BACARDI CORPORATION

EXHIBIT

A

August 12, 2011

Chief, Clean Water Regulatory Branch
USEPA Region 2
290 Broadway, 24th floor
New York, NY 10007

Re: Bacardi Corporation
Cataño, Puerto Rico
NPDES Permit No. PR0000591

Dear Sir or Madam:

Bacardi Corporation ("BC") has reviewed the referenced Draft National Pollutant Discharge Elimination System ("NPDES") permit, issued on July 1st, 2011. BC offers the following comments to EPA for its review and consideration.

If you have any question in relation to this matter, please contact Julio Torruella at 787-788-1500.

Sincerely,

Jorge Marcano
VP, Operations

Enclosures

c: Karen O' Brien, USEPA-Region 2
Roberto Ayala, EQB

BACARDI CORPORATION
COMMENTS ON THE ENVIRONMENTAL PROTECTION AGENCY
DRAFT NPDES PERMIT NO. PR 0000591

Comment #1 – (Page 2 of 42)

EPA acknowledges that the proposed effluent limitations are more stringent than those included in the EQB WQC, and justifies the more stringent limitations on two premises: 1) that those more stringent limitations are achievable by the permittee during normal operational conditions; and 2) that dischargers should be held to the level of discharge achievable through treatment rather than assume all assimilative capacity of the receiving water, particularly for bacterial parameters.

The first premise is only partially correct. While Bacardi operated at a rate of production of 65,000 to 70,000 proof gallons per day, it generally complied with the more stringent limitations during normal operations. However, for various months Bacardi has been operating at a rate of production of 80,000 proof gallons (which is allowed under the current and draft permits) and has not been consistently complying with the more stringent limitations during normal operations. The effluent limitations proposed by EPA for Enterococci and Fecal Coliform in the BC wastewater treatment system (WWTS) are not consistently achievable based on recent sampling results (see Figure 1 and Figure 2).

Figure 1. Bacardí WWTS DMR *Enterococcus* Data with Proposed Limitations

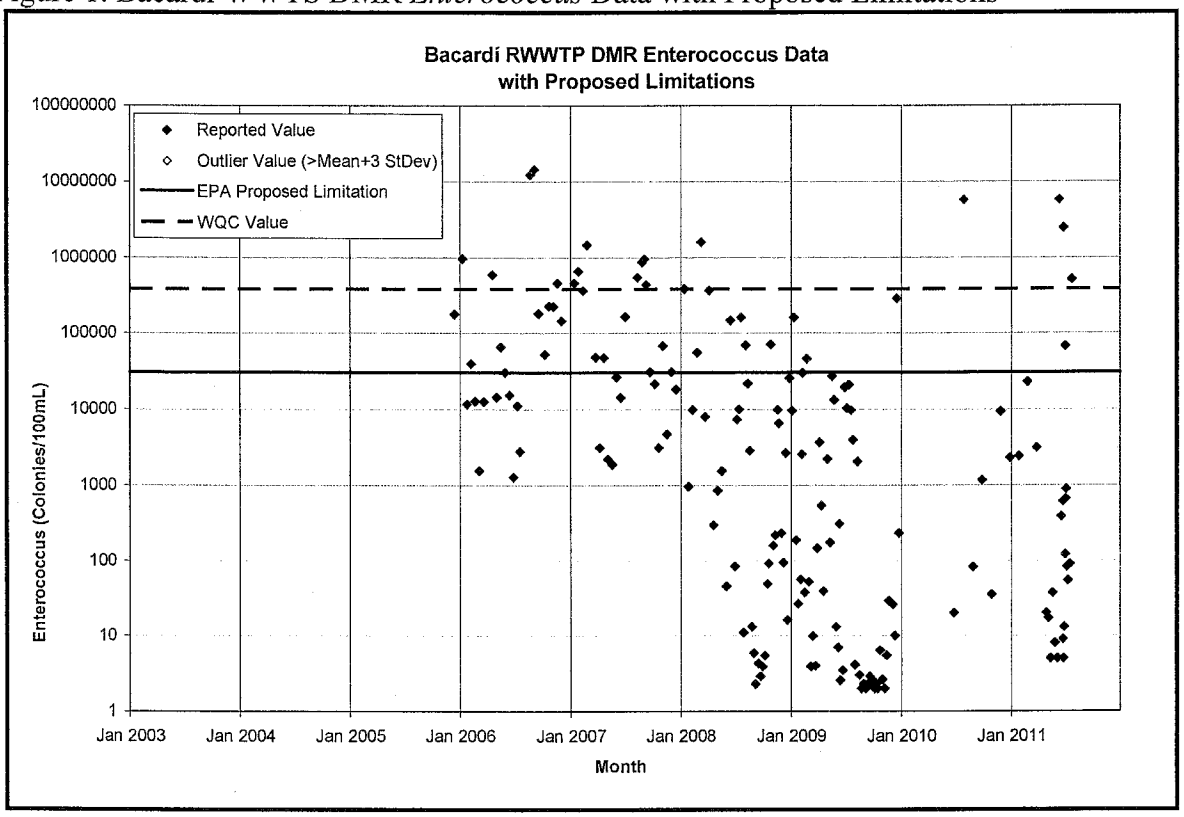
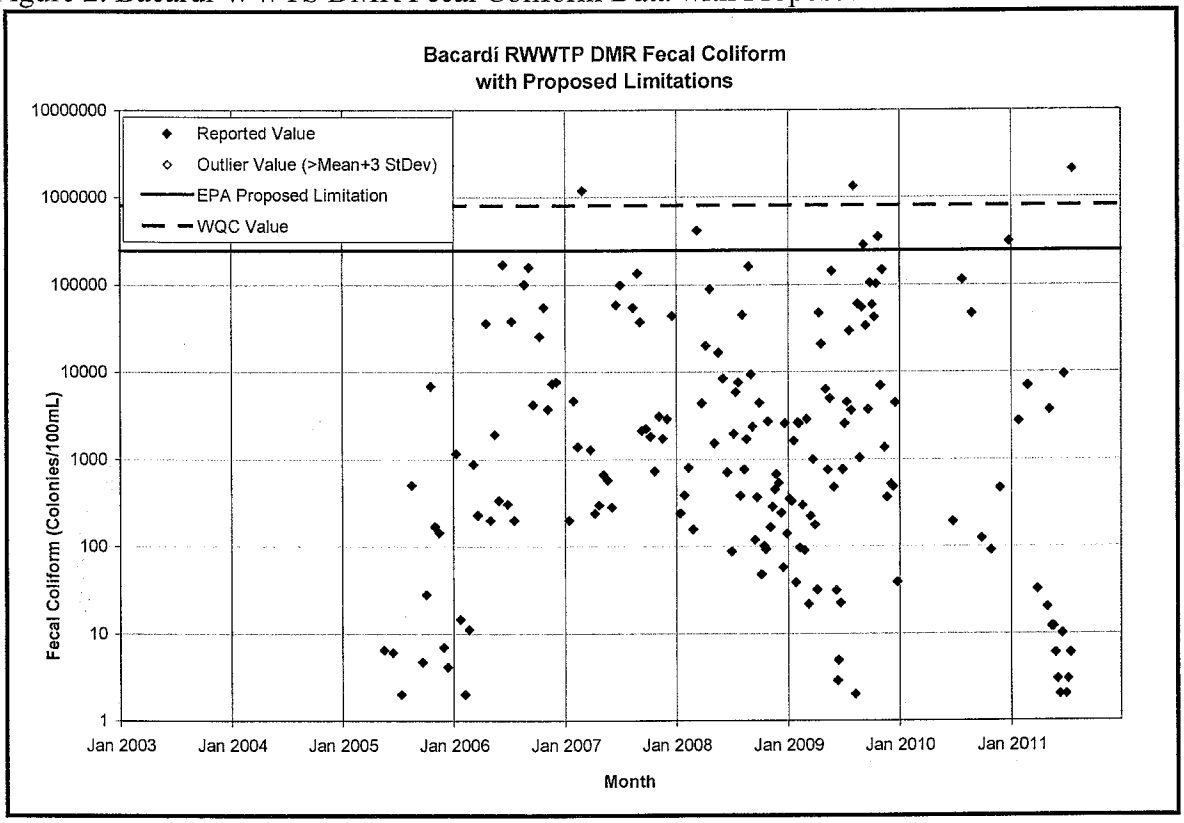


Figure 2. Bacardí WWTS DMR Fecal Coliform Data with Proposed Limitations



The second premise also is only partially correct. Bacardi agrees that the entire assimilative capacity of the receiving water should not be used to avoid technology and other control methods to achieve compliance. But, that is not the case of BC. The EQB approved the WQC, and EPA did not oppose the granting of the WQC, because: 1) BC implemented aggressive operational controls and source reduction; 2) the operational controls and source reduction implemented by BC resulted in a significant reduction of regulated bacteria in the effluent at the 001 discharge point; 3) BC upgraded the sanitary wastewater treatment plant and added a disinfection system; 4) the alternative of an enhanced pasteurization system would likely be unnecessary, and possibly environmentally counter-productive; and 5) the operational controls, source reduction, and upgrade of the sanitary wastewater treatment system implemented by BC significantly reduced the bacteria levels and, when combined with a conventional BMZ, assure nearly complete compliance with the final limitations in the WQC. From the above, it is clear that the entire assimilative capacity of the receiving waters would not be used to avoid technology and other control methods to achieve compliance.

In addition, the receiving waters in the discharge area are not used for human contact or shellfish harvesting, which is a major factor in the EQB decision to approve a small mixing zone for bacteria in its final WQC, of identical size and consistent with the mixing zones approved by both EQB and EPA for water quality-based toxic parameters. For these reasons, BC requests that the effluent limitations for bacteria (Enterococci and Fecal Coliform) in Table A-1 be based on the final WQC issued by EQB in June 2010. The requested limitations are shown in Figure 3.

Figure 3. Requested Limitations for Enterococci and Fecal Coliform

Parameter	Requested Limitation
Enterococci (Geomean, col/100 ml)	382,602
Fecal Coliform (Geomean, col/100 ml)	803,378

Comment #3 – (Page 6 of 42)

BC requests a correction to Table A-1, Notes section (Footnote @), of the draft permit. This footnote indicates that the value for the detection limit for sulfide is 100µg/L. This appears to be a typographical error; it is assumed that the detection limit should be 2µg/L.

Comment #4 – (Page 6 of 42)

BC requests a correction to Table A-1, Notes section (Footnote @), of the draft permit. This footnote indicates that the effluent limitation for H_2S is 2µg/L. The correct effluent limitation for H_2S is 89,007µg/L.

Comment #5 – (Page 9 of 42)

BC requests a change to the language indicated in Table A-3 (last statement) of the draft permit (Treated Sanitary Wastewater). The statement requires that the samples shall be taken at sampling location 003 in the vicinity of the sanitary wastewater treatment plant. BC requests EPA to modify the statement as follows: *"...samples should be taken at the sampling location 003 in the vicinity of the sanitary wastewater treatment plant (after disinfection and filtration)."*

Comment #6 – (Page 13 of 42)

The diffuser description, included in Special Condition 17.a, is not correct based on the most recent inspection. It should be corrected to be consistent with, or referenced to, the description in the EPA Fact Sheet, as follows: *"The discharge is through a high-rate, Y-shaped diffuser consisting of two (2) legs that are each 1,010 ft (308 m) in length and a constant 84-inch diameter. The west leg of the diffuser has 100 bell- mouthed ports and the east leg of the diffuser has 102 bell-mouthed ports, each at 15 degrees from the horizontal. There are a total of 202 ports. On the west diffuser leg, there are 80 inshore ports that have a diameter of 6 in (15.2 cm), 19 offshore ports that have a diameter of 7 in (17.8 cm), and 1 10-inch (25.4 cm) port. On the east diffuser leg, there are 81 inshore ports that have a diameter of 6 in (15.2 cm), 20 offshore ports that have a diameter of 7 in (17.8 cm), and 1 10-inch port. The ports discharge on alternating sides of the diffuser and are evenly spaced at 10 ft (3.05 m) intervals. The diffuser is currently operated with all 202 ports open."* [Note the 10-inch ports are on the end gates and are approximately 4.2 meters from the nearest 7-inch port.]

The coordinates shown in SC 17.a, which are those specified in the final WQC, refer to Diagram-I, which is missing from the draft permit. BC requests EPA to include Diagram-I in the final permit.

Comment #7 – (Page 15 of 42)

BC requests EPA to delete the reference to acute toxicity testing for *Arbacia,* included in Special Condition 17.c. Although toxicity tests for *Arbacia* are required, the only EPA-approved test for this organism is for chronic toxicity.

Comment #8 – (Page 17-18 of 42)

BC requests EPA to eliminate Special Condition 20 of the draft permit. Special Condition 20.a thru 20.l is a duplicate of Special Condition 17.c thru 17.o. The circular reference in the first paragraph of Special Condition 20 should be moved to Special Condition 17 and should reference Special Condition 18. Numbering should be updated for subsequent conditions. There is no Special Condition 18 or 19 in the draft permit.

Comment #9 – (Page 19 of 42)

BC requests a change to Special Condition 21.b of the draft permit. Contrary to EPA's statement in its Fact Sheet, the PRWQSR does have a numerical TUc limitation (incorporated by reference to EQB's *Mixing Zone and Bioassay Guidelines*). Therefore, this limitation should be treated in the same manner as all other limitations listed in Table A-1 that are subject to a mixing zone. The appropriate value is 102 TUc, not 83.32 TUc. In addition, the limitation for *Arbacia* should be specifically based on the IC25 endpoint.

These requests are consistent with the PRWQSR, the existing permit, and EPA's own guidance on how to apply WET test results to compliance evaluations. The bases for these conclusions are discussed in detail in Appendix B and Appendix C, respectively.

A 60-day reporting period for WET test reports is also requested, which is consistent with EQB requirements.

Comment #10 – (Page 19 of 42)

BC requests changes to Special Condition 21.c. The stipulated Toxicity Reduction Evaluation (TRE) process addresses steps the permittee will take if the "toxicity is measured below the chronic toxicity effluent limitation ...," which is inconsistent with the limitation defined as a maximum value. Also the sentence is not clearly written. The wording should read as follows: "This plan shall include steps the permittee intends to follow if the toxicity limitation is violated and must include, at a minimum: ..."

Comment #11 – (Page 21 of 42)

BC requests changes to Special Condition 21.d.6. This item refers to Special Condition 21.g.3. There is no g.3; it is presumed this is supposed to refer to f.3.

Comment #12 – (Pages 21 & 23 of 42)

BC requests changes to Special Conditions 21.d.6 and 21.f.3. These items require reporting to be done within 30 days after permittee's receipt of the laboratory results. This is inconsistent with Special Condition 17.g, which requires reporting within 60 days following completion of the test.

Wording should be changed to maintain consistency with the final WQC, which requires reports within 60 days of the completion of the tests.

Comment #13 – (Page 22 of 42)

BC requests changes to Special Condition 21.f.1. The language should be revised as indicated in bold typeface as follows:

> *21.f.1 "A procedure report shall be **submitted** to EPA and EQB no later than ninety (90) days from the effective date of the permit. The following information shall be included in the procedure report:"*

Comment #14 – (Page 38 of 42)

BC requests EPA to clarify the language in General Condition 12.f of the draft permit, which states the following:

> *The permittee shall report any non-compliance which may endanger health or the environment. Any information shall be provided orally within 24 hours from the time the permittee becomes aware of the circumstances to the Regional administrator at (732) 548-8730 and State Director.*

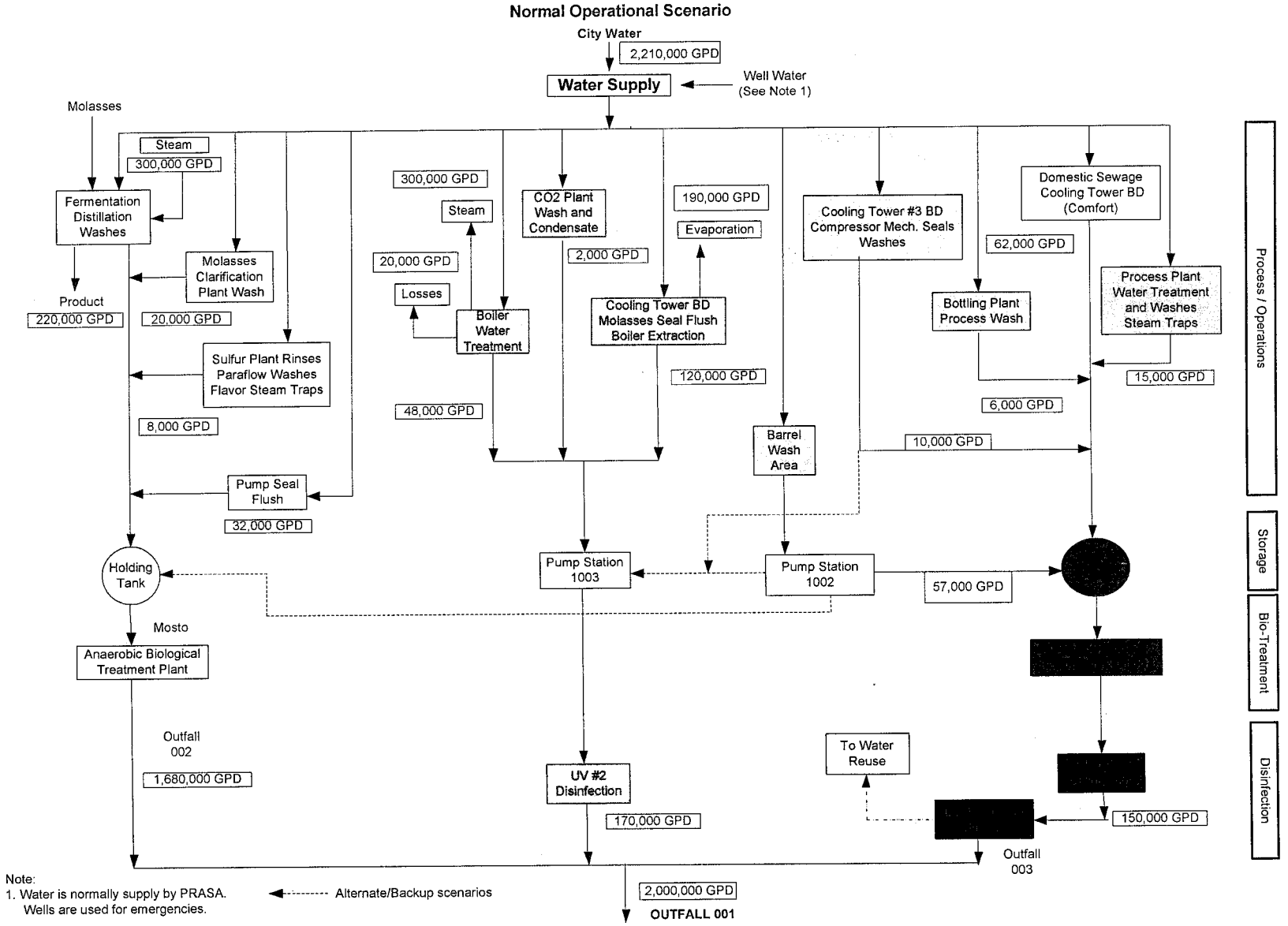
The provided phone number is for the National Response Center (NRC). On previous instances, BC used this number to notify non-compliance situations (e.g., pH excursions), triggering the unnecessary mobilization of US Coast Guard (USCG) personnel. The USCG has told BC that calls for this kind of incident are not appropriate or necessary.

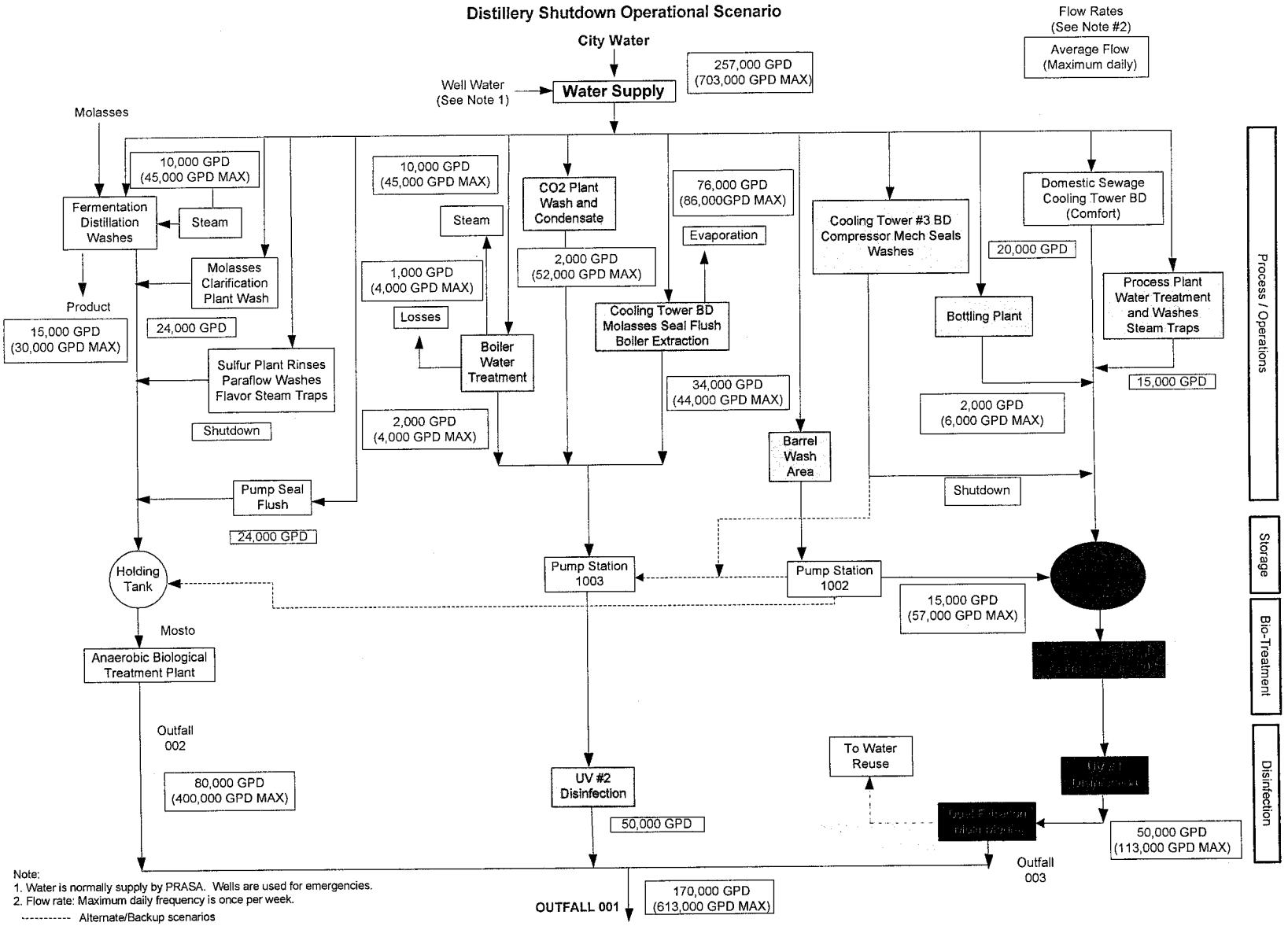
BC requests EPA to provide an appropriate phone number or clarify in which specific instances BC is required to notify the NRC.

Comment #15

BC requests a change to update Attachment I: Site Location and Process Diagrams in the Fact Sheet for the draft permit. The flow diagrams were modified to add the UV Disinfection treatment as a backup treatment for streamflow from Cooling Tower #3 blowdown. The revised flow diagrams are included in the Appendix A of this document.

APPENDIX A
Revised Flow Diagrams


Normal Operational Scenario
City Water
2,210,000 GPD
Water Supply
Well Water
(See Note 1)
Molasses
Steam
300,000 GPD
Fermentation
Distillation
Washes
Molasses
Clarification
Plant Wash
20,000 GPD
Product
220,000 GPD
Sulfur Plant Rinses
Paraflow Washes
Flavor Steam Traps
8,000 GPD
Pump Seal
Flush
32,000 GPD
300,000 GPD
Steam
20,000 GPD
Losses
Boiler
Water
Treatment
48,000 GPD
CO2 Plant
Wash and
Condensate
2,000 GPD
190,000 GPD
Evaporation
Cooling Tower BD
Molasses Seal Flush
Boiler Extraction
120,000 GPD
Cooling Tower #3 BD
Compressor Mech. Seals
Washes
Barrel
Wash
Area
Domestic Sewage
Cooling Tower BD
(Comfort)
62,000 GPD
Bottling Plant
Process Wash
6,000 GPD
Process Plant
Water Treatment
and Washes
Steam Traps
15,000 GPD
10,000 GPD
Holding
Tank
Pump Station
1003
Pump Station
1002
57,000 GPD
Mosto
Anaerobic Biological
Treatment Plant
Outfall
002
1,680,000 GPD
UV #2
Disinfection
170,000 GPD
To Water
Reuse
150,000 GPD
Outfall
003
Note:
1. Water is normally supply by PRASA.
Wells are used for emergencies.
Alternate/Backup scenarios
2,000,000 GPD
OUTFALL 001
Process / Operations
Storage
Bio-Treatment
Disinfection


Distillery Shutdown Operational Scenario
Flow Rates
(See Note #2)
Average Flow
(Maximum daily)
City Water
Well Water
(See Note 1)
Water Supply
257,000 GPD
(703,000 GPD MAX)
Molasses
10,000 GPD
(45,000 GPD MAX)
Fermentation
Distillation
Washes
Steam
Molasses
Clarification
Plant Wash
Product
15,000 GPD
(30,000 GPD MAX)
24,000 GPD
Sulfur Plant Rinses
Paraflow Washes
Flavor Steam Traps
Shutdown
Pump Seal
Flush
24,000 GPD
10,000 GPD
(45,000 GPD MAX)
Steam
1,000 GPD
(4,000 GPD MAX)
Losses
Boiler
Water
Treatment
2,000 GPD
(4,000 GPD MAX)
CO2 Plant
Wash and
Condensate
2,000 GPD
(52,000 GPD MAX)
76,000 GPD
(86,000GPD MAX)
Evaporation
Cooling Tower BD
Molasses Seal Flush
Boiler Extraction
34,000 GPD
(44,000 GPD MAX)
Barrel
Wash
Area
Cooling Tower #3 BD
Compressor Mech Seals
Washes
Shutdown
Domestic Sewage
Cooling Tower BD
(Comfort)
20,000 GPD
Bottling Plant
2,000 GPD
(6,000 GPD MAX)
Process Plant
Water Treatment
and Washes
Steam Traps
15,000 GPD
Holding
Tank
Mosto
Anaerobic Biological
Treatment Plant
Outfall
002
80,000 GPD
(400,000 GPD MAX)
Pump Station
1003
Pump Station
1002
15,000 GPD
(57,000 GPD MAX)
UV #2
Disinfection
50,000 GPD
To Water
Reuse
50,000 GPD
(113,000 GPD MAX)
Outfall
003
OUTFALL 001
170,000 GPD
(613,000 GPD MAX)
Process / Operations
Storage
Bio-Treatment
Disinfection
Note:
1. Water is normally supply by PRASA. Wells are used for emergencies.
2. Flow rate: Maximum daily frequency is once per week.
---------- Alternate/Backup scenarios

APPENDIX B
Whole Effluent Toxicity Evaluation

Whole Effluent Toxicity (WET) Requirements Evaluation

The current and proposed NPDES permits for the Bacardí WWTS and the PRASA Bayamón, and Puerto Nuevo RWWTPs include WET test compliance limitations in reference to flow-proportional combined 24-hr composite samples of the individual effluents from each facility. The permits also require WET test monitoring of each individual effluent so that, if compliance is not demonstrated by the combined sample, there is a mechanism to evaluate which of the three effluents may have been responsible and then focus additional testing on that effluent.

The current NPDES permit (SC 21.B) includes an effluent limitation for WET as follows:

> No single IC25 test result for any species or effect in the combined discharge shall be less than 1.00%.

The proposed permit effluent limitation in the new permit (SC 20.b) states:

> No test result for any species or effect in the combined discharge shall be greater than 83.32.TUc.

The proposed limitation is more restrictive than the current limitation (83.32 TUc is equivalent to an effluent concentration of 1.20%). Unlike the existing permit, the language in the proposed permit does not specify that the endpoint used, particularly for *Arbacia punctulata*, should be the IC25. The proposed requirement is also inconsistent with the Puerto Rico Water Quality Standards Regulation (PRWQSR), which requires a TUc of ≤1.0 at the edge of the mixing zone (this is equivalent to an effluent TUc of 102 (based on the critical initial dilution).

The EPA Fact Sheet incorrectly indicates that the PRWQSR does not provide a numeric criterion for toxicity. However, the EQB Mixing Zone and Bioassay Guidelines, which are incorporated into the PRWQSR by reference, do provide numeric water quality criteria for toxicity (in Section II, Chapter 3) for discharges into open coastal waters with high-rate diffusers.[1] The chronic toxicity criterion at the edge of the mixing zone is ≤1.0 TUc. Following the same approach used for other parameters with effluent limitations in the draft permit, this requirement is equivalent to an effluent TUc of 102.

The IC25 endpoints for the *Arbacia* tests of the compliance samples indicate general compliance with the proposed effluent limitation (1.20%) for the combined effluent. However, if the NOEC end point were used, the *Arbacia* test results would indicate non-compliance in a significant number of cases, as shown by the shaded entries in Exhibit 1.

[1] The Bayamón/Puerto Nuevo/Bacardí discharge system definitively qualifies under this category.

EXHIBIT 1
Bioassay Test Results for the Bayamón/Puerto Nuevo/Bacardí Flow-weighted Effluent Composite
Comments on the Draft NPDES Permit WEL Limitation for the Bacardi WWTS

Date	Organism	Percent Effluent	
		Chronic NOEC	Chronic IC25
September 2005	*Mysidopsis bahia*	6.25	0.68
	Cyprinodon variegatus	25	40.50
	Arbacia punctulata	Organism Not Available	N/A
February 2006	*Mysidopsis bahia*	6.25	3.04
	Cyprinodon variegatus	25	29.2
	Arbacia punctulata	Not definitive	7.25
March 2006	*Mysidopsis bahia*	3.13	2.72
	Cyprinodon variegatus	25	51.8
	Arbacia punctulata	6	7.31
April 2006	*Mysidopsis bahia*	12.5	13.1
	Cyprinodon variegatus	25	34
	Arbacia punctulata	3	5
September 2006	*Mysidopsis bahia*	12.5	20
	Cyprinodon variegatus	50	59.6
	Arbacia punctulata	<0.78	1.68
November 2006	*Mysidopsis bahia*	6.25	8.6
	Cyprinodon variegatus	50	56.3
	Arbacia punctulata (Nov 4)	<0.78	1.7
	Arbacia punctulata (Nov 7	1.56	4
April 2007	*Mysidopsis bahia*	10.7	2.96
	Cyprinodon variegatus	10.7	30.3
	Arbacia punctulata (Apr 17)	0.29	3.09
	Arbacia punctulata (Apr 19)	<0.09	2.12
	Arbacia punctulata (Apr 21)	<0.09	4.47
May 2007	*Mysidopsis bahia*	*Not definitive*	0.49
	Cyprinodon variegatus	*10.7*	18.1
	Arbacia punctulata (May 1)	*0.09*	4.92
	Arbacia punctulata (May 3)	*0.96*	14.8
	Arbacia punctulata (May 5)	*0.032*	14.4
May 2007	*Mysidopsis bahia*	10.7	17.9
	Cyprinodon variegatus	10.7	18.2
	Arbacia punctulata (May 15)	0.09	4.88
	Arbacia punctulata (May 17)	0.96	3.01
	Arbacia punctulata (May 19)	0.29	5.23

EXHIBIT 1
Bioassay Test Results for the Bayamón/Puerto Nuevo/Bacardí Flow-weighted Effluent Composite
Comments on the Draft NPDES Permit WEL Limitation for the Bacardi WWTS

May/June 2007	*Mysidopsis bahia*	10.7	0.21
	Cyprinodon variegatus	10.7	24.2
	Arbacia punctulata (May 31)	3.2	5.91
September 2008	*Mysidopsis bahia*	8.00	7.20
	Cyprinodon variegatus	16.0	>16.0
	Arbacia punctulata	0.96	4.15
December 2008	*Arbacia punctulata*	3.20	5.57
February 2009	*Arbacia punctulata*	9.00	13.5
June 2009	*Arbacia punctulata*	3.00	9.51
August 2009	*Arbacia punctulata*	1.00	4.34
November 2009	*Mysidopsis bahia*	16.0	14.5
	Cyprinodon variegatus	16.0	>16.0
	Arbacia punctulata	3.00	4.31
March 2010	*Arbacia punctulata*	3.00	4.68
May 2010	*Arbacia punctulata*	9.00	13.96
September 2010	*Arbacia punctulata*	3.00	12.9
November 2010	*Mysidopsis bahia*	16.0	>16.0
	Cyprinodon variegatus	16.0	.16.0
	Arbacia punctulata	1.00	13.4
March 2011	*Arbacia punctulata*	9.00	13.9
May 2011	*Arbacia punctulata*	3.00	5.25

Shaded entries indicate IC25 < 1.2% effluent.

Exhibit 2 shows WET test results for *Arbacia* for the individual effluent streams. The effluent from the Bacardí WWTS would typically be out of compliance with the existing and proposed combined effluent limitations based on either the IC25 or the NOEC.[2]

[2] Compliance is based on the combined effluent stream, but these single-effluent data are required by EPA in both the current and proposed permit.

EXHIBIT 2
Bioassay Test Results for the Bayamón/Puerto Nuevo/Bacardí Individual Flows using *Arbacia Punctulata*
Comments on the Draft NPDES Permit for the Puerto Nuevo RWWTP

Date	WWTP	Chronic NOEC	Chronic IC_{25}
		Percent Effluent	
September 2008	Bacardí WWTP	0.09%	0.16%
	Bayamón WWTP	0.29%	4.03%
	Puerto Nuevo WWTP	<0.09%	0.07%*
	* The observed data at the 0.09 percent Puerto Nuevo concentration may be anomalous. Removal of the 0.09 percent data and recalculation results in an IC_{25} value of 3.86		
December 2008	Bacardí WWTP	10.70%	15.90%
	Bayamón WWTP	0.09%	0.48%
	Puerto Nuevo WWTP	0.96%	1.92%
February 2009	Bacardí WWTP	0.27%	0.49%
	Bayamón WWTP	2.70%	10.90%
	Puerto Nuevo WWTP	5.40%	15.60%
June 2009	Bacardí WWTP	0.27%	0.80%
	Bayamón WWTP	2.70%	3.36%
	Puerto Nuevo WWTP	5.40%	20.00%
August 2009	Bacardí WWTP	0.81%	>2.43%
	Bayamón WWTP	2.70%	5.12%
	Puerto Nuevo WWTP	5.40%	8.58%
November 2009	Bacardí WWTP	0.27%	0.41%
	Bayamón WWTP	2.70%	4.53%
	Puerto Nuevo WWTP	5.40%	8.84%
March 2010	Bacardí WWTP	0.27%	0.35%
	Bayamón WWTP	2.70%	3.79%
	Puerto Nuevo WWTP	5.40%	7.96%
May 2010	Bacardí WWTP	<0.003%	0.91%
	Bayamón RWWTP	8.10%	10.52%
	Puerto Nuevo WWTP	<0.054%	17.77%
September 2010	Bacardí WWTP	2.43%	>2.43%
	Bayamón WWTP	8.10%	14.60%
	Puerto Nuevo WWTP	0.18%	16.50%
November 2010	Bacardí WWTP	0.27%	0.41%[1]
	Bayamón WWTP	2.70%	11.20%
	Puerto Nuevo WWTP	1.80%	9.04%
March 2011	Bacardí WWTP	0.27%	0.42%
	Bayamón WWTP	2.70%	9.35%
	Puerto Nuevo WWTP	5.40%	12.60%

EXHIBIT 2
Bioassay Test Results for the Bayamón/Puerto Nuevo/Bacardí Individual Flows using *Arbacia Punctulata*
Comments on the Draft NPDES Permit for the Puerto Nuevo RWWTP

May 2011	Bacardí WWTP	0.09%	0.14%
	Bayamón WWTP	2.70%	6.43%
	Puerto Nuevo WWTP	1.80%	8.05%

[1] This value was incorrectly reported as 41.2% in the November 2010 report.

Contrary to EPA's statement in its Fact Sheet, the PRWQSR has a numerical TUc limitation (which is included by reference to the Mixing Zone and Bioassay Guidelines). Therefore, the toxicity limitation should be treated in the same manner as for all other limitations listed in Table A-1 that are subject to a mixing zone. The appropriate value is 102 TUc, not 83.32 TUc.

In addition, the limitation for *Arbacia* should be based on the IC25 endpoint. This is consistent with the existing permit and with EPA's own guidance on using WET test results to evaluate permit limitation compliance as documented in the White Paper provided as Appendix C to this document.[3]

The conclusions are unequivocal that the use of IC25 point estimate techniques or biologically-based NOECs (> 70% fertilization rates, only) as the definitive toxicity evaluation would provide a better estimate of true toxicity than the NOEC tests using unscreened fertilization values. The IC25 evaluation is particularly well supported by EPA recommendations in 2001 and 2002 for the NPDES permit program and WET test methodologies that both state the preference of this method for the determination of chronic toxicity (as referenced in the attached White Paper).

Recent EPA recommendations for WET test evaluations using the Test of Significant Toxicity (TST) (EPA, 2010)[4] also support the conclusions of the White Paper. The TST analysis method declares a test to be toxic when the mean percent effect is greater than 25 percent and nontoxic for effects less than 10 percent. It is designed to solve problems of false negative results, but also provides an improvement on avoiding false positives. A recent EPA evaluation tested 775 valid WET tests for a comparison of results using the TST or NOEC approaches (EPA 2011)[5] and found that:

- Both approaches yielded similar results as a percentage of tests non-toxic or toxic.
- For tests with mean effects less than the IC25, the TST found fewer of them toxic (2.9 percent) as compared to NOEC tests (5.3 percent).

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[3] CH2M HILL, 2007. WHITE PAPER Discussion and Recommendations Related to Arbacia punctulata Whole Effluent Toxicity Testing Using Combined Effluent from the Bayamon, Puerto Nuevo and Bacardi Wastewater Treatment Plants.

[4] EPA, 2010. National Pollutant Discharge Elimination System Test of Significant Toxicity Technical Document. EPA/833-R-10-004, USEPA, Office of Environmental Management, Washington, D.C.

[5] EPA, 2011. Whole Effluent Toxicity Test Drive Analysis of the Test of Significant Toxicity (TST). USEPA, Region 9, Sacramento, CA. July, 2011.

- Truly non-toxic samples were more often declared non-toxic using the TST than NOEC approaches to testing.
- The addition of minimal replicates (over 4) to the TST resulted in samples with effect levels less than 25 percent being declared non-toxic that had been originally declared toxic.

In summary, recent EPA modifications of WET test evaluations using the TST approach are supportive of continuing to use the IC25 evaluation that is incorporated in the existing NPDES permit and is supported by the attached White Paper (Appendix 3). The IC25 point estimate generally provides a more reliable indicator of chronic WET results than other methods and should be maintained for future chronic WET testing for *Arbacia*.

Appendix C
Toxicity White Paper

WHITE PAPER

Discussion and Recommendations Related to *Arbacia punctulata* Whole Effluent Toxicity Testing Using Combined Effluent from the Bayamón, Puerto Nuevo and Bacardí Wastewater Treatment Plants

Prepared for

Bacardi Corporation

Prepared by

CH2MHILL

May 2007

Introduction

The wastewater treatment plant at the Bacardi Corporation (Bacardí) rum distillery in Cataño, Puerto Rico shares an ocean outfall with the Puerto Rico Aqueduct and Sewer Authority (PRASA) Bayamón and Puerto Nuevo regional wastewater treatment plants (RWWTPs). The combined effluent of the three facilities is discharged more than one-half mile offshore at a depth of 140 ft below mean sea level into dynamic ocean waters through a high-rate (>100:1 dilution) diffuser.

Bacardí and PRASA have submitted requests for National Pollutant Discharge Elimination System (NPDES) permit renewals for the three wastewater treatment facilities. The Puerto Rico Environmental Quality Board (EQB), in its statement of intent to issue a water quality certificate (WQC) for the existing NPDES permit for the Bacardi Corporation (Bacardí), required "a detailed description of the methodology to be utilized in the performance of the tests" for three sensitive marine test species used to evaluate possible short- and long-term effects of mixed effluent from the Bacardí, Bayamón, and Puerto Nuevo wastewater treatment plants (EQB, 2001).

Similarly, the new WQC that will be incorporated in the new NPDES permit (Permit No. PR0000591) may require acute and chronic whole effluent toxicity (WET) tests (bioassays) using the sheepshead minnow (*Cyprinodon variegatus*) and a mysid shrimp (*Mysidopsis bahia*), as well as chronic toxicity tests for the sea urchin *Arbacia punctulata (Arbacia)* using the existing EQB-approved WET test protocols. Per these protocols, the tests are performed on flow-proportional samples taken from the three effluents. A 24-hr composite sample is obtained from each facility; flow during the compositing period at each plant is recorded. The three effluent samples are sent to the bioassay laboratory with instructions about how to combine the samples in a proportional fashion based these flows. These flow-proportional composite samples are then used for WET testing and data evaluation.

The flow-proportional composite approach allows for an evaluation of whatever synergisms and/or antagonisms may be present in the three effluents in relation to the relative toxicity of the mixed effluent that is ultimately discharged to the marine environment. The WET test results are used by EQB to evaluate whether its receiving water toxicity requirements will be met at the edge of a small permitted mixing zone that is established around the outfall diffuser. A series of four tests are conducted during the first year of the permit, followed by annual testing during the remainder of the 5-year permit cycle to ensure that the relative toxicity of the effluent is not exceeding the receiving water requirements.

Bacardí has complied with similar requirements in its existing NPDES permit, reporting the WET results in terms of both statistical hypothesis testing and point estimates of relative toxicity for all three species: the minnow, the mysid shrimp, and the urchin. However, it has recently become apparent that the two data evaluation methods lead to very different conclusions in the case of the *Arbacia* tests.

In brief, the hypothesis-testing method relies on a No Observed Effects Concentration (NOEC) that is based on the statistical difference in variances between control and test populations of the organisms tested. The point estimate method uses a broader range of the WET test data to estimate (through interpolation) a sub-lethal biological response endpoint. Thus, the two methods may result in numerically different estimates of chronic endpoints.

An evaluation of published EPA guidance for WET test data interpretation indicates that the point estimation technique is preferred for purposes of regulatory compliance evaluations. This white paper is intended to clarify the most appropriate method to use for interpreting *Arbacia* test results with respect to both past and future WET test data obtained from the Bacardí, Bayamón, and Puerto Nuevo wastewater treatment plants. It discusses how NOECs derived from hypothesis testing frequently lead to "false positive" toxicity indications and summarizes key issues, presents case-specific data with respect to WET test findings and conclusions, questions whether statistical hypothesis testing should be used to evaluate the results of the chronic definitive bioassays conducted using *Arbacia*, and offers recommendations for what are considered to be appropriate WET test data evaluation methods when using *Arbacia* as a test organism.

Summary of *Arbacia* WET Test Results to Date

For the existing permit, the critical initial dilution (CID) and acceptable toxicity unit concentration (TUc) per the Puerto Rico Mixing Zone and Bioassay Guidelines are 142, equating to an acceptable NOEC of ≥ 0.70% effluent. For the renewal of the WQCs and NPDES permits for the Bacardí distillery and the Bayamón and Puerto Nuevo RWWTPs, which are expected to be issued by EQB and EPA, respectively, in 2007, the CID and compliance TUc are 104, equating to an acceptable NOEC of ≥ 0.96%.

Using the existing permit acceptable NOEC of ≥ 0.70% and statistical hypothesis testing to assess compliance, most of the tests indicate that the permitted chronic toxicity limit for *Arbacia* was not met. It is not clear whether the tests conducted on 8/29/2006 and 11/04/2006 complied at a NOEC of ≥ 0.70%. Using the anticipated NOEC of ≥ 0.96% for the new permit and statistical hypothesis testing to assess compliance, only the tests of 3/16/2006, 11/07/2006, 5/3/2007, 5/5/2007, and 5/17/2007 would have definitively complied with the Permit chronic toxicity limits.

These toxicity interpretations rely exclusively on statistical hypothesis testing to determine the NOEC (using Bonferroni's T-test), which is directly correlated to the degree of statistical variance in controls. Because this variance may be very small among control replicates, T-test results are purely statistically-based (i.e., based on statistical variance alone without respect to biological responses) and therefore are prone to "false positive" or Type I errors.

This is shown in Exhibit 1, where nine out of fourteen tests appear to be toxic (i.e., NOEC < 0.96% effluent) if evaluated by statistical hypothesis testing, but where using alternative EPA-approved (and preferred) data evaluation techniques (IC25[6] and biological significance testing) leads to the conclusion that there is no unacceptable toxicity indicated at the compliance TUc (or 0.96% combined effluent concentration).

In addition to the hypothesis testing-based NOECs, Exhibit 1 shows biologically-based NOEC values. These are based on an EPA test acceptability criterion that does not allow for a test to be considered valid if control fertilization rates are less than 70% (USEPA, 2002). Exhibit 1 also shows point estimates of chronic toxicity based on the IC25, which is commonly used and widely accepted by EPA and other regulatory agencies as a comparable

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[6] The IC25 is the percent concentration of a test solution that results in a 25% inhibition of a measurable biological response – in this case fertilization success of *Arbacia* eggs.

value of the chronic toxicity threshold. In the case of the biological significance and the IC25 toxicity evaluations, all of the values are ≥ 0.96% effluent, suggesting that none of the tests indicate unacceptable levels of toxicity. It is noted that IC25 point estimates allow the use of all of the WET test response data to determine, through linear interpolation, the point at which the toxicity response is equal to the target value (i.e., a 25% inhibition of fertilization).

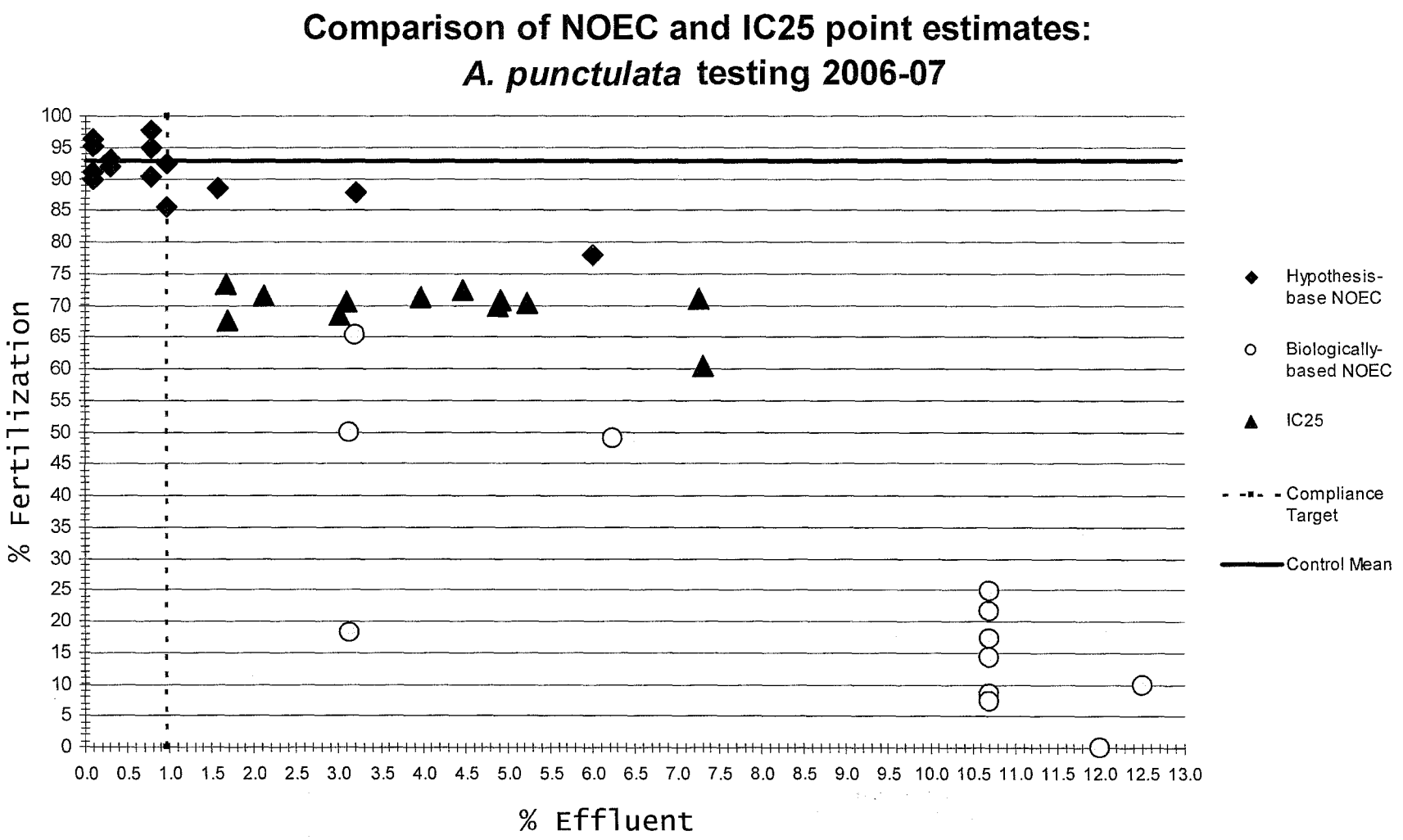
Exhibit 1. Summary of *Arbacia* Bioassay Tests Conducted to Date with Combined Bacardi/Bayamon/Puerto Nuevo Effluent, showing Comparison of NOECs with IC25 Point Estimates of Chronic Toxicity

Test Date	Hypothesis-based NOEC	% Fertilization	IC25	% Fertilization	Biologically-based NOEC	% Fertilization
2/16/06	0.78	95	7.25	71	12.5	10
3/16/06	6	78	7.31	60.4	3.13	50
8/29/06	<0.78	>68.8	1.68	67.7	3.13	18.25
11/4/06	<0.78	>91	1.67	73.3	6.25	48.9
11/7/06	1.56	88.6	3.97	71.3	10.7	8.6
4/17/07	0.29	93	3.09	70.5	3.2	65.4
4/19/07	<0.09	>90.8	2.12	71.6	10.7	7.4
4/21/07	<0.09	>91.5	4.47	72.3	12.0	0
5/1/07	0.09	91.1	4.92	70.7	10.7	14.2
5/3/07	0.96	92.4	14.8	69.6	35.5	1
5/5/07	3.2	87.8	14.4	67.9	35.5	4.3
5/15/07	0.09	89.8	4.88	70	10.7	24.8
5/17/07	0.96	85.5	3.01	68.5	10.7	17.3
5/19/07	0.29	92	5.23	70.4	10.7	21.5

Mean Control Fertilization = 92.9%

Exhibit 2 is a scatter plot showing percent fertilization and percent effluent for hypothesis-based NOECs, IC25 point estimates, and biologically-based NOEC values. It is clear that the only data points that appear to indicate non-compliant toxicity (i.e., are to the left of the 0.96% compliance target for the new WQC) are NOEC values derived from statistical hypothesis testing. Both the IC25 point estimates and the biologically-based NOEC data points do not provide evidence of unacceptable (non-compliant) effluent toxicity.

Exhibit 2. Percent Fertilization and Percent Effluent for Hypothesis-Based NOECs, IC25 Point Estimates and Biologically-Based NOEC Values



Alternative EPA-Approved *Arbacia* WET Test Data Evaluation Methods

EPA, in a recent evaluation of the WET test data developed by Bacardí in relation to its NPDES permit renewal and WQC applications, has assessed NOECs for *Arbacia* that are based solely on statistical hypothesis testing. The EPA interpretation of the data using that evaluative technique was that an unacceptable level of toxicity may exist in the effluent. Bacardí was ordered by EPA to perform a series of four additional tests at two-week intervals, according to the protocols in the existing NPDES permit, to obtain a more definitive evaluation of effluent toxicity.

As noted above, using statistical hypothesis testing to evaluate *Arbacia* WET test data is liable to introduce Type I errors because the percent fertilization variance within the control group replicates is normally very small. Thus, even a very small difference between the control group replicates and the effluent test group replicates would be calculated as statistically different from the variance for the control group, indicating an "effect" that is interpreted as "toxicity." This can either make it difficult to define a NOEC (as in the indeterminate <0.78 values in Exhibit 1) or may define a NOEC at an artificially low concentration that results in reported false positives for toxicity, and possibly erroneous findings of noncompliance with NPDES permit limits.

EPA has carefully addressed these and other issues related to toxicological data interpretation in several of its guidance documents. For example, in its 1991 *Technical Support Document for Water Quality-Based Toxics Control* (TSD; USEPA 1991), EPA compared results from hypothesis testing and point estimate endpoints such as the IC25 and concluded that:

> "Comparisons of both types of data indicate that a NOEC derived using the IC25 is the approximate analogue of a NOEC derived using hypothesis testing. For the above reasons, if possible, the IC25 is the preferred statistical method for determining the NOEC." (emphasis added)

Moreover, EPA (2000) specifically addresses effluent toxicity variability and states the following (on p. 6-4):

> "EPA recommends that point estimates be used to estimate effluent variability, to determine the need for limits, and to set permit limits. This is recommended whether the self-monitoring test results will be determined using hypothesis tests or point estimates. Point estimates have less analytical variability than NOECs using current experimental designs.... Point estimates make the best use of the whole effluent toxicity (WET) test data for purposes of estimating the coefficient of variation, long term average, and relative percent factors and calculating the permit limit." (emphasis added)

An EPA sponsored review committee was formed several years ago to assess this issue. The committee found that in the case of a species with low control variability, such as that exhibited by *Arbacia*, using only the NOEC derived from statistical hypothesis testing is problematic and may not be an effective approach for monitoring toxicity compliance and reporting. As a result of these issues EPA Region 1 modified the hypothesis testing approach to include the species test acceptability criteria (TAC) for determining permit compliance. This approach provides a more biologically relevant reporting endpoint for compliance evaluation. Documentation is provided at the following web page (http://www.epa.gov/region1/npdes/epa_attach.html)

under the link Marine Chronic Test Procedure and Protocol. The basis of the biological significance evaluation is that the TAC for control fertilization rate (>70% fertilization) is applied *in combination with* the statistical hypothesis testing results to determine the "biologically significant" effects concentrations (as opposed to only statistically-derived effects concentrations).

For its part, the Puerto Rico Water Quality Standards Regulation (PRWQSR) defines chronic toxicity testing and evaluation as follows:

> Chronic Bioassay
> Toxicity test designed to determine if the response to a stimulus such as, a total effluent, a specific substances, or combination of these has sufficient severity to induce a long-term effect that could linger for up to one-tenth of the life span of the organism. A chronic effect could be lethality, growth rate reduction, reproduction rate reduction, etc. A chronic bioassay shall be performed according to procedures described in "Mixing Zone and Bioassay Guidelines", approved by the Board.
>
> Chronic Effect
> Organism response to a stimulus, detected during a chronic bioassay, that comprises a stimulus that lingers or continues for a relatively long period of time, which could be of the order of one-tenth of the life span of the organism used in the test. A chronic effect could imply lethality, growth rate reduction, reduced reproduction rate, etc.
>
> Chronic Toxic Unit
> The reciprocal of the effluent dilution that causes no unacceptable effect on the test organisms by the end of the chronic exposure period, obtained during a chronic bioassay, as defined by the following equation:
>
> $$TUc = \frac{100}{NOEC}$$
>
> (The NOEC value should be expressed in terms of the percent (%) of the effluent in the dilution water).

It is noted that, although the PRWQSR chronic toxicity definition refers to a NOEC, it does not refer to a specific method by which a NOEC is to be obtained. It is further noted that the PRWQSR refers to the *Puerto Rico Mixing Zone and Bioassay Guidelines*, which are defined as follows:

> Technical guidelines developed by the Board which describe procedures, methods, models, techniques and organisms to be used to calculate the initial dilution; perform chronic and acute bioassays; to collect field data, or to establish the natural background concentration value, as required to verify compliance with inherent mixing zone conditions. These Guidelines are based on the following EPA publication: "Technical Support Document for Water Quality Based Toxics Control" and Users Guide to the Conduct and Interpretation of Complex Effluent Toxicity Tests at Estuarine/Marine Sites".7 The guidelines will be revised, as necessary, in accordance with updated versions of these documents or other documents released by EPA which directly impact the guidelines in effect at the time of publication of the final document.

There are several alternative EPA-approved methods that are available to evaluate compliance with toxicity criteria that do not rely solely on statistical hypothesis testing. These include

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7 It is noted that the most recent version of the Puerto Rico Mixing Zone and Bioassay Guidelines is a 1989 draft that predates the 2001 EPA Technical Support Document, and that advances in methods and technology in the last 17 years are therefore not reflected in the Guidelines. However, the Guidelines explicitly provide EQB with the ability to approve alternative methods.

biological significance evaluation (as described above used by EPA Region 1), IC25 point estimate evaluation, and test variability evaluation.[8] Of the three, the first two are in more common use for *Arbacia* fertilization tests. These are simply WET test data evaluation alternatives; they are not WET test protocol alternatives. The following subsections discuss these alternative methods. It is noted that these data evaluation alternatives should also be applicable to other Puerto Rico NPDES permits that use *Arbacia* as a test organism.

Biological Significance Evaluation

EPA Region 1 has recognized that evaluation of *Arbacia* fertilization tests using statistical hypothesis testing often results in putative statistically-based "toxicity effects" at effluent concentrations that are much lower than likely biological effects. When the fertilization success in the control group replicates varies by only small percentages, a statistically significant difference between the control and a test group could be interpreted as a "toxic" response, without respect to biological significance.

The EPA Region 1 website (see Marine Chronic Testing Methods, Section V: Test Methods, Item #16 in the Table of Recommended Test Conditions under "Acceptability of Test") stipulates that fertilization rates for the control group of replicates should be greater than 70%. For the purposes of evaluating permit compliance, if test group results yield fertilization rates greater than 70% (i.e., within the range of acceptable control group fertilization), but are shown to be statistically different from the control using hypothesis testing, those test group concentrations are not considered different from the control for the purposes of assessing toxicity (i.e., they are not biologically significant; see biologically-based NOEC data in Exhibit 1). In a test where that occurs, the NOEC concentration corresponds to the highest test group concentration that has a fertilization rate greater than or equal to 70%, without regard to whether it is statistically different from the control using hypothesis testing.

This combined hypothesis testing/biological significance method for *Arbacia* WET test data compliance evaluation is considered by EPA Region 1 to be a reliable approach and is preferred over the sole use of statistical hypothesis testing. Therefore, it is believed that evaluating the biological significance results for the Bayamón/Puerto Nuevo/Bacardí discharge system WET tests using this approach is a practical and acceptable means by which to evaluate compliance with toxicity criteria for *Arbacia*. This approach could replace statistical hypothesis testing alone as per EPA Region 1 data evaluation protocols.

IC25 Evaluation

Exhibit 1 also shows the IC25 point estimates for the *Arbacia* WET tests that have been conducted to date for the Bayamón/Puerto Nuevo/Bacardí discharge system. The IC25 is a commonly used, widely accepted point estimation technique that is calculated to estimate chronic toxicity thresholds. The IC25 method uses all of the WET test data as opposed to statistical hypothesis testing, which does not. As seen in Exhibit 1, if IC25 values were used to evaluate the data, all *Arbacia* chronic WET test results would have met permit compliance requirements of no chronic toxicity at the edge of the mixing zone at concentrations less than either the existing (0.70%) or anticipated future (0.96%) compliance targets.

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[8] Test variability evaluation is discussed in Appendix 1 to this white paper.

In the preamble to its *Final Rule for Guidelines Establishing Test Procedure for the Analysis of Pollutants; Whole Effluent Toxicity Test Methods*, Fed. Reg. 69951-69972 (November 19, 2002) EPA states in two separate discussions:

> "EPA recommends the use of point estimation techniques over hypothesis testing approaches for calculating endpoints for effluent toxicity tests under NPDES Permitting Program."

(*Id.* at 69957 and 69958.) This statement is reiterated in EPA (2002). On Page 44, section 9, EPA states:

> "**NOTE: For the NPDES Permit Program, the point estimation techniques are the preferred statistical methods in calculating end points for effluent toxicity tests.**" (emphasis in original).

Therefore, it is believed that evaluating the IC25 point estimate for the Bayamón/Puerto Nuevo/Bacardí discharge system bioassays (or other NPDES permits requiring *Arbacia* testing) not only represents a reliable alternative with which to evaluate permit compliance relating to *Arbacia* test data, it is the preferred method of evaluation.

Summary

Arbacia is a species for which conventional statistically-based hypothesis testing alone typically fails to provide biologically meaningful results with respect to identifying toxicity for the purposes of permit compliance reporting. The problem stems largely from the very low variability in the control test fertilization responses. Because of this low variability, a very small difference between test dilutions and controls may be found to be statistically significant and interpreted as "toxic", when instead the results may lie within the range of the normal biological variability that is considered to be acceptable for the control replicates.

EPA (1991) and other subsequent EPA documents that address statistical variability, WET test analysis methodology, and NPDES compliance reporting provide insight and interpretive guidance that support a broader and more flexible evaluation of *Arbacia* WET test results than relying only on statistical hypothesis testing. In fact, EPA WET test evaluation guidance consistently recommends point estimation methods in preference to statistical hypothesis testing.

Conclusions and Recommendations

There are clearly problems inherent with using statistical hypothesis testing to evaluate toxicity data from *Arbacia* fertilization tests. EPA provides toxicity test evaluation guidance that explicitly recommends point estimate techniques as preferred alternatives to statistical hypothesis testing. Further, the PRQWSR and the associated Puerto Rico Mixing Zone and Bioassay Guidelines provide the flexibility to use alternative, EPA-approved approaches to compliance evaluations as they become available.

It is believed that a review of alternative methods for evaluating *Arbacia* test data and incorporating more appropriate agency-approved methods in new NPDES permits is warranted. Based on the above analysis, it is suggested that Bacardí (and PRASA) request that

EPA and EQB consider the following options as the basis for toxicity compliance evaluations for WET tests using *Arbacia*:

1. Use the IC25 point estimate methodology as the definitive toxicity evaluation.
2. Adopt the EPA Region 1 test acceptability criterion, using biological significance (i.e., the biologically significant NOEC as shown on Exhibit 1) in combination with statistical hypothesis testing.
3. Use both biological significance-based NOECs and IC25 point estimates to determine effluent toxicity using Arbacia data.

Options 1 or 2 are preferred, as they follow clear EPA guidance, and have already proven acceptable to EPA for use in NPDES permits for *Arbacia* WET test evaluation, and are therefore presumed to be acceptable (after careful review and evaluation) by EQB in light of the flexibility offered by the Puerto Rico Mixing Zone and Bioassay Guidelines. However, Option 3 is also acceptable and is consistent with EPA guidance concerning evaluation of acceptable whole effluent toxicity.

References

Environmental Quality Board. 2001. Intent to Issue Water Quality Certificates to Define and Authorize a Mixing Zone and Approve Compliance Plans. NPDES Permit No. PR0000591. Authorization to Bacardi Corporation to discharge under the NPDES System.

Federal Register. *Final Rule for Guidelines Establishing Test Procedure for the Analysis of Pollutants; Whole Effluent Toxicity Test Methods*, Fed. Reg. 69951-69972 (November 19, 2002)

National Association of Clean Water Agencies (NACWA). 2006. *Whole Effluent Toxicity (WET) NPDES Permit Testing and Limitations for Public Agencies.* White paper, January 2006.

USEPA. 2002. *Short-Term Methods For Estimating the Chronic Toxicity of Effluents and Receiving Water to Marine and Estuarine Organisms* (EPA-821-R-02-014, Third Edition).

USEPA. 2000. *Understanding and Accounting for Method Variability in Whole Effluent Toxicity Applications under the National Pollutant Discharge Elimination System.* EPA 833-R-00-003, June 2000.

USEPA. 1991. *Technical Support Document for Water Quality-Based Toxics Control* (TSD), EPA/505/2-90/001. USEPA Office of Water.

Appendix A

Test Variability Evaluation when using Hypothesis Testing Methods

In the Preamble to its Final Rule, 67 Fed. Reg. at 69968, EPA states:

> "....to reduce the within-test variability and to increase statistical sensitivity when test endpoints are expressed using hypothesis testing rather than the preferred point estimation techniques, variability criteria must be applied as a test review step when NPDES permits require sublethal hypothesis testing endpoints (i.e., NOEC or LOEC) and the effluent has been determined to have no toxicity at the permitted receiving water concentration."

(67 Fed. Reg. at 69967 (emphasis added).) For tests for which in-test variability assessment is required, EPA defines this variability term as the percent minimum significant difference (PMSD). The Preamble to the EPA Final Rule states:

> "Within-test variability, measured as the percent minimum significant difference (PMSD), must be calculated and compared to upper bounds established for test PMSDs. Under this new requirement, tests conducted under NPDES permits that fail to meet the variability criteria (i.e., PMSD upper bound) and show "no toxicity" at the permitted receiving water concentration (i.e., no significant difference from the control at the receiving water concentration or above) are considered invalid and must be repeated on a newly collected sample."

(*Id.*) The EPA Final Rule did not include specific language requiring mandatory application of variability criteria for *Arbacia* fertilization tests, although a number of species with similar control test variability characteristics were defined. The Preamble to that Final Rule indicates that for the chronic methods that were not evaluated in the WET Interlaboratory Variability Study, EPA does not have sufficient data to support the implementation of mandatory variability criteria at this time.

Important to the issue of test variability, especially in the case of the *Arbacia* fertilization tests, are the following statements by EPA in the Preamble to the Final Rule:

> "Lower bounds on the PMSD are also applied, such that test concentrations shall not be considered toxic (i.e., significantly different from the control) if the relative difference from the control is less than the lower PMSD bound."

(*Id.* at 69957.) and

> "According to the proposed approach, any test treatment with a percentage difference from the control (i.e., [mean control response-- mean treatment response]/ mean control response * 100) that is greater than the upper PMSD bound would be considered as significantly different; and any test treatment with a percentage difference from the control that is less than the lower PMSD bound would not be considered as significantly different."

(*Id.* at 69958.)

Because EPA, at the time of issuing its Final Rule, did not have sufficient data from an Interlaboratory Variability Study to develop variability criteria and PMSD bounds for the *Arbacia* fertilization test, there are no existing criteria with which to examine test variability. While test variability might prove to be an acceptable WET test data evaluation option for *Arbacia*, using it would require constructing a database that is not currently available. It is not believed that this approach is compatible with the current Bacardí and PRASA permit renewal schedules and it is further noted that there are other EPA-approved alternatives that are both appropriate and already in use for NPDES permit toxicity compliance evaluations for *Arbacia*.