Proposal for Task Force Consideration at the 2009 Biennial Meeting Interstate Shellfish Sanitation Conference	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter:	*Vibrio* Management Committee (VMC)
Affiliation:	Interstate Shellfish Sanitation Conference (ISSC)
Address:	209-2 Dawson Road Columbia, SC 29223-1740
Phone: **Fax:** **Email:**	803-788-7559 803-788-7576 issc@issc.org
Proposal Subject:	Time Requirement for Achieving Internal Oyster Temperature of 50°F (10°C)
Specific NSSP Guide Reference:	NSSP Guide Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.05 *Vibrio parahaemolyticus* Control Plan
Text of Proposal/ Requested Action	Insert new item and re-letter subsequent items. B. Control Plan (4) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following: (a) Establish one or more… (b) Implement one or more… **(c) Require the original dealer to cool oysters to an internal temperature of 50°F (10°C) or below within 10 hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *Vibrio parahaemolyticus* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters has reached 50°F (10°C) or below within 10 or less as determined by the Authority hours of being placed into refrigeration. Oysters without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled "*for shucking only*", or other means to allow the hazard to be addressed by further processing.** ~~(c)~~ **(d)** Evaluate the effectiveness… ~~(d)~~ **(e)** Modify the Control Plan when… ~~(e)~~ **(f)** Optional cost benefits analysis…
Public Health Significance:	*Vibrio parahaemolyticus* is the leading cause of bacterial illnesses associated with consumption of raw molluscan shellfish in the U.S. The ISSC adopted a *Vibrio parahaemolyticus* Control Plan for oysters in August 2007. The Plan was fully implemented by states as of June 20, 2008. The major control measure under the plan is a reduction in the time between exposure of oysters to air and initial placement into refrigeration. Once placed under refrigeration, the only Model Ordinance requirement is that the refrigeration unit be maintained at 45°F (7.2°C) or less. There is no

	requirement for reducing product temperature to a specified level within a specified period of time. The scientific literature indicates that *Vibrio parahaemolyticus* can grow in oysters at temperatures above 50°F (10°C). The FDA *Vibrio parahaemolyticus* Risk Assessment assumes that oysters are cooled to 50°F (10°C) within 10 hours after placement in refrigeration and that controlling growth after initial refrigeration is a key factor affecting the risk of illness. However, cooling systems for shellstock are diverse and little is known about their individual cooling performance under the variety of circumstances in which they are used. According to scientists involved in refrigeration technology, the time required to drop product temperature to 50°F (10°C) on refrigerated vehicles can take as long as 100 hours depending on initial product temperature. According to manufacturers of refrigerated truck compressors, cooling systems generally used on refrigerated trucks are only intended to maintain product temperature, not reduce it. Therefore, product, such as shellfish, needs to be prechilled to the desired temperature prior to truck loading and transport. Additionally, the FDA/ISSC 2007 Retail Oyster Study indicated levels of both *Vibrio parahaemolyticus* and *Vibrio vulnificus* frequently exceeded 100,000 MPN per gram, further strengthening the need for mandatory time to temperature requirements following placement under refrigeration. A major premise of the *Vibrio parahaemolyticus* Control Plan is that 10 hours represents the maximum time to cool oysters to 50°F (10°C). Therefore, it is critical that the Model Ordinance support a system to ensure that the 10 hour cool down time is met. Without measures to ensure that oyster shellstock is cooled to 50°F (10°C) within 10 hours, the level of protection intended by the ISSC, the *Vibrio parahaemolyticus* Control Plan will not be achieved.
Cost Information (if available):	Potential costs associated with this action: 1. Cost to upgrade and operate effective refrigeration systems at processing plants. 2. Loss of product value due to withdrawal from raw consumption market Potential savings that may result from this proposal include: 1. Reduction in cost to individuals or society from fewer illnesses 2. Avoidance of product recall and loss of consumer confidence associated with recalls and recall press 3. Longer shelf life for properly chilled product

Refrigeration Facts

The cooling of Any Food Product Depends on Several Factors

- The Density of the Food Product
- Air Circulation Around the Product or Product Containers
- The Type, Size, Depth of the Product Containers
- Initial Temperature of the Food Product Placed Under Refrigeration

Factors Also Include the Type of Refrigeration Unit

- **Forced Air Cooling =Walk-In Cooler Unit**
- **Passive Cooling Unit=Refrigerated Truck/Trailer**

Source: Dr. Patrick Brecht-PEB Commodities

Refrigeration Facts Continued

Forced-Air Cooling

Walk-In Refrigeration Unit-Cooling

- Rapid Cooling of Products
- Factors Include
  - Size of the Walk-in
  - Compressor Rating/Capacity
  - Air-Circulation Around Container
  - Location of Air Blower Fans

Source: Dr. Peter Brecht-PEB Commodities Inc.

Refrigeration Facts Continued

Passive Cooling

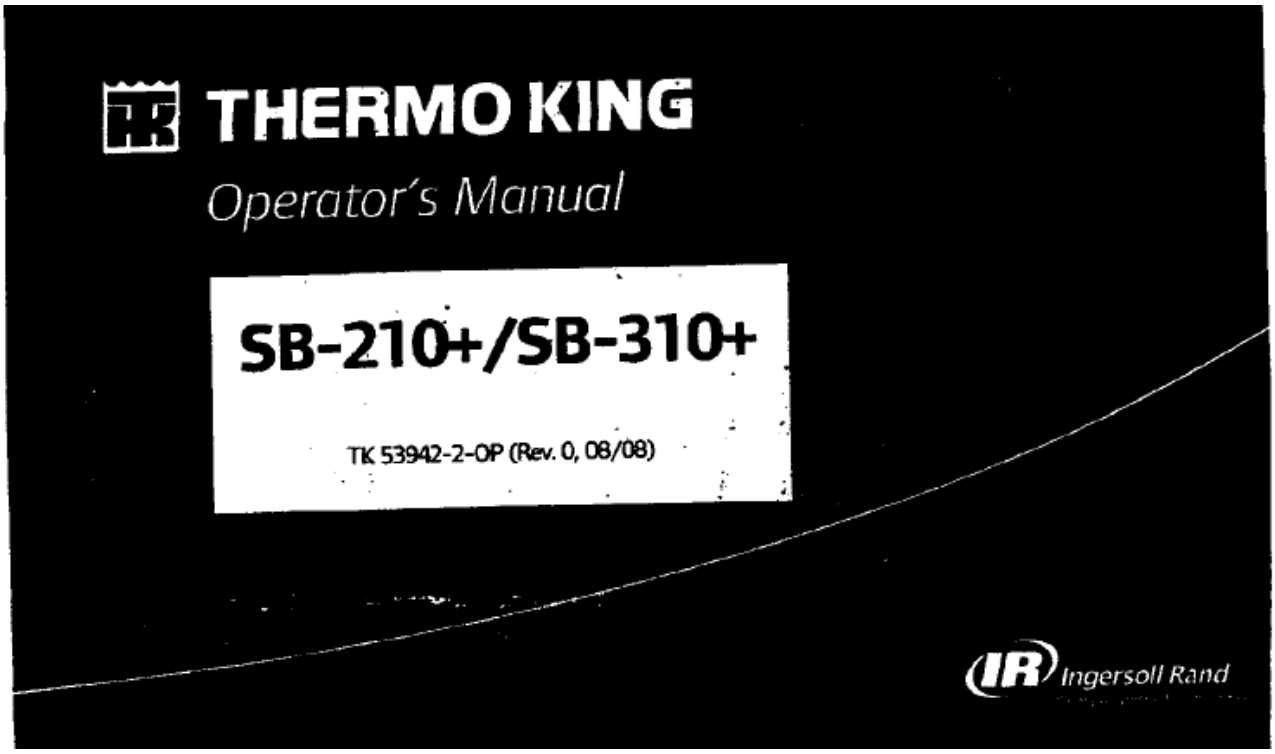
Refrigerated Trailers/Trucks

Most Are Not Designed to Rapidly Lower Product Temperatures

These Units Are Designed To Maintain Product Temperatures; NOT to Cool an Above-Temperature Load

"These Products Must be Pre-Cooled to Proper Temperature Before Loading"

Source: Thermo-King Operators Manual page167 attached



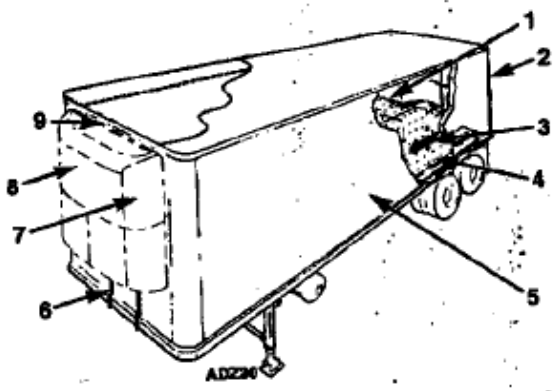
Loading and Enroute Inspections

This chapter describes pre-loading, post loading, and enroute inspection procedures. Thermo King refrigeration units are designed to maintain the required product load temperature during transit. Follow these recommended loading and enroute procedures to help minimize temperature related problems.

Pre-Loading Inspection

1. Pre-cool products before loading. Note any variances on the manifest.
2. Inspect door seals and vent doors for condition and a tight seal with no air leakage.
3. Inspect the trailer inside and out. Look for:
   - Damaged or loose trailer skin and insulation
   - Damaged walls, air ducts, floor channels or "T" flooring
   - Clogged defrost drain tubes
   - Blocked return air bulkhead
4. Verify that the setpoint temperature is correct for your cargo. Pre-cool the trailer as required.
5. Supervise product loading to ensure sufficient air space around and through the load. Airflow around the cargo must not be restricted.

NOTE: If the warehouse is not refrigerated, operate the unit with doors closed until cargo is ready to be loaded. Then turn off the unit, open cargo doors and load cargo. When cargo is loaded, close trailer doors and restart the unit.
The unit can be operated with the cargo box doors open if the truck is backed into a refrigerated warehouse and the dock door seals fit tightly around the trailer.



1.	Correct load height (trailers without chutes)
2.	Tight doors and gaskets
3.	Good air circulation around load
4.	Proper cargo temperature (prior to loading)
5.	Interior/exterior walls and insulation in good condition
6.	Clear defrost drains
7.	Good outside air circulation
8.	Unit inspection
9.	Tight seals

Figure 124: Loading Considerations

Post-Loading Inspection

Post-loading inspections ensure the cargo has been loaded properly. To perform a post-load inspection:

1. Inspect the evaporator outlets for blockage.
2. Turn the unit off before opening the cargo box doors to maintain efficient operation.

   NOTE: The unit can be operated with the cargo box doors open if the truck is backed into a refrigerated warehouse and the dock door seals fit tightly around the trailer.
3. Perform a final check of the load temperature. If the load is above or below temperature, make a final notation on the manifest.

CAUTION: Cargo must be pre-cooled to the proper temperature before loading. The unit is designed to maintain temperature, not cool an above-temperature load.

4. Close or supervise the closing of the cargo box doors. Make sure they are securely locked.
5. Make sure the setpoint is at the temperature listed on the manifest.
6. If the unit was stopped, restart using the correct starting procedure. See the Operating Instruction chapter in this manual.
7. Start a manual defrost cycle 30 minutes after loading. See the Manual Defrost procedure in this manual.

Loading and Enroute Inspections

Enroute Inspections

Complete the following enroute inspection every four hours. This will help minimize temperature related problems.

Inspection Procedure

1. Verify setpoint is correct.
2. Check the return air temperature reading. It should be within the desired temperature range.
3. Initiate a manual defrost cycle after each enroute inspection.

Inspection Troubleshooting

1. If a temperature reading is not within the desired temperature range, refer to the troubleshooting table on the following pages. Correct problem as required.
2. Repeat the Enroute Inspection every 30 minutes until the compartment temperature is within the desired temperature range. Stop the unit if the compartment temperature is not within the desired temperature range on two consecutive 30 minute inspections, especially if the compartment temperature appears to be moving away from the setpoint.
3. Immediately contact the nearest Thermo King Service Center or your company office.
4. Take all necessary steps to protect and maintain proper load temperature.

CAUTION: Stop the unit if the compartment temperature remains higher than the desired temperature range from the setpoint on two consecutive 30 minute inspections. Contact the nearest Thermo King Service Center or your company office immediately. Take all necessary steps to protect and maintain proper load temperature.

Comparisons of Cooling Rates of Foods in General

Passive Air (ie;Refrigerated Trailer)

Typical Cooling Times: 20-100 Hours

Forced-Air (ie; Walk-in Cooler)

Typical Cooling Times:1-10 Hours

Data Provided on attached e-mail to this document by Dr. Patrick Brecht
Expert in Refrigeration Technology and Transport of Perishable Foods

Source: Dr Patrick Brecht of PEB Commodities and University of California

P E B Commodities, Inc.

PEB Commodities, Inc. ("PEB") is made up of a unique team of experts and specialists with extensive experience and capabilities in perishable product quality attributes, food safety, handling, precooling, packinghouse operations, cold storage, controlled atmosphere, transportation, refrigeration technology, marine cargo insurance, marketing and sales.

Our Mission

We provide expert and consultation services to growers, shippers, packinghouses, insurance underwriters, transportation companies, P&I Clubs, law firms, manufacturers and others. We are currently offering expert services for alleged losses exceeding $10 million that involve fruit, vegetables, seafood, meat, wine, flower bulbs, grains and blood products.

Company Profile

Founder and President Dr. Patrick E. Brecht, was a professor at Cornell University and senior executive for four multi-national companies. He has post harvest and postmortem expertise with a multitude of perishable products. In the past 5 years, he was the principal consultant for over 175 perishable product and equipment projects. He wrote Shipping Special Commodities and co-authored recently released University of California publications entitled Marine Container Transport of Chilled Perishable Produce and Refrigerated Trailer Transport of Perishable Products. He also jointly authored an atmosphere management book and the soon to be released Air Transport of Perishable Products. He has given perishable product and refrigerated technology workshops in Australia, Asia, North America, Hawaii, Europe and South America.

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Last modified: 09/04/07

Wolf, Gary J.

From: SCSDoctor@aol.com
Sent: Monday, December 15, 2008 5:27 PM
To: Wolf, Gary J.
Subject: Re: Refrigeration Information-Important

Good Afternoon Gary:

I have been looking for **non-proprietary** test data on truck trailers with limited success (so far). I will keep looking.

For reference, reefer trailers are equipped with a top air delivery airflow system, which means that the air "should be" delivered from the reefer unit to the cargo space via a duct extension and an air chute attached to the trailer's ceiling. The air returns passively and horizontally from the cargo space through a front bulkhead (if equipped) and back to the refrigeration unit. Images of airflow and temperature management inside refrigerated trailers are attached to this email. Please refer to the guidebook that I jointly authored for reefer truck SOP's practices (Thompson, J.F. P.E. Brecht and T. Hinsch. 2002. Refrigerated Trailer Transport of Perishable Products. Univ. of Calif. Div of Agri. & Nat. Res. Pub. No. 21614.

The principal controlling and recording device for reefer trailers is a computer or microprocessor that is sometimes referred to as a Data Management System ("DMS") or a data logger. The microprocessor records operational events and alarm codes as they occur and at preset intervals. Trip data can be retrieved (but not erased) from the microprocessor memory using compatible laptop or desktop computers. The controlling, tracking and recording operations of the refrigeration system includes, in part, the temperature set point, return air sensing, discharge air sensing, operating modes, safety alarms and probe sensing. Temperatures can be recorded in degrees Celsius (C), formerly known as Centigrade) or Fahrenheit (°F).

As a general rule, the product temperature reduction is relatively fast at the start of cooling and much slower as the product temperature nears the cold air temperature. The rate of temperature drop is related in part to the difference between the product temperatures and the cold air temperature. This process is approximated by ½, ¾, 7/8 and 15/16 cooling times. To illustrate, if the initial temperature of seafood was 39F and the temperature of the cool air was 31F, the time to drop half of the difference (i.e. 35 F) between the initial temperature and the temperature of the cold air would be the half cooling time.

Beware – based on many years research experience, I have found that the recorded air temperatures are typically not the same as product temperatures. In fact, air temperatures (either colder or warmer) lag way behind the actual pulp temperatures of the cargo.

In any event, I located data showing "passive" cooling in cold rooms, which are similar to "passive" cooling in reefer trucks. The comparison shows typical cooling times for passive cooling verses various precooling methods such as forced air cooling. My colleague at the University of California (Professor Jim Thompson) published these data As you will note, passive cooling is markedly slower than all of the "fast' precooling methods.

Typical cooling times

• Forced air cooling	1 - 10 hours
• Hydrocooling	0.1 - 1 hours
• Vacuum cooling	0.3 - 2 hours
• water spray cooling	0.3 - 2 hours
• packaged ice cooling	0.1 - 0.3 hours
• room cooling (i.e., passive cooling like reefer trucks)	20 - 100 hours

Although I **was unable to open the photos** that you sent me (please send them via JPEG files), I suspect that

12/16/2008

cooling the seafood in a reefer truck with the containers that you described will take a substantial amount of time.

By way of example, the effect of container design, packing and stowage method cannot be over looked. For instance, plums stowed in a passive cooling system will take 84 hours to cool (7/8 cooling time) with no vents or spacing between corrugated cartons and 22 hours (7/8 cooling time) with a 4% vent area (carton surface) and 1" spacing between containers. Pears take up to 40 hours (7/8 cooling time) to cool in a telescopic container with 5% vents area and no spacing whereas hydrocooled pears cool in 42 minutes (7/8 cooling time) !

Based on many "live" load tests over the years, I have witnessed similar results with reefer trucks and reefer containers equipped horizontal airflow systems to the passive cooling times delineated above **when the cargo was not precooled to the desired carrying temperature.**.

More later.

Patrick Brecht, PhD

In a message dated 12/15/2008 11:49:08 A.M. Pacific Standard Time, gary.wolf@fda.hhs.gov writes:

Actual Oyster Cooling Studies

Cooling Rates to Monitor Internal Oyster Meat Temps. using Temp Recording Device

1. 2003 Study State of Alabama and FDA for Oysters in Mesh Sacks (15 Sacks/Pallet). Monitored internal meat temp post harvest in a walk-in cooler

2. 2003 Study State of New Jersey and FDA for Oysters stored in Metal Cages (approx. 25 Bushels/Cage). Monitored internal meat temp post harvest in a walk-in cooler.

Source: Attached time-temperature study summaries and cooling response rate graphs.

Oyster Cooling Rate Studies
Study #1

- State of Alabama
- July 18th 2003
- Oysters Stored in a Walk-in Cooler
- Oysters in Mesh Sacks with 15 Sacks/Pallet
- See Charts-Internal Shellfish Temps using TRD

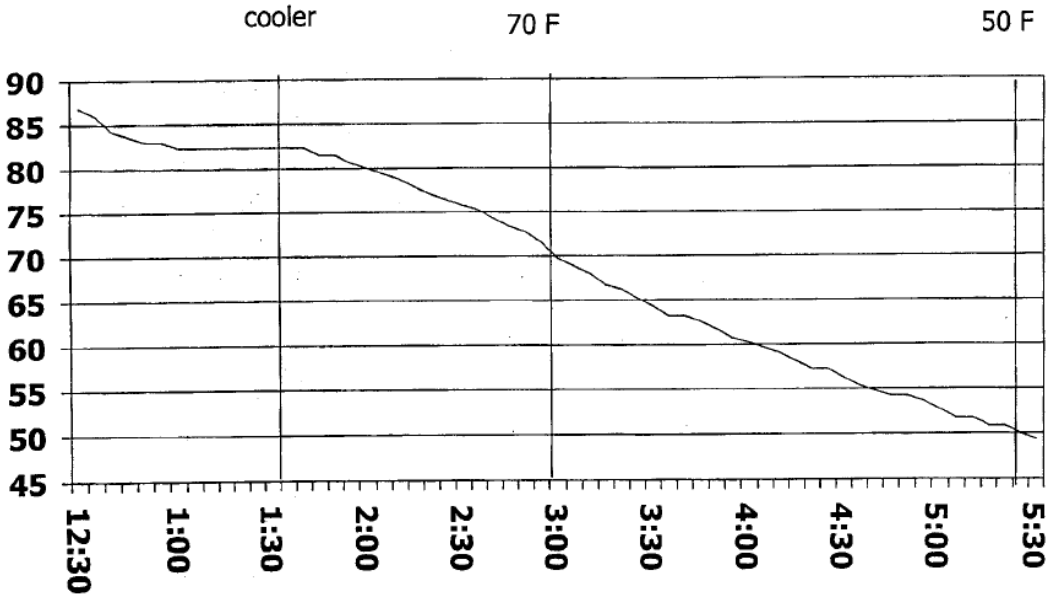
METEROLOGICAL CONDITIONS DURING HARVEST

Location	Cedar Point, AL
Date	July 18, 2003
Average Air Temp.	85 F
Average Water Temp.	84 F
Conditions	PC/Hot

STORAGE CONDITIONS AT DEALER

Cooler Set Temperature	42 F
Cooler Temperature Range	33- 44 F
Cooler Load	Medium
Shellstock Container	Palletized sack oysters w/ 15 sacks

TEMPERATURE MEASUREMENTS
MIDDLE SACK



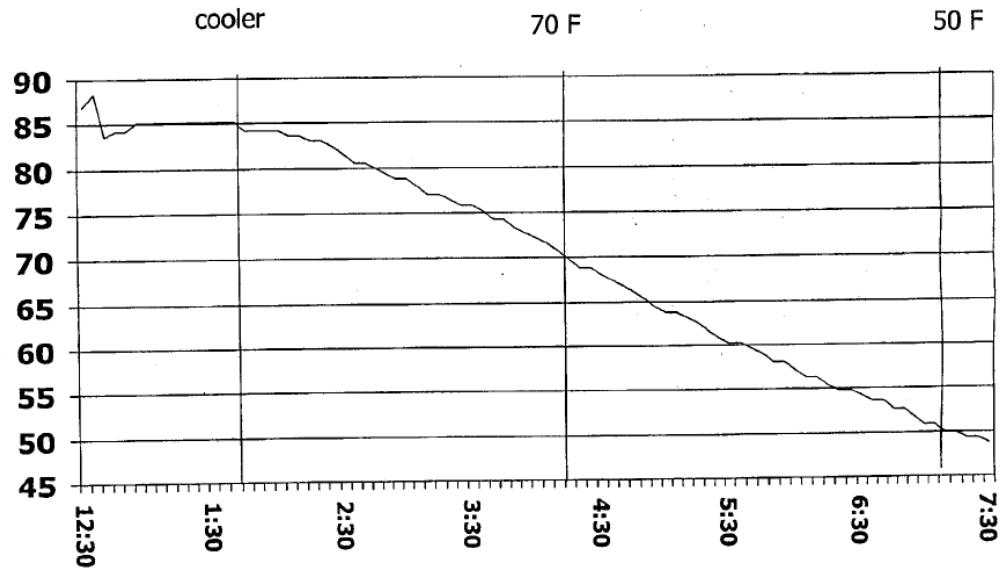
Time to Temperature

Receipt time and temperature	12:30 PM/ 86.9 F
Product in cooler	1:35 PM/82.4 F
Product at 70 F	3:00 PM/69.8 F (1 h 25 min)
Product at 50 F	5:25 PM/50.0 F (3 h 50 min)

Time to Temperature

Receipt time and temperature	12:30 PM/ 86.9 F
Product in cooler	1:45 PM/84.2 F
Product at 70 F	4:15 PM/69.8 F (2 h 30 min)
Product at 50 F	7:10 PM/50.0 F (5 h 25 min)

TEMPERATURE MEASUREMENTS MIDDLE SACK



Oyster Cooling Rate Studies

Study # 2

- State of New Jersey
- July 9th 2003
- Oyster Stored in Walk-in Cooler
- Oysters in Metal Cages at 25 Bushels per Cage
- See Charts-Internal Shellfish Temps using TRD

Oyster Cooling Rate Studies

- State of New Jersey
- July 9th 2003
- Oyster Stored in Walk-in Cooler
- Oysters in Metal Cages at 25 Bushels per Cage
- See Charts-Internal Shellfish Temps using TRD

METEROLOGICAL CONDITIONS DURING HARVEST

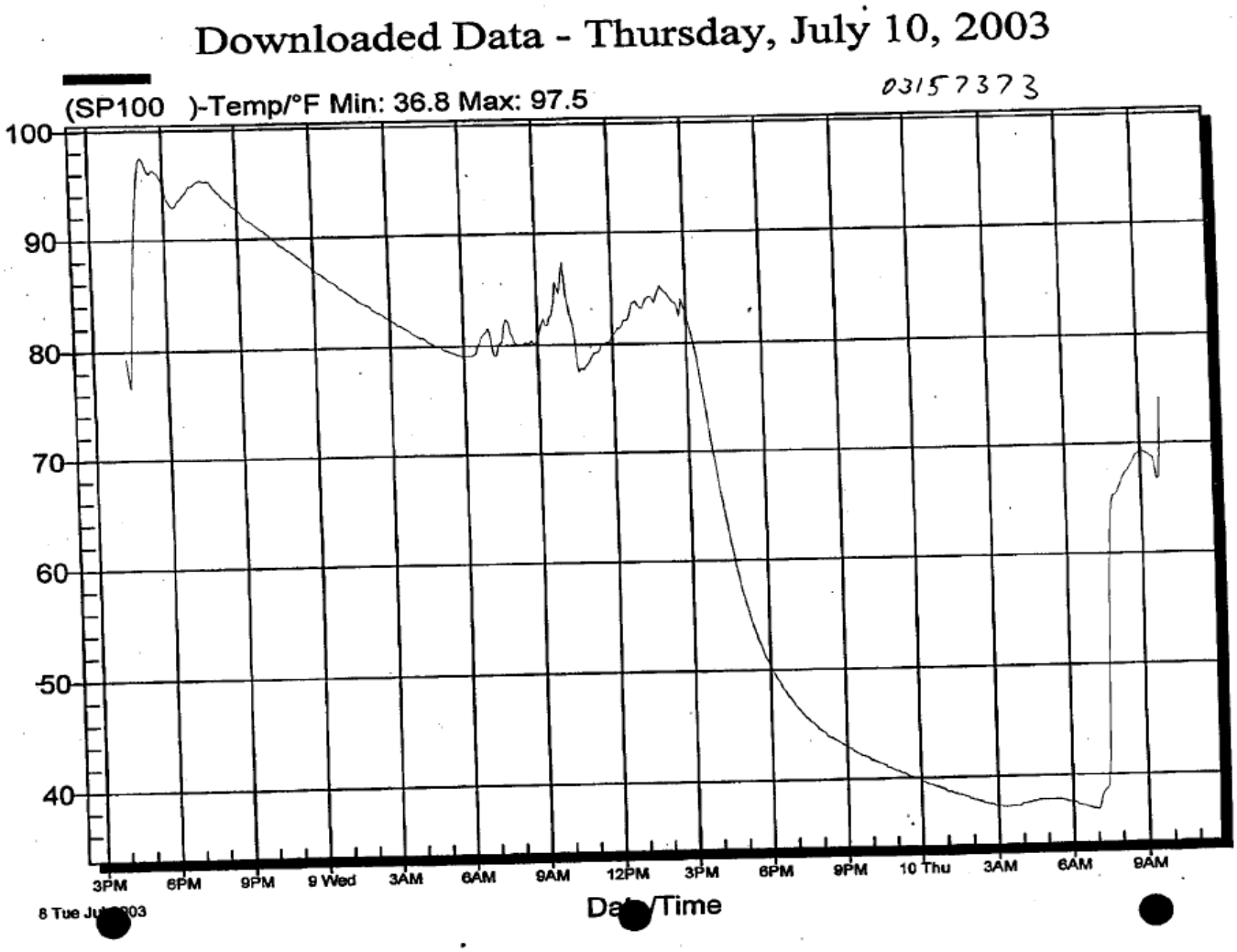
Location	Delaware Bay, NJ
Date	July 9, 2003
Average Air Temp.	86 F
Average Water Temp.	83 F
Conditions	Sunny/Hot

STORAGE CONDITIONS AT DEALER

Cooler Set Temperature	40 F
Cooler Temperature Range	41- 45 F
Cooler Load	Medium
Shellstock Container	3x4x3 Cage w/ 25 bushels

Time to Temperature

Receipt time and temperature	2:30 PM/ 83.7 F
Product in cooler	3:15 PM/80.6 F
Product at 70 F	4:00 PM/69.5 F (45 min)
Product at 50 F	6:10 PM/49.8 F (ca. 3 h.)



Results of AL & NJ Studies

- **The Data Validates the Technical Information provided by Refrigeration Experts regarding Rapid Cooling Rates in a Walk-in Cooler/Forced Air**

- **1-10 Hours**