussed. The form as adopted from past meeting was presented. Discussion centered on the questions in the form. A number of changes were suggested to the Vv illness reporting form. This resulted in the following motion:

Recommendations
MOTION: The Vv illness reporting form addendum shall be adopted with the changes suggested by the Vv subcommittee.

Motion passed

The form is as adopted follows:

DRAFT Form for Added Vibrio vulnificus Data Collection

Case #_____

1. Did the oysters conform to required time/temperature limits at harvest?	YES ☐ NO ☐ DK * ☐
2. Did the oysters conform to required time/temperature limit at the certified processor?	YES ☐ NO ☐ DK ☐
3. Did the oysters conform to required time/temperature limits during the:	

	Yes	No	DK
Trucking	☐	☐	☐
Wholesale	☐	☐	☐
Retail	☐	☐	☐
Restaurant	☐	☐	☐
Home	☐	☐	☐

If No to any of the above, please explain.

_____
_

_____
_

_____
_

_____
_

4. Were the oysters consumed: Check all that apply:

In Shell ☐ Shucked Meat ☐ Raw ☐ Cooked ☐ Post harvest treated ☐

If Cooked, How _____

If Post-Harvest Treated, How_____

Comments:

_____

_____

_____

5. Was the patient aware of a pre-existing medical condition? YES ☐ NO ☐ DK ☐

If yes,

(a) Explain

_____

(b) Was the patient under the care of a physician or other health care provider? YES ☐ NO ☐ DK ☐

(c) If Yes to (b), did the physician or other health care provider inform the patient of the risk of consuming raw oysters?

YES ☐ NO ☐ DK ☐

6. Other than a physician or other health care provider, was the patient aware of the risk of eating raw oysters from other information sources? YES ☐ NO ☐ DK ☐

(a) If yes, check all that apply: Electronic media ☐ Print media ☐ Internet ☐
Consumer Advisory or Posted warnings ☐
Family ☐ Friends ☐ Other ☐ (specify):

_____

7. Was a warning or consumer advisory of the risk of eating raw oysters posted at the retail establishment?
YES ☐ NO ☐ DK ☐

If yes, (a) How was the warning or consumer advisory displayed?
_____

(b) Did the patient see the warning? YES ☐ NO ☐ DK ☐

Thank you for responding to these questions which are not included in the official CDC form 52.79.

*DK = Don't know

Discussion
The letter to be sent to the states requesting that they use the disease reporting from addendum was discussed. John Painter stated that CDC will compile the data from these forms as they receive them as part of their reporting forms.

Recommendations
MOTION: Request by letter from the ISSC that states use the Vv illness disease reporting addendum form as an addition to the CDC illness reporting form. The letter should emphasize the importance of the addendum form in the ISSC Vv illness control effort. The letter should be reviewed by CDC to assure no problems in the collection of this addendum form information on their part.

Motion passed

CHARGE 2

2. Evaluate Year 2001 survey results and compare with Year 2003 or 2004 survey results to determine effectiveness in meeting the objectives of the Vv education effort: -- 40% increase in awareness of risk from Vv; -- 15% increase in at-risk consumers no longer eating raw oysters; -- minimize impacts to non-at-risk consumers. – 30 minutes

Principle points of discussion
- Work in conjunction with Vv education subcommittee in developing evaluation criteria
- Determine the effectiveness of the Vv education effort through comparison of the 2001 survey results with the 2003 survey results at the 2003 Annual meeting and 2004 survey results at the July 2004 Vv subcommittee meeting.

Discussion
A report was given to the Vv subcommittee by the Vv education subcommittee concerning the Vv education survey. The recently completed survey provides the baseline data upon which the education effort goals will be measured in subsequent years. The Vv education will be working with the ISSC executive office in soliciting proposals to perform the education survey in later 2003 - early 2004. The subject of evaluation criteria was discussed and the Vv subcommittee offered any help necessary to the Vv education subcommittee concerning development of these criteria.

Recommendations
Not applicable

CHARGE 3

3. Compile and review data on rates of illness. - 30 minutes

Principle points of discussion

- The Vv illness data analysis work group (Members: Jennifer Tebaldi, Chair; Susan Wilson; Angela Ruple; Mark Glatzer; Al Rainosek and Dr. John Painter) shall present the Vv illness data with a focus upon the progress attained toward the Vv illness reduction goals.

Discussion

Jennifer Tebaldi presented the Vv illness data workgroup report. The report is as follows:

ISSC Vibrio vulnificus Reduction Goals

Data Tracking and Communication

July 2003

The V.v. data is contained in an Excel spreadsheet maintained in the ISSC office. The information should be updated annually by ISSC staff.

Data Sources:

Data	Source	Frequency
Population Estimates	US Census Bureau	July 1 estimates
Illness Reports	FDA (reconciled with CDC at end of each year)	9 months after the end of each calendar year

Data Standards:

Vv cases – identified by state in which illness is reported
only includes cases where raw or undercooked oysters were consumed
lab confirmed only?

Communication:

Updated information should be provided annually to the ISSC Executive Board, the Vv subcommittee and posted to the ISSC website.

Contact Person:

Ken Moore
ISSC Executive Director
(803)788-7559

YEAR	AL	AR	AZ	GA	IL	MD	ME	MO	OK	OR	TN	NC	VA	SC	WI	Total		Core States
1995																0		21
1996																0		22
1997																0		14
1998																0		24
1999																0		26
2000																0		22
2001	1	1	1	6	1										1	11		30
2002			1	5		2	1	1	1	1	1	1	1	3		18		17
2003																0		0
2004																0		0
2005																0		0
2006																0		0
2007																0		0
2008																0		0
2009																0		0
2010																0		0
Data compiled by reporting state																		

Only Core State Illnesses Counted

YEAR	FL	LA	TX	UNK	Total
1995	3	3	4	11	21
1996	2	5	9	6	22
1997	3	4	1	6	14
1998	6	7	3	8	24
1999	4	8	10	4	26
2000	0	11	6	5	22
2001	7	9	3	11	30
2002	0	9	5	3	17
2003					0
2004					0
2005					0
2006					0
2007					0
2008					0
2009					0
2010					0
Total	25	56	41	54	176

UNK = any unknown source or multiple source or source with ? mark
All States Illnesses Counted

YEAR	FL	LA	TX	UNK	Total
1995					0
1996					0
1997					0
1998					0
1999					0
2000					0
2001	7	10	4	20	41
2002	1	15	6	13	35
2003					0
2004					0
2005					0
2006					0
2007					0
2008					0
2009					0
2010					0
Total	8	25	10	33	76

YEAR	CA	FL	LA	TX		Total
1995	31,493,525	14,185,403	4,327,978	18,679,706		68,686,612
1996	31,780,829	14,426,911	4,338,763	19,006,240		69,552,743
1997	32,217,708	14,683,350	4,351,390	19,355,427		70,607,875
1998	32,682,794	14,908,230	4,362,758	19,712,389		71,666,171
1999	33,145,121	15,111,244	4,372,035	20,044,141		72,672,541
2000	34,040,375	16,051,395	4,469,769	20,955,248		75,516,787
2001	34,600,463	16,373,330	4,470,368	21,370,983		76,815,144
2002	35,116,033	16,713,149	4,470,368	21,779,893		78,079,443
2003						0
2004						0
2005						0
2006						0
2007						0
2008						0
2009						0
2010						0

1995 - 1999 Population Average

70,637,188

2005 - 2006 Population Average

0

2007 - 2008 Population Average

0

Based upon this report the following motion was made:

Recommendations

- **Motion:** Recommend to the Vibrio Management Committee that the baseline illness reduction rate 1995-99 of .306 cases per million be changed to .303 per million to reflect the elimination of 1 case from the database. This case was removed because it could not be directly associated with oysters from a Gulf state.
- **Motion passed**

Discussion

Additionally, it was recommended that the Executive office maintain the Vv illness information from the quarterly report sent to them from Marc Glatzer.

- Evaluate effect of CA regulation on our ability to evaluate success of Vv illness reduction plan

Recommendations

- **Motion**: Communicate to Vibrio Management Committee that the Vv subcommittee believes that it is to early to evaluate the impact of the CA regulation on the importation of Gulf oysters on our ability to evaluate the success of the Vv illness reduction plan and add a new item in the Vv subcommittee work plan to evaluate if the CA regulation may have an effect upon the commerce of Gulf oysters to other states. This will not become part of the work plan if the CA regulation does not become permanent.
- **Motion passed**
- Determine if the compilation effort is satisfactory.

Discussion

Based upon the discussion of the Vv illness workgroup report the compilation effort was deemed satisfactory.

Recommendations

Not applicable

CHARGE 4

4. Evaluate the effectiveness of illness reduction efforts, which will be conducted collectively at the end of the 5th year – 12/31/06. – 30 minutes

Principle points of discussion

- Semi - annual evaluation of illness reduction efforts

Discussion

The discussion of this issue took place as an ancillary discussion to the Vv illness reporting workgroup report. The review of the illness data indicated that there was a 28% reduction in Vv illness in 2002 versus the baseline data for 1995-99. The rate in 2002 was .218 cases per million as compared to .303 cases per million for the baseline data.

Recommendations

Not applicable

CHARGE 5

5. Evaluate the requirements in Section .04C to determine if changes in controls are necessary to achieve targeted illness reduction goals. – 30 minutes

Principle points of discussion

- Semi - annual evaluation of controls in place to achieve illness reduction goals

Discussion
Through previous discussions it was determined that it was not necessary to change the controls at this time. The current set of illness reduction goals continues to be pursued by through state and conference actions.

Recommendations
No changes necessary to Section.04 C at this time.

CHARGE 6

6. Review the progress on market and shelf life study efforts currently being pursued. – 30 minutes

Principle points of discussion

- Review the current ISSC sponsored effort in determining consumer acceptance and shelf life research studies of PHT shellfish products

Discussion
Dr. Steve Otwell gave an update on the market study. This market study is titled "Product characterization to advance the use of post-harvest treatments for raw oysters" This proposal is as follows:

PRODUCT CHARACTERIZATION TO ADVANCE THE USE OF
POST-HARVEST TREATMENTS FOR RAW OYSTERS

W. Steven Otwell, Jon Bell & Mike Morrissey
February 2003

Goal

Develop a sensory characterization or profile descriptions for raw oysters that can be used to assess the sensory attributes of raw oysters as influenced by harvest location and season, post harvest processing methods, and subsequent shelf life. The intent is to provide a non-bias, science based tool to help direct commercial practice and decisions for processing and marketing of raw oysters, be they, traditional, post-harvest treated (PHT) or valued added.

Justification

Non-bias, scientific-based characterizations of new oyster products is necessary to support the development of processing alternatives that assure market development of safer oyster products. In addition to maintaining quality attributes for the traditional oyster products, alternative processing methods (i.e., PHT's) and new packaging schemes must be assessed relative to the sensory consequences that influence shelf life, seasonal attributes, and general product acceptance. Reliance on preference testing and blind market ventures alone is more prone to chance and lacks development of reasons for the success or failure of a particular product. Sensory profile descriptions or product characterizations by non-bias, trained individuals will provide a more detailed understanding of the specific product attributes that influence acceptance and preference for oysters.

Trained product profiling panels can identify the changes in key sensory attributes that must be considered in processing, storage, and product preparation/presentation. Sensory profiling with trained panelist is an established and proven technique that can be used to describe product variations without grading or comparing products for acceptance or preference. The intent is to provide a "sensory tool" that can be used to describe the particular attributes of individual products. This information can be used

to direct commercial responses to distinguish product types, alter processing methods, or develop certain product specifications to suit particular market demands or expectations.

Objectives

Obj. 1. Establish the sensory characterization for raw oysters through use of standard 'profile description' with trained sensory panelists;

Obj. 2. Demonstrate the utility of the sensory characterization in profiling various raw oyster products differing by harvest location and season, post harvest processing methods, and subsequent shelf-life; and

Obj. 3. Establish additional and concurrent sensory panel capability that can continue oyster product profiling across the oyster producing regions of the Nation.

Procedures

Objective 1. Establish the sensory characterization for raw oysters through standard sensory profiling

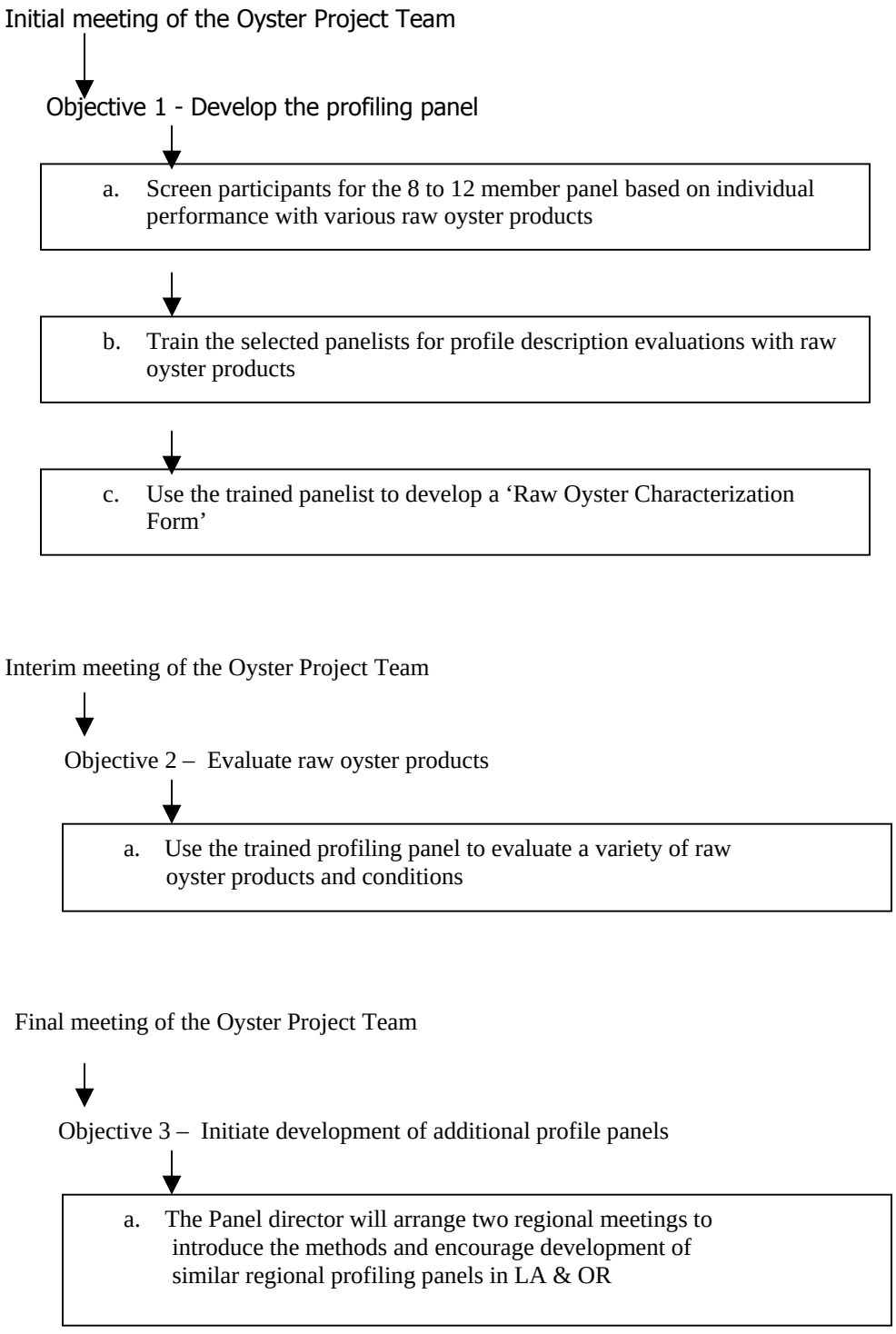
Initially an **'oyster profiling panel'** must be selected and trained in sensory characterization techniques applicable to raw oysters (Figure 1). Panel candidates (approx. 25 to 30 individuals) will be pre-screened for their ability to detect and differentiate basic product attributes. These attributes will involve differences in product color, aroma, texture and taste. Standard product differences will be presented in paired comparisons that are pre-staged for the screening sessions. The individuals that demonstrate the best ability to distinguish the staged differences will be selected for the profiling panel. The selected panelist will include 8 to 12 individuals that are familiar with raw oysters, and they must agree to consume raw oysters as part of the sensory techniques.

The selection process will also assure balanced demographics by sex and age. The candidates will be screened for an equal portion of male and females ranging in age from 20 to 50 years. They must be comfortable and familiar with consumption of raw oysters. Likewise, they must agree to participate by signing a standard IRB (Institutional Review Board) agreement prepared in accordance with the University of Florida research protocol involving human subjects (Appendix). This agreement confirms the participant's knowledge of raw oyster consumption and assures no prior health issues that would preclude their participation.

All panel candidates will be screened from the immediate population about Gainesville, Florida. Immediate accessibility is necessary to control the costs for panel participation. Based on established profiling procedures, the individuals will be paid for their participation. This payment must account for the travel and time provided by each panelist. Cost for the selection process is estimated at $3600 based on 30 candidates x $20/hr/candidates/session and three 2-hour sessions. Costs for subsequent profile panel sessions is estimate at $960/session (12 panelists x $20/hr/panelist for each one day session of 4 hours) with at least one panel session at 4 week intervals through twelve months ($960 x 12 sessions) totaling $11,520 for the duration of the project. These cost estimates do not include reimbursements for local travel.

Continuous 'coaching' or training will be provided by a Panel Director to prevent bias by the candidates or the eventual profile panelists. This training will emphasize detection of sensory attributes rather than preference for any particular oyster or sensory attributes. The purpose of the 'trained' panel is to detect and describe differences rather than expressing preferences. Likewise, the training will prevent comparisons or ratings amongst products. The intent is to characterize the sensory attributes of each oyster product. Each oyster product could have a different and unique sensory profile. Individual sensory profiles may suit a particular market or may require alternative processing methods to improve the product. Oyster profiling through product characterization offers a standardized measure by which a processor or buyer can make more appropriate product judgments.

Figure 1. Work plan for development of the profiling panel and panel evaluations.



Once the selected profiling panel convenes, standard product references will be established as benchmarks to help the panel distinguish and gauge product differences. These standards will be used in a series of panel training sessions (approx. 4 to 6 panel sessions) to develop the formal **Raw Oyster Characterization Form** (Figure 2). Initially this characterization may include numerous attributes that could include greater that 50 features noted by the panelists. This initial listing must be reduced or honed to the most common and distinguishable product descriptors. This characterization process must involve products from the major regions of oyster production (NE, SE, NW) as well as various seasons, processes and periods of product storage. The intent is to expose the panelists to the range of product attributes that must be considered in formulating the final, comprehensive characterization form for profiling raw oysters. After the profiling panel has been selected and trained with the new characterization form, they will be ready to evaluate various raw oyster products.

Objective 2. Profile a series of raw oyster products

The trained profile panel will use the established raw oyster characterization form to evaluate a series of different raw oyster products based on previous commercial requests through the ISSC Post-Harvest Treatment Subcommittee. The products will include raw oysters -

- from various regions around the nation with major traditional harvests and processing (i.e., North Gulf of Mexico- FL, LA, TX; Northwest-WA; and Northeast-VA through ME);
- by seasonal differences pertinent to regional production (i.e., Summer vs. Fall-Winter);
- from post-harvest treatments designed to reduce certain microbial load (i.e., freezing, high pressure, and cool pasteurization); and
- by duration (days) in refrigerated storage (shelf-life)

This listing and the numerous combinations of product types and conditions will require extensive work by the panel. To avoid confusion and exhausting panel performance, product exposure will be restricted to six variables or product types per one-day sessions, which include two panel sittings (morning and afternoon) per day. Likewise, the panel will meet in three to four week intervals to maintain training and product familiarity without excessive imposition on the panel participants. Assuming the initial panel selection and training requires six months, the trained profiling panel work will extend for twelve months to assure service through a complete range of seasonal changes that influence product conditions (see Schedule of Work). This work schedule assumes twelve to sixteen possible panels through twelve months with allowances for holidays and associated travel obligations. A matrix of possible product types for profiling illustrates the expected workload (Figure 3).

Completion of this workload within twelve months is ambitious. Priorities will be established with commercial and ISSC liaison to focus on the more significant issues. The major issue of current concern is the mandated PHT's, shelf-life consequences, and seasonal differences for North Gulf of Mexico products. The project plans to address all product types in the matrix, but the degree of product scrutiny will focus on Gulf of Mexico products subject to mandated PHT's. Further product profiling of other regional products will be supported by development of profiling panels in the respective regions (see Objective 3).

Figure 2. Probable oyster sensory profiling based on product characterization by a trained panel. The listed descriptors and profiles are simply prepared as fictitious examples.

Oyster Product Characterization

Descriptors	**Oysters from a region**	**Oysters from a process**
COLOR: pale / dark □ □ □ □ □ white / tan □ □ □ □ □ milky /translu.□ □ □ □ □	COLOR: pale / dark □ □ □ □ □ white / tan □ □ □ □ □ milky /translu.□ □ □ □ □	COLOR: pale / dark □ □ □ □ □ white / tan □ □ □ □ □ milky /translu.□ □ □ □ □
APPEARANCE: plump / flaccid□ □ □ □ □ uniform / blochy□ □ □ □ □ moist / dry □ □ □ □ □	APPEARANCE: plump / flaccid□ □ □ □ □ uniform / blochy□ □ □ □ □ moist / dry □ □ □ □ □	APPEARANCE: plump / flaccid□ □ □ □ □ uniform / blotchy□ □ □ □ □ moist / dry □ □ □ □ □
AROMA: bland / earthy□ □ □ □ □ sea / earthy □ □ □ □ □ fresh / old □ □ □ □ □	AROMA: bland / earthy□ □ □ □ □ sea / earthy □ □ □ □ □ fresh / old □ □ □ □ □	AROMA: bland / earthy□ □ □ □ □ sea / earthy □ □ □ □ □ fresh / old □ □ □ □ □
TEXTURE: firm / mushy □ □ □ □ □ moist / dry □ □ □ □ □ clean / gritty □ □ □ □ □	TEXTURE: firm / mushy □ □ □ □ □ moist / dry □ □ □ □ □ clean / gritty □ □ □ □ □	TEXTURE: firm / mushy □ □ □ □ □ moist / dry □ □ □ □ □ clean / gritty □ □ □ □ □
FLAVOR: bland / salty □ □ □ □ □ bland / earthy□ □ □ □ □ fresh / old □ □ □ □ □	FLAVOR: bland / salty □ □ □ □ □ bland / earthy□ □ □ □ □ fresh / old □ □ □ □ □	FLAVOR: bland / salty □ □ □ □ □ bland / earthy□ □ □ □ □ fresh / old □ □ □ □ □

Figure 3. Product matrix indicating the possible combinations of oyster products that can be evaluated by the raw oyster profiling panel. For example, 4 different PHT methods evaluated for 2 different seasons could include 8 possible product combinations. This listing includes 92 possible combinations.

	PHT (4)	*Shelf-Life* (4)	*Season* (2)
Shelf-Life (4)	4 x 4 = 16		
Season (2)	4 x 2 = 8	4 x 2 = 8	
Location (6)	4 x 6 = 24	4 x 6 = 24	2 x 6 = 12

Key:
Location represents 6 possible harvest locations (FL, LA, TX, WA, VA & ME).
Season represents 2 harvest water temperatures (Summer & Fall-Winter).
Shelf Life represents 4 progressive periods (days) in refrigeration.
PHT represents 4 possible post-harvest treatments (freezing, high-pressure, mild pasteurization and irradiation)

Objective 3. Establishing additional and concurrent sensory paneling capability

The methodology and results generated during the training and development of the initial profiling panel based in Gainesville, FL will be made available to support development of similar sensory characterization panels in other regions. Additional panels can reference the training material, product characterization forms, and initial product profiles. The experienced Panel Director will organize at least two site visits (Louisiana and Washington) to introduce and explain the materials and training process. These site visits will encourage and assist development of proven profiling panels to continue support for the regional oyster industries.

Management of this proposed project was intentionally organized to include regional expertise that can serve in further development of profiling panels in their respective regions (i.e., Jon Bell-LA and Mike Morrissey-OR and WA). Likewise, a second project or second year continuation of this project is anticipated to support these efforts (see Project Management and Project Continuation).

Project Management

Project management is specially designed to assure regional representation and to account for product types per the various regions of production. The **Oyster Project Team** will include:

Project Directors
Dr. Steve Otwell, University of Florida (Principle Investigator)
Aquatic Food Products Program, Food Science & Human Nutrition Department

Dr. Jon Bell, Louisiana State University
Food Science Department

Dr. Mike Morrissey, Oregon State University
OSU Seafood Lab - Astoria

Sensory Experts
Dr. Charles Sims, University of Florida
Food science & Human Nutrition Department

Dr.---------- , Louisiana State University

Dr. Anna Marin, Oregon State University
Food Innovation Center, Food Science & Technology Department

Panel Director
Project position (half-time, MS level) to be hired at University of Florida
Food Science & Human Nutrition Department

This team is familiar with the oyster industry, ISSC and regional issues influencing oyster processing and marketing. The complimentary Sensory Experts will provide advice for the selection, organization, and training of the profile panel. The Project Directors will assist in product procurement, shipment and storage. This team approach is essential for procurement of authentic products from actual processing operations in the respective regions. Product authenticity must observe and document the product history form the particular approved harvest waters through actual processing procedures and firms, and in distribution and storage prior to any panel evaluations. Authenticity is necessary to prevent any potential commingling or misrepresentation of the actual oyster product types or conditions.

The Oyster Project Team will convene at least three times –

1. Initial meeting to design the panel selection and training protocol
2. Interim meeting to critique the development of the raw oyster product characterization form.
3. Final meeting to review the profile panel results for various oyster products

The optional meeting locations will be Gainesville, FL; Baton Rouge, LA; Portland, OR; and/or Columbia, SC (ISSC). Travel funds will be itemized to assist team travel and participation will be further support with conference call /video capabilities at the respective universities.

A Panel Director will be identified at the University of Florida to coordinate and compile all panel activities from selection and training through the various product evaluations. This Director will also organize the two meetings (LA and OR) to encourage and initiate development of additional oyster profile plans in other regions. Participants in these programs will be arranged by the respective project directors, Bell-LA and Morrissey-OR.

Project Continuation

The proposed project fully anticipates continuation of the proposed work with addition support or a second project for profile panel development in LA or OR. The second project should begin within eighteen months following the beginning of this initial project in order to share concurrent training from the established product characterization. This approach assures national uniformity and provides panel expertise with more regional representation and product access. The concurrent approach caters to available research funds while maintaining project momentum before the mandated deadlines for PHT performance/compliance.

Project Schedule

Year	2003				2004												2005
Months	- 9	10	11	12	- 1	2	3	4	5	6	7	8	9	10	11	12	- 1	2
Oyster Proj. Team Meetings	X					X									X			
Obj. 1 – Develop Panel	X	X	X	X	X	X	X	X	X									
Obj. 2 – Profile Oysters						X	X	X	X	X	X	X	X	X	X	X	X	X
Obj. 3 - Regional Panels															X	X	X	X
Project Reports							X											X

Project Deliverables

1. An historical 'Oyster Sensory Profile' and 'Raw Oyster Characterization' for use by industry in advancing processing method and markets of raw oyster products, both traditional and PHT.

2. An initial demonstration of the ability and utility of the 'Oyster Sensory Panels' to assess variable products by location, season, process (PHT's), and shelf life.

3. List of recommendations to improve product sensory attributes during harvest, processing, packaging and storage based on non-biased, science-based sensory profiles.

4. Sensory assessment of shelf-life consequences for both traditional and PHT oysters.

5. Initiate and support development of regional oyster sensory profile panels with uniform, recognized methods

6. Foster a national oyster quality and sensory evaluation 'team' involving expertise from major regions of oyster production including production addressing PHT mandates.

7. Final reports and presentations for the oyster industry, which can be incorporated in marketing efforts, and any necessary support for ISSC issues in 2003-04.

Budget

Salaries and fringe benefits …….. for one halftime (½) technical position for 18 months with MS degree and experience to serve as Panel Director. Listed cost includes all required fees for health insurance, worker's compensation, unemployment compensation, retirement, and social security.	$35,000
Compensation for Panel Participants …….. to include 3 sessions to screen participants for the panel ($3600), actual training session to prepare the panel ($2880), and the multiple sessions for panel evaluations of product ($11,520).	$18, 000
Travel …… for 3 meetings of the Oyster Project Team based on three different locations and travel for 5 to 6 persons per location ($15,000), and for 2 regional sessions with three participants to initiate additional panels ($2,500).	$17, 500
Supplies …… to include raw oysters, packaging materials to transport and store oysters, glassware and materials for panel evaluations, and miscellaneous office supplies in support of the panels and project communications (paper, binders, discs, etc.)	$3,500
Transportation/Delivery Costs …… for shipment of raw oysters under refrigeration with protection and temperature monitoring devices	$1,000
PROJECT TOTAL ……..	$75,000

CHARGE 7

7. Update on the efforts to obtain information from the states on the number of harvest vessels with refrigeration on board and the capacity of these vessels to add refrigeration. – 30 minutes

Principle points of discussion

- Develop a survey to determine the existing and potential refrigeration and/or chilling capability on harvest vessels and work with GOIC in administering this survey (Executive Office). These results should be obtained in time to present at the August Vv subcommittee meeting.

Discussion

PHT Summary Results – 22 Respondents from 3 States

(as of July 23, 2003)

State (No. of surveys)	Pounds shipped as Certified Dealer/No. of establishments responding	Percent Marketed for halfshell (no. of respondents)	Percent Harvested with refrigerated boat	PHT Processing (No. of Respondents)		
				No	Yes	Type
Alabama (6)	3,069,976 (2)	100 (1) 0 (5)	0 (5 plants responding)	X (5)	X (1)	IQF
Texas (5)	267,080 1 of 5 provided info on poundage	100 (1)	0 (4 plants responding)	X (4)		
Louisiana (12)	30,638,874 (6/10 responding 2/10 no poundage given)	25 Percent of 13,000,000 (1)	20		X (1)	IQF
		15 Percent of 66,000 (1)	0	X (1)		
		49 Percent of 10,922,871 (1)	10		X (1)	IQF Hydrostatic Pressure
		100 Percent No poundage given (1)	33	X (1)		
		No other information given (1)			X (1)	Ice Chilling
		2 Percent 150,003 (1)	80	X (1)		
		No other information given (4)		X (1)		
		No information given (1)		X (1)		
		90% (1) of 6.5 million				
		No information given (1)			X (1)	Mild Heat Pasteurization

The Post Harvest Treatment survey results were presented. The table of results is as follows:

Respondents:
Alabama – 6, Louisiana – 12 , Texas – 5

The Post Harvest Treatment survey includes questions concerning the percentage of vessels utilizing on board refrigeration. The survey did not receive adequate response to gauge the use of on board refrigeration. Additionally, it did not include determining the use of icing for Vv reduction. Based upon this the following motion was made:

Recommendations
MOTION: The latest icing study involving the affect of icing on Vv in oysters performed by Dr. Schwarz at Texas A&M should be reviewed by the Vv subcommittee. Action on this issue should be deferred until the early 2004 Vv subcommittee meeting at which time the icing study can be adequately evaluated and discussed.

Motion passed

- Discuss the current capacity in the harvest fleet to provide on board refrigeration

Discussion
This information was presented in the survey results and did not provide an adequate response to determine present capacity.

Recommendations
The earlier motion addresses the additional information requirements.

- Determine if there is potential weight load and space capacity on board these vessels to add refrigeration.

Discussion
This information was not obtained in the PHT survey instrument The survey results presented did not provide an adequate response to determine weight load and space capacity.

Recommendations
The earlier motion addresses the additional information concerning the need to obtain additional survey information.

CHARGE 8

8. Review the need to make changes to the e current contents and recent additions to Chapter 16, Post-Harvest Treatment, in the Model Ordinance. – 30 minutes

Principle points of discussion

- Determine if it is more appropriate to incorporate the elements in Chapter 16 to other Chapters in the Model Ordinance and do away with Chapter 16. The Post Harvest Treatment Chapter workgroup will present their recommendations at the 2003 Annual meeting Vv subcommittee meeting.

Discussion
Angela Ruple reported that the work group met and deliberated the issues before the group. Their findings are as follows:

Findings
Based upon our discussions at the March meeting in Portland, the group felt it was too soon to develop the chapter at this time. There have been additional developments since then including: 1) A new workgroup to look at levels of Vv above the <3 currently used to make labeling claims, 2) A Post Harvest Processing Committee will make recommendations regarding the establishment of a new PHT dealer classification; and 3) The validation/verification workgroup continues to expand and modify their

recommendations. In February I sent a draft Chapter 16 to you for review. This was followed by some discussion as to the need to repeat much of the information that is already in other chapters in the Model Ordinance. Based upon our conversations in March and the developments since then, I don't think that this workgroup is ready to make a recommendation to the Vv Subcommittee on what should or should not be included in a Post Harvest Treatment Chapter at this time. Issue 01-224 is our current placeholder for a new Post Harvest Treatment Chapter. I suggest that this workgroup continue to follow the activities of the Validation/verification workgroup, the committee dealing with new classification, and the workgroup looking at Vv standards other than <3 and continue to think about what aspects of these workgroup products would not fit into other areas of the Model Ordinance and thus would need to be incorporate into a PHT Chapter.

Recommendations

The workgroup will continue to follow the deliberations of the Vv subcommittee and make recommendations as necessary for changes to Chapter 16.

CHARGE 9

9. Review the issue recommendations from the Post Harvest Treatment Vv levels workgroup.

Principle points of discussion

- The Conference Chairman appointed a work group to evaluate all new pertinent information concerning the current allowable levels of Vibrio *vulnificus* in Post Harvest Treated products as it relates to labeling incentives and attainment of illness reduction goals and report to the Vv subcommittee at the August 2003 meeting. The workgroup shall report their findings to the Vv subcommittee at the August 2003 meeting.

Discussion

Don Kramer presented the work group findings. These findings indicated that a non detect level of 30 MPN Vibrio vulnificus for labeling claim purposes was suggested based upon the FAO-WHO risk assessment. The subsequent discussion centered on the potential for a higher level for non-detect and labeling claims. The work group report and suggested changes to Issue 03-212 are as follows:

Findings

Proposal for Task Force Consideration
At the 2003 Biennial Meeting
Interstate Shellfish Sanitation Conference

Name of Submitter:	*Vibrio vulnificus* Subcommittee	
Affiliation:	ISSC Executive Office	
Address:	209-2 Damson Road Columbia, SC 29223	
Phone: 803-788-7559	**Fax:** 803-788-7576	**Email:** issc@issc.org
Proposal Subject: Validation/Verification Process for PHT Product		**Growing Area** ☐ **Plant** ☒ **Sanitation** ☐ **Administrative**
Specific Model Ordinance Reference:		
Key Words:	Validation; Verification; PHT	

Text of Proposal/ Requested Action:

VALIDATION/VERIFICATIN INTERIM GUIDANCE:

Process Validation ~~(level1)~~ – used for the initial validation of a process or when there has been a change to a previously validated process.

- Data on ten processed samples obtained on each of three processing days (total of 30 samples) are required.
- All samples used on a processing day must come from the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of 100,000 per gram or greater as described below for initial load testing. (If some lower initial levels are used the process will only be validated for those maximum initial levels.)
- Samples should be distributed throughout the processing day. A sample will consist of a composite of 10 to 12 oysters processed at one time.
- The zero hour level may be achieved through naturally occurring Vibrio levels in shellfish and, where not practical, by time/temperature abuse. **(Inoculated pack samples may be used as appropriate.)**
- ~~For Vibrio parahaemolyticus, the 03:K6 serotype shall be used for the initial load through an inoculation process.~~
- Analytical methodology to determine Vibrio levels should be the official methods previously endorsed by the ISSC.
- Microbiological testing for processed samples will be by a single dilution five-tube MPN, inoculating with 0.01 g of shellfish per tube.
- The numerical value of the endpoint criteria should represent the lowest sensitivity of the MPN method, which is less than 30 per gram.
- For the process to be validated, no more than three samples out of 30 may fail. Failure is indicated by more than two out of five MPN tubes in any sample being positive. If any one sample has all five MPN tubes positive, the validation process will fail.

Equipment Validation – used to ensure that each unit of equipment will deliver the validated process. May be accomplished using either of two methods:

- The process described under "Revalidation, below;
- A physical test of the equipment (e.g., thermal distribution study) that is

designed to ensure that, when properly operated, it will consistently deliver the validated process.

Re~~V~~validation ~~(level2)~~ – used when ~~a validated process is changed or when~~ verification sampling indicates a failure in the process

- Data on ten processed samples obtained throughout a processing day are required.
- All samples used on a processing day must come form the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of 100,000 per gram or greater as described below in initial load testing.
- A sample will consist of a composite of 10 to 12 oysters processed at one time.
- **The zero hour level may be achieved through naturally occurring vibrio levels in shellfish and, where not practical, by time/temperature abuse.** (Inoculated pack samples may be used as appropriate).
- Microbiological testing for processed samples will be by a single dilution five-tube MPN, inoculating with 0.01 g of shellfish per tube.
- The numerical value of the endpoint criteria should represent the lowest sensitivity of the MPN method, which is less than 30 per gram.

- For level 2 validation, no more than one sample out of ten may fail. Failure is indicated by more than two out of five MPN tubes in any sample being positive. If any one sample has all five MPN tubes positive, the validation process will fail.

Initial Load Testing

Initial level of vibrios in shellfish for each lot of shellfish used in validation shall be 100,000 MPN per gram or greater based on the adjusted geometric mean (AGM) of the MPNs/g of four samples where the AGM is given by:

AGM = the geometric mean of the 4 MPNs/g multiplied by an adjustment factor of 1.3

Note: If 4 samples from a lot of shellfish with a true density of 100,000 cells per gram are examined by the MPN procedure, the probability of the geometric mean of the MPNs showing 100,000 or greater is about 50%. In an attempt to improve the probability of samples being accepted when the true density is 100,000/g an adjustment factor of 1.3 was selected based upon statistical analysis provided by Dr. Bob Blodgett.

Verification – Used to verify that a previously validated process is working properly.

- Process verification by microbiological testing should be done monthly
- The number of samples/sub samples for verification and the pass/fail criteria for the verification process will be determined by the validation/verification workgroup following evaluation of statistical data to be supplied by Dr. Bob Blodgett.
- The dealer in conjunction with the SSCA shall annually evaluate the previous 12 months of data and the HACCP plan.

- The dealer may elect, with SSCA concurrence, to conduct quarterly sampling if the previous 12 verification samples pass.

See Attachment

Public Health Significance: None submitted.

Cost Information (if available): None submitted.

Vibrio vulnificus PHT Validation/Verification Work Group Meeting Report

The Work Group met on August 3, 2003. The Work Group's discussions on Proposal 03-212 centered on (1) clarification of several factors relating to the purpose and application of the proposed Validation Level 1 and 2, (2) the need to provide for verification procedures premised upon other methods (e.g. HACCP documented performance compliance with equipment design specifications relative to a predetermined scheduled process), and (3) the need to develop a microbiological sampling and analysis verification procedure to verify that a previously validated process is working properly, including the necessary number of samples and sub-samples and the associated pass/fail decision criteria and performance characteristics.

LEVEL 1 AND 2 VALIDATION DISCUSSIONS

It was resolved that Level 1 should be retitled "Process Validation" and is to be used for those PHT processes which have never been validated Level 2 validation has been retitled as "Revalidation" and is to be employed when there has been a change in the process or when a verification has failed in accordance with the verification decision tree. Further, a new validation category was added for equipment validation which allows for the provision of not requiring microbiological testing, provided that it can be reliably demonstrated that the equipment or process can meet predetermined process parameters.

VIBRIO PARAHAEMOLYTICUS CONSIDERATIONS

The fifth bulleted item under Validation dealing with Vp should be removed form the proposal. Nevertheless, a recommendation is to have the PHT Validation/ Verification Work Group next address Vp and other pathogens of concern.

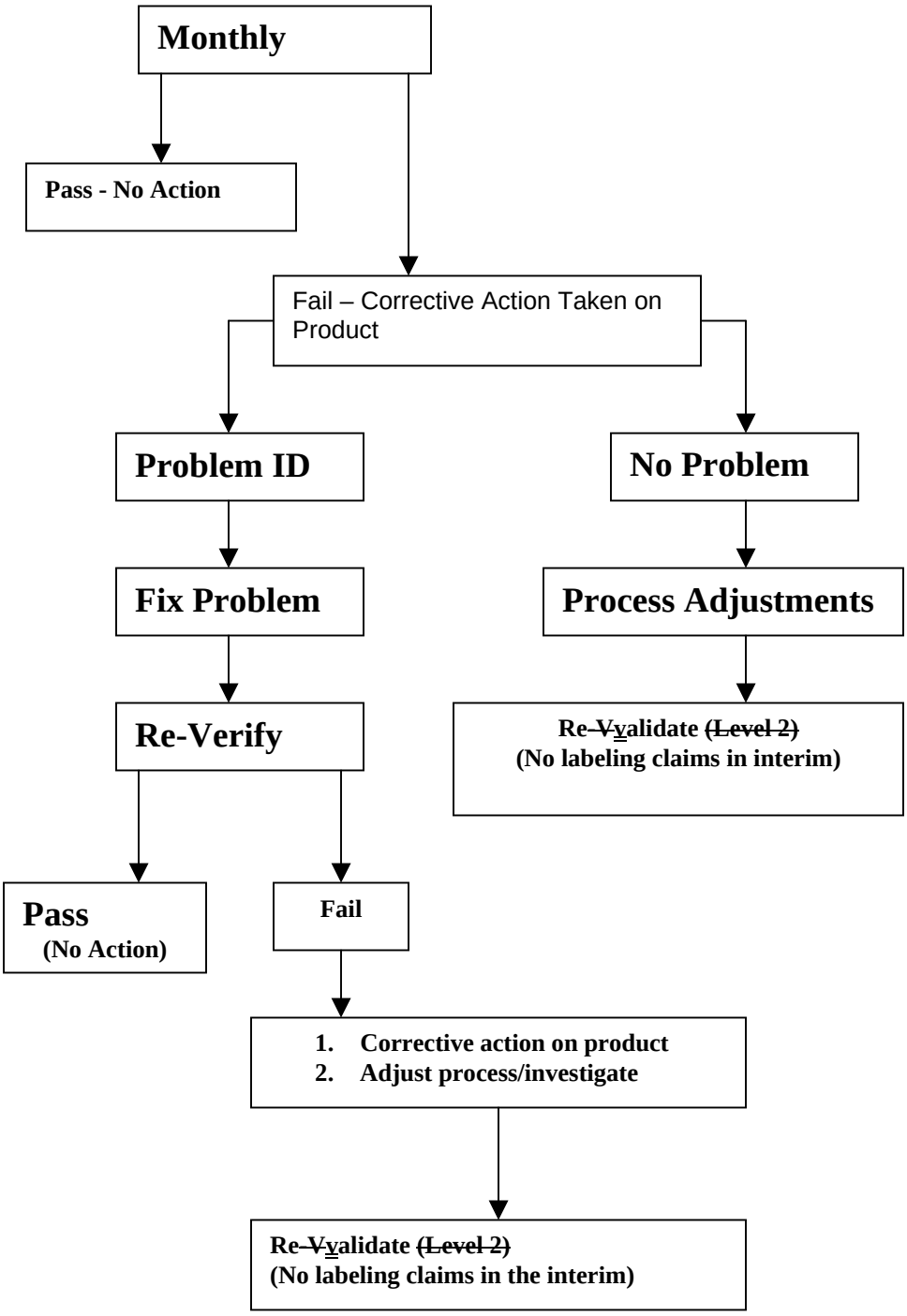
VERIFICATION PROCESSES OTHER THAN MICROBIOLOGICAL ANALYSIS

The current verification sampling protocol decision tree attached to Proposal 03-212 needs to be either augmented to incorporate the concept of verification, when effective corrective actions are taken when HACCP records indicate a trend toward nonconformance to specific critical limits or critical limits are violated and/or when nonconformance is indicated specific processing protocols or failure of equipment to meet specific design criteria; or a new decision tree should be constructed for this purpose. There needs to be a consideration that expensive end-product sampling and microbiological analyses should not be the only verification approach, when effective corrective actions can be taken incorporating physical parameter changes (e.g., temperature, time, reprocessing, etc.) under a facility's operational HACCP plan.

DEVELOPMENT OF MICROBIOLOGICAL VERIFICATION PROTOCOLS

A verification approach protocol modeled after that used for the Validation protocol should be developed in terms of the number of samples to be drawn and analyzed, pass/fail decision criteria indicated and associated performance characteristics stated for the indicated protocol.

Verification Sampling Protocol Decision Tree



- Develop recommended amendments as appropriate to issue 03-212 to incorporate a Vv standard other than less than 3 MPN for labeling post harvest treated.

Discussion

The discussion of this issue was included in the discussion on issue 03-212.

After discussion of the workgroup recommendations the following motion was made:

Recommendations

- **Motion:** The Vv subcommittee recommends to the Vibrio Management Committee that the Post Harvest Vv levels workgroup recommendations be adopted. The workgroup report states the <3 MPN level for post harvest labeling be changed to 30 MPN. The 30 MPN will become the non-detect level and post harvest treatment labeling claim can be made for non-detect at 30 MPN. Additionally it is recommended that the Executive Board be allowed to change this non detect level to a higher number if the data supports such a change. Recommend that the VMC make these recommendations to Task Force as direction issue 03-212.
- **Motion passed**

CHARGE 10

Issue 97-205- Nomenclature and Handling Practices for raw shellfish

Discussion
The Vv subcommittee reviewed the work of the Chapter 16 Post Harvest Treatment workgroup. This effort is ongoing and has not yet included the task of defining raw shellfish. The workgroup has examined the whole issue of post harvest treatment and how the requirements and guidance may affect the definition of raw. The workgroup findings to this point are stated as follows:

Recommendations
The Vv subcommittee does not have a recommendation on issue 97-205 at this time. It is expected that by the early 2004 Vv subcommittee meeting that the workgroup will have a recommendation for the subcommittee. After that time the Vv subcommittee will be in a position to make a recommendation on issue 97-205

CHARGE 11
Issue 00-201 – Provide oversight for implementation of requirements of the issue

Discussion
The Vv subcommittee reviewed the previous work plan elements as they related to the implementation of the Vv control plan. There was one motion made that involved a change to the language in the Chapter II @04 B. That motion is as follows:

Recommendations

- **Motion:** Recommend to the Vibrio Management Committee that the baseline illness reduction rate 1995-99 of .306 cases per million be changed to .303 per million to reflect the elimination of 1 case from the database. This case was removed because it could not be directly associated with oysters from a Gulf state.
- **Motion passed**

CHARGE 12

Issue 01-208 – Consider process as future satisfactory compliance and for consideration of other pathogens; develop specific satisfactory compliance language for framework specified in the interim guidance.

Discussion

The Vv subcommittee reviewed issue 01-208 as part of the overall discussion of the validation/verification.

Recommendations

It was determined that the concerns stated in issue 01-208 would be addressed by the recommendations made for issue 03-212.

CHARGE 13

Issue 03-212 - Validation/verification process for PHT product

Discussion

The Vv subcommittee received the report from of Vibrio *vulnificus* in Post Harvest Treated products workgroup. The workgroup report is shown in Charge 9 above.

Recommendations

Based upon these recommendations the Vv subcommittee made the following recommendations in its comments on proposal 03-212:

- **MOTION:** The Vv subcommittee recommends to the Vibrio Management Committee that the Post Harvest Vv levels workgroup recommendations be adopted. The workgroup report states the <3 MPN level for post harvest labeling be changed to 30 MPN. The 30 MPN will become the non-detect level and post harvest treatment labeling claim can be made for non-detect at 30 MPN. Additionally it is recommended that the Executive Board be allowed to change this non detect level to a higher number if the data supports such a change. Recommend that the VMC make these recommendations to Task Force as direction issue 03-212.

- **Motion passed**