APPENDIX A

Autoridad de Acueductos
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CUMPLIMIENTO Y CONTROL DE CALIDAD

August 15, 2011

Chief, Clean Water Regulatory Branch
U.S. Environmental Protection Agency, Region 2
290 Broadway, 24th Floor
New York, NY 10007

Re: Puerto Rico Aqueduct and Sewer Authority Comments on the Draft NPDES Permit (PR0021555) Issued by the U.S. Environmental Protection Agency on July 1, 2011

Dear Sir or Madam:

The Puerto Rico Aqueduct and Sewer Authority (PRASA) has reviewed the referenced Draft National Pollutant Discharge Elimination System (NPDES) permit issued for the Puerto Nuevo Regional Wastewater Treatment Plant by the U.S. Environmental Protection Agency (EPA) on July 1, 2011. PRASA offers its comments and requests to EPA in Attachment 1 to this letter for EPA's review and consideration. Substantiating information is provided in Attachments 2 through 4.

If you have any questions regarding this matter, please contact Eng. Juan Carlos Pérez Bofill at 787-620-2277 ext. 2390.

Cordially,

por Juan Carlos B

José Capeles, P.E.
Executive Director,
Compliance and Quality Control

Enclosures

c: Jaime Géliga, EPA Region 2-Caribbean Environmental Protection Division
Yasmin Laguer, EPA Region2-Caribbean Environmental Protection Division
Karen O'Brien, EPA Region 2
Roberto Ayala, EQB
Wanda García, EQB

Attachment 1
Comments on the July 1, 2011, Draft NPDES Permit (PR0021555) for the Puerto Nuevo Regional Wastewater Treatment Plant

ATTACHMENT 1

Puerto Rico Aqueduct and Sewer Authority Comments on the July 1, 2011, Draft NPDES Permit (PR0021555) for the Puerto Nuevo Regional Wastewater Treatment Plant

PRASA offers the following comments on the draft NPDES permit, including specific requests for changes in the final permit.

Section	Page	Comments/Concerns	Action Requested
Table 1	3 of 28	The draft permit was issued in response to PRASA's request for increased monthly average flow. In its request, PRASA agreed during discussions with EPA and the Puerto Rico Environmental Quality Board (EQB) to maintain current BOD_5 and TSS loadings, with concomitant decreases in effluent concentrations. The monthly average BOD_5 limitations proposed in the draft permit reflect this agreement. However, the decrease in the BOD_5 weekly average loading is inconsistent with the unchanged monthly average and is unexplained in the Fact Sheet issued by EPA. Additionally, the monthly average TSS loading limitation is higher than the current limitation because EPA did not reduce the concentration limitation as expected, but maintained it as in the current permit. The decrease in the TSS weekly average loading is inconsistent with the increased monthly average and is unexplained in the Fact Sheet issued by EPA.	It has been documented through over a decade of intensive monitoring, with reports submitted to EPA and EQB, that the existing BOD_5 and TSS limitations have not caused any environmental problems. Therefore, PRASA requests that EPA not change the limitations for BOD_5 and TSS from those requested by PRASA in its NPDES renewal application.
Table A-1	8 of 28	Footnote "@" indicates that the detection limit for sulfide is 100 µg/L. This appears to be a typographical error; it is assumed that the detection limit should be 2 µg/L.	Correct footnote "@" to refer to a detection limit of 2 µg/L for sulfide.
Table A-1	8 of 28	Footnote "@" indicates that the permit limitation is 2 µg/L. The correct effluent limitation is 84 µg/L. (The limitation at the edge of the mixing zone is 2 µg/L.)	Correct footnote "@" to correctly refer to the permit limitation.

Section	Page	Comments/Concerns	Action Requested
SC 19.a	12 of 28	The diffuser description is not correct based on the most recent inspection. It should be corrected to be consistent with the description in the draft fact sheet.	Replace the description in the draft permit with the one from the draft 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 nearest 7-inch port.]
SC 19.a	12 of 28	The coordinates shown in SC 19.a, which are those specified in the final WQC, do not match those in Diagram-I (page 21 of 28).	Change the coordinates in Diagram-I to the coordinates shown in SC 19.a.
SC 19.c	13 of 28	Acute toxicity tests for *Arbacia* are required, but the only EPA-approved test for this organism is for chronic toxicity.	Delete the reference to acute toxicity testing for *Arbacia*.
SC 20.a	15 of 28	The second paragraph refers to Bacardí effluent, but presumably should refer to Puerto Nuevo effluent.	Replace the reference to Bacardí effluent with reference to Puerto Nuevo effluent.
SC 20.b	15 of 28	This requires that no test result for any species or effect in the combined discharge shall be greater than 83.32 TUc, a limit that was calculated by EPA on the basis that there are no numerical standards in the PRWQSR. However, contrary to EPA's statement in its draft 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 TUc value is 102, not 83.32. In addition, the limitation for *Arbacia* should be specifically based on the IC25 endpoint. PRASA requests that these changes be made to the final permit. 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 Attachments 2 and 3 to this comment document.

Section	Page	Comments/Concerns	Action Requested
SC 20.c	15 of 28	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.	Change the wording to read as follows: "This plan shall include steps the permittee is to follow if the toxicity limitation is violated and must include, at a minimum:"
SC 20.d.1, 2, and 3	16 of 28	These items reference Bacardí, but presumably should reference Puerto Nuevo.	Change the references from Bacardí to Puerto Nuevo.
SC20.d.3.3	17 of 28	The requirement states that the TRE may be performed in conjunction with the Puerto Nuevo and Bayamón facilities.	Change the wording to state that the TRE may be performed in conjunction with the Bayamón and Bacardí facilities.
SC 20.d.6	17 of 28	This item refers to SC 20.g.3. There is no g.3; it is presumed this is supposed to refer to f.3.	Change the reference to SC 20.f.3.
SC 20.d.6 and SC 20.f.3	18 of 28	These items require reporting to be done within 30 days after permittee's receipt of the laboratory results. This is inconsistent with SC 19.g, which requires reporting within 60 days following completion of the test.	Change to maintain consistency with the final WQC, which requires reports within 60 days of the completion of the tests.
Diagram-I	21 of 28	The coordinates shown in Diagram-I do not match those in SC 19.a, which are those specified in the final WQC.	Change the coordinates in both Diagram-I to those referenced in SC 19.a.
CSO Outfall Table	1 of 7	In the proposed permit, the Outfall 002 Barriada Figueroa location is indicated at the discharge location of the Department of Natural and Environmental Resources (DNER) pump station (near the San Juan Natatorium). The DNER pump station receives waters from numerous sources. PRASA does not have the authority to regulate all the flows received at the DNER Pump station. Additionally, PRASA has identified one overflow weir located near the intersection of San Ramón and Del Carmen Streets in the sanitary sewer system. This is the only known location where sewage may flow into the storm sewer system related to Barriada Figueroa. PRASA has the authority to operate and maintain the sanitary sewer at this location.	Replace the reference to Outfall 002 as "Barriada Figueroa" with a reference to the overflow weir installed in the manhole located near the intersection of San Ramón and Del Carmen Streets.
CSO Outfall Table	1 of 7	The coordinates for the corrected Outfall 002 location near the intersection of San Ramón and Del Carmen Streets are 18°27'2.47 N, 66°4'34.05" W and should be indicated in the Overflow Outfall Location column.	Correct the Outfall 002 coordinates as indicated.

Section	Page	Comments/Concerns	Action Requested
CSO Outfall Table	1 of 7	To avoid confusion, discussion of Outfall 002 should consistently reference its corrected location, which is near the intersection of San Ramón and Del Carmen Streets.	Change Outfall 002 references to "*Outfall 002 near the intersection of San Ramón and Del Carmen Streets.*"
CSO Outfall Table	1 of 7	The receiving water body for Outfall 002 near the intersection of San Ramón and Del Carmen Streets is more correctly described as Caño Martín Peña via the storm sewer, not San Juan Bay Estuary.	Correct references to the Outfall 002 receiving water body to Caño Martín Peña via the storm sewer.
CSO Outfall Table	1 of 7	To avoid confusion, discussion of Outfall 003 should be consistently referenced as "Puerta de San Juan".	Correct the Outfall 003 "*Outfall 003 Puerta de San Juan*".
CSO Outfall Table	1 of 7	The coordinates for Outfall 003 Puerta de San Juan are incorrect as shown in the Overflow Outfall Location column.	Correct the Outfall 003 coordinates to 18°27'53.524" N, 66°7'11.538" W.
CSO Outfall Table	1 of 7	The stated receiving water body (the Atlantic Ocean) for Outfall 003 Puerta de San Juan is not correct.	Change the Outfall 003 receiving water body to San Juan Bay.
CSO Outfall Table	1 of 7	There is a misspelling in the description of Outfall 004	Change "*Cortez Industrial*" to "*Cortes Industrial*".
CSO Outfall Table	1 of 7	The coordinates for Outfall 004 Miramar (behind Cortes Industrial) are incorrect as shown in the Overflow Outfall Location column.	Change the coordinates to 18°26'50.060" N, 66°5'7.551" W.
CSO Outfall Table	1 of 7	The receiving water body for Outfall 004 Miramar (behind Cortes Industrial) is incorrect.	Change the description of the receiving water for Outfall 004 to San Juan Bay.
CSO Outfall Table	1 of 7	The coordinates for Outfall 005 Los Angeles (Retention Pond) are incorrect as shown in the Overflow Outfall Location column. Further, PRASA has permanently removed sanitary sewer input to the Los Angeles Retention Pond.	Remove Outfall 005 Los Angeles (Retention Pond) from the CSO outfall table in the final permit.
CSO Outfall Table	1 of 7	Two CSO outfall locations have been identified in the Paseo La Princesa area. The first location is identified as Outfall 003 in the draft NDPES permit CSO Outfall Table. The second location has been identified at the end of the pier near the Puerta de San Juan.	Add a new CSO outfall to the table and identify it as Outfall 005 at the Paseo La Princesa Pier. The coordinates for Outfall 005 are 18°27'54.383" N, 66°7'10.887" W. The corresponding receiving water body is San Juan Bay.
CSO Outfall Table	1 of 7	The process to add CSO outfalls to the permit is not balanced by a process to remove them.	Add the following sentence to the end of the paragraph following the CSO Outfalls table: "*In a similar manner, if any of the CSO outfalls covered by this permit is confirmed to have been eliminated, the permittee will be allowed to discontinue the practices at the eliminated outfall that are required for active CSO outfalls.*"

Section	Page	Comments/Concerns	Action Requested
I.A.4	1 of 7	Operating the publicly owned treatment works [POTW] at maximum treatable flow (144 mgd according to the proposed permit limitation) may not be in the best interest of protecting the facility or the environment.	Edit the final sentence of Item I.A.4 to read as follows: *"The permittee shall maximize flows to the treatment plant within the constraints of the current treatment capacity of the POTW and the existing conveyance capacity of the collection system."*
I.A.7	2 of 7	PRASA does not have the authority to implement or manage stormwater pollution prevention activities such as street sweeping, trash collection, and erosion control during third party construction projects on roadways.	Edit Item I.A.7 to read as follows: *"The permittee shall implement a pollution prevention program, consistent with the permittee's authorities, focused on reducing the impact of CSOs on receiving waters;"*
I.A.9	2 of 7	The second sentence of Item I.A.9 states: *"This shall include collection of data that will be used to document the existing baseline conditions, evaluate the efficacy of the technology-based controls, and determine the baseline conditions upon which the long-term control plan will be based."* This language fails to identify the specific types of data that will be collected.	Edit the second sentence of Item I.A.9 to read as follows: "This shall include collection of data according to an EPA-approved data collection Quality Assurance Project Plan (QAPP) based on standard CSO guidelines. The QAPP will be developed by PRASA and used to document the existing baseline conditions, evaluate the efficacy of the technology-based controls, and determine the baseline conditions upon which the long-term control plan will be based. The data collection QAPP will be submitted to EPA for review and comment within 90 days of the Effective Date of Permit (EDP). Implementation of QAPP activities will begin no later than 180 days after receipt by PRASA of formal approval of the QAPP by EPA. Reporting frequency will occur as established in the QAPP, but will occur on no less than an annual basis."
I.A.9.e	2 of 7	The proposed permit language includes the following: *"e. Water quality impacts directly related to CSOs (e.g., beach closing, floatables wash-up episodes, fish kills)."* There is simply no economically feasible way to design a data collection program that would be able to establish cause-and-effect relationships that would distinguish the effects of CSO discharges from water quality degradation caused by other environmental factors, such as nonpoint source runoff.	Delete the language in I.9.e from the permit.
I.B; first paragraph	2 of 7	The proposed permit language states: *"The permittee shall not discharge any pollutant at a level that causes or contributes to an in-stream excursion above numeric or narrative criteria developed and adopted as part of Puerto Rico's water quality standards."* This is too generic in relation to supporting Long Term Control Plan (LTCP) goals.	Edit the first paragraph of Item I.B to read as follows: *"The permittee shall not discharge any pollutant specified in the data collection QAPP at a level that causes or contributes to an in-stream excursion above numeric or narrative criteria developed and adopted as part of Puerto Rico's water quality standards."*

Section	Page	Comments/Concerns	Action Requested
II.A.	3 of 7	A number of the nine minimum control (NMC) measures requested in Section III.E of Attachment 2 of the draft NPDES permit will take years to complete. In addition, it will not be possible to develop an NMC report that indicates any real progress towards implementation of the nine minimum controls within the schedule stipulated in the draft permit because of the amount of information that needs to be obtained during records reviews and personnel interviews and the subsequent information synthesis and evaluation required.	Edit Item II.A to read as follows: *"A. Nine Minimum Controls Report* *The permittee shall submit documentation that indicates progress towards implementation of each of the nine minimum controls that includes the elements below. With the exception of number nine (9) below, the permittee shall submit this documentation to the permitting authority no later than EDP + 6 months. The permittee shall submit such documentation for number nine (9) below no later than EDP + 1 year."*
II.A.1	3 of 7	"Operation and maintenance" is defined on page 8 of Attachment 2.	Edit Item II.A.1 to read as follows: *"Operation and maintenance programs for the sewer system and the CSOs;"*
III.B; first sentence	4 of 7	The proposed permit language states: *"The permittee shall develop and implement a plan that will result in a comprehensive characterization of the CSS developed through records review, monitoring, modeling, and other means as appropriate to establish the existing baseline conditions, evaluate the efficacy of the CSO technology-based controls, and determine the baseline conditions upon which the long-term control plan will be based."* This is too generic in relation to supporting the LTCP goals.	Edit first sentence of Item III.B to read as follows: *"The permittee shall develop and implement a plan based on the information collected as a result of implementing the EPA-approved QAPP that will result in a comprehensive characterization of the CSS developed through records review, monitoring, modeling, and other means as appropriate to establish the existing baseline conditions, evaluate the efficacy of the CSO technology-based controls, and determine the baseline conditions upon which the long-term control plan will be based."*
III.B	4 of 7	The second paragraph of section III.B is too prescriptive.	Edit the second paragraph of Item III.B to read as follows: *"To complete the characterization, the permittee shall employ methods such as the following:"*
III.B.1	4 of 7	The CSO outfall receiving water bodies include the Martín Peña Channel and San Juan Bay. Flow variation evaluations, as required by the draft permit, cannot be determined in these receiving water bodies. (That concept is more appropriate for rivers than for marine embayments and tidal channels.)	Edit Item III.B.1 to read as follows: *"Rainfall Records Review. The permittee shall examine rainfall records from the USGS, NOAA, and the FAA to characterize the rain event intensities within the geographic areas of the CSS. Additional rain fall monitoring may be required to more accurately model the CSS."*

Section	Page	Comments/Concerns	Action Requested
III.B.3	4 of 7	The proposed permit language states: "CSO and Water Quality Monitoring. The permittee shall develop and submit a monitoring program that measures the frequency, duration, flow rate, volume, and pollutant concentration of CSOs and assesses the impact of the CSOs on receiving waters. Monitoring shall be performed at a representative number of CSOs for a representative number of events. The monitoring program shall include CSOs and ambient receiving water body monitoring and, where appropriate, other monitoring protocols, such as biological assessments, toxicity testing, and sediment sampling." This is too generic in relation to supporting LTCP goals.	Edit Item III.B.3 to read as follows: *"CSO and Water Quality Monitoring. The permittee shall develop and submit a data collection QAPP for EPA review and approval that supports achieving Long Term Control Plan goals. The data collection QAPP will be submitted to EPA for review and comment within 90 days of EDP. Implementation of QAPP activities will begin no later than 180 days after receipt by PRASA of formal approval of the QAPP by EPA. Reporting frequency will occur as established in the QAPP, but will occur on no less than an annual basis."*
III.C.2	5 of 7	The proposed permit language does not take practicability into account. CSO control alternatives considered must be practicable for them to be implemented.	Edit Item III.C.2 to read as follows: *"The permittee shall evaluate each of the alternatives developed in accordance with Section III.C.1 to select the practicable CSO controls that will improve compliance with CWA requirements; and..."*
III.D.3	5 of 7	The proposed permit language states: "Post-Construction Compliance Monitoring Program. The permittee shall develop and submit a post-construction monitoring program that (a) is adequate to ascertain the effectiveness of the CSO controls and (b) can be used to verify attainment of water quality standards. The program shall include a plan that details the monitoring protocols to be followed, including CSO and ambient monitoring and, where appropriate, other monitoring protocols, such as biological assessments, whole effluent toxicity testing, and sediment sampling." This is too generic in relation to supporting LTCP goals.	Edit Item III.D.3 to read as follows: *"The permittee shall develop and submit a data collection QAPP for EPA review and approval that supports achieving Long Term Control Plan goals. The data collection QAPP will be submitted to EPA for review and comment within 90 days of EDP. Implementation of QAPP activities will begin no later than 180 days after receipt by PRASA of formal approval of the QAPP by EPA. Reporting frequency will occur as established in the QAPP, but will occur on no less than an annual basis."*
III.E.2	6 of 7	Development of a monitoring and modeling plan requires thorough knowledge of the sanitary sewer system and the combined sewer system. Initial site assessment of the service area associated with each CSO outfall location will have to be completed, and a clear understanding of the extent of the service area are required to effectively develop a monitoring and modeling plan. A period of 2 years from EDP will be necessary to complete the CSS Characterization Monitoring and Modeling Plan.	Change the period of time to complete the CSS Characterization Monitoring and Modeling Plan required to comply with Item III.E.2 to EDP + 2 years.

Section	Page	Comments/Concerns	Action Requested
III.E.3	6 of 7	The proposed permit languages states: "The permittee shall develop, in accordance with the requirements specified in Sections III.A through III.D, and submit the following items no later than the dates set forth below:..." and goes on to list a number of activities – specifically those set forth in items 4 through 8 – that cannot be completed within the allotted time or even within the permit period. Activities such as developing a thorough understanding of the sewer system, selection of monitoring sites, and monitoring of the sewer system and water quality require a significant amount of time to complete. These activities are required for the development of a sewer model and running the model afterwards to obtain useful results. A total of 4 years will be necessary to comply with Item III.E.3.	Change the period of time to complete the characterization and modeling results required to comply with Item III.E.3 to EDP + 4 years.
III.E.4-8	6 of 7	Items III.E.4 through III.E.8 in the proposed permit cannot be completed until after Item III.E.3 is completed; therefore, they cannot be completed within this permit cycle.	Include reference to a separate compliance plan to be developed between PRASA and EPA for completion of tasks that follow Item III.E.3.
General	NA	Although the 2008 AO against CSOs (CWA-02-2008-3155) names the two pinch valves referred to as the Plaza Las Américas and Constitution Bridge pinch valves as individual CSO locations, the draft NPDES permit is silent with respect to these structures.	PRASA requests that EPA include the Plaza Las Américas and Constitution Bridge pinch valves in the final NPDES permit as "Emergency Waste Water Exits" (EWWEs), a precedent for which exists in the current Milwaukee Metropolitan Sewer District NPDES permit. This request is discussed in more detail in Attachment 5 to this comment document, which includes requested permit language.

Attachment 2
Whole Effluent Toxicity Evaluation

ATTACHMENT 2

Whole Effluent Toxicity Requirements Evaluation

The current and proposed National Pollutant Discharge Elimination System (NPDES) permits for the Bacardí Wastewater Treatment System (WWTS) and the Puerto Rico Aqueduct and Sewer Authority (PRASA) Bayamón, and Puerto Nuevo Regional Wastewater Treatment Plants (RWWTPs) include Whole Effluent Toxicity (WET) test compliance limitations in reference to flow-proportional combined 24-hour 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 percent). 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 draft EPA Fact Sheet[1] 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.[2] 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 No Observed Effect Concentration (NOEC) end point were used, the *Arbacia*

[1] EPA. Fact Sheet for Draft National Pollutant Discharge Elimination System (NPDES) Permit to Discharge Into the Waters of the United States NPDES Permit No. PR0021555.

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

test results would indicate non-compliance in a significant number of cases, as shown by the shaded entries in Exhibit 2-1.

EXHIBIT 2-1
Bioassay Test Results for the Bayamón/Puerto Nuevo/Bacardí Flow-weighted Effluent Composite

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 2-1
Bioassay Test Results for the Bayamón/Puerto Nuevo/Bacardí Flow-weighted Effluent Composite

Date	Organism	Percent Effluent	
		Chronic NOEC	Chronic IC25
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

Note:
Shaded entries indicate IC25 < 1.2% effluent.

Exhibit 2-2 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.[3]

[3]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 2-2
Bioassay Test Results for the Bayamón/Puerto Nuevo/Bacardí Individual Flows using *Arbacia Punctulata*

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%[a]
	[a]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%[b]
	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%
May 2011	Bacardí WWTP	0.09%	0.14%
	Bayamón WWTP	2.70%	6.43%
	Puerto Nuevo WWTP	1.80%	8.05%

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

Contrary to EPA's statement in its draft 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 Attachment 3 to this document.[4]

The conclusions are unequivocal that the use of IC25 point estimate techniques or biologically-based NOECs (>70 percent 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)[5] 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[6] tested 775 valid WET tests for a comparison of results using the TST or NOEC approaches 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).
- Truly non-toxic samples were more often declared non-toxic using the TST than NOEC approaches to testing.
- The addition of minimal replicates (more than four) 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 (Attachment 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*.

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[4]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.

[5]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.

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

Attachment 3
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[7] 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

[7] 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).

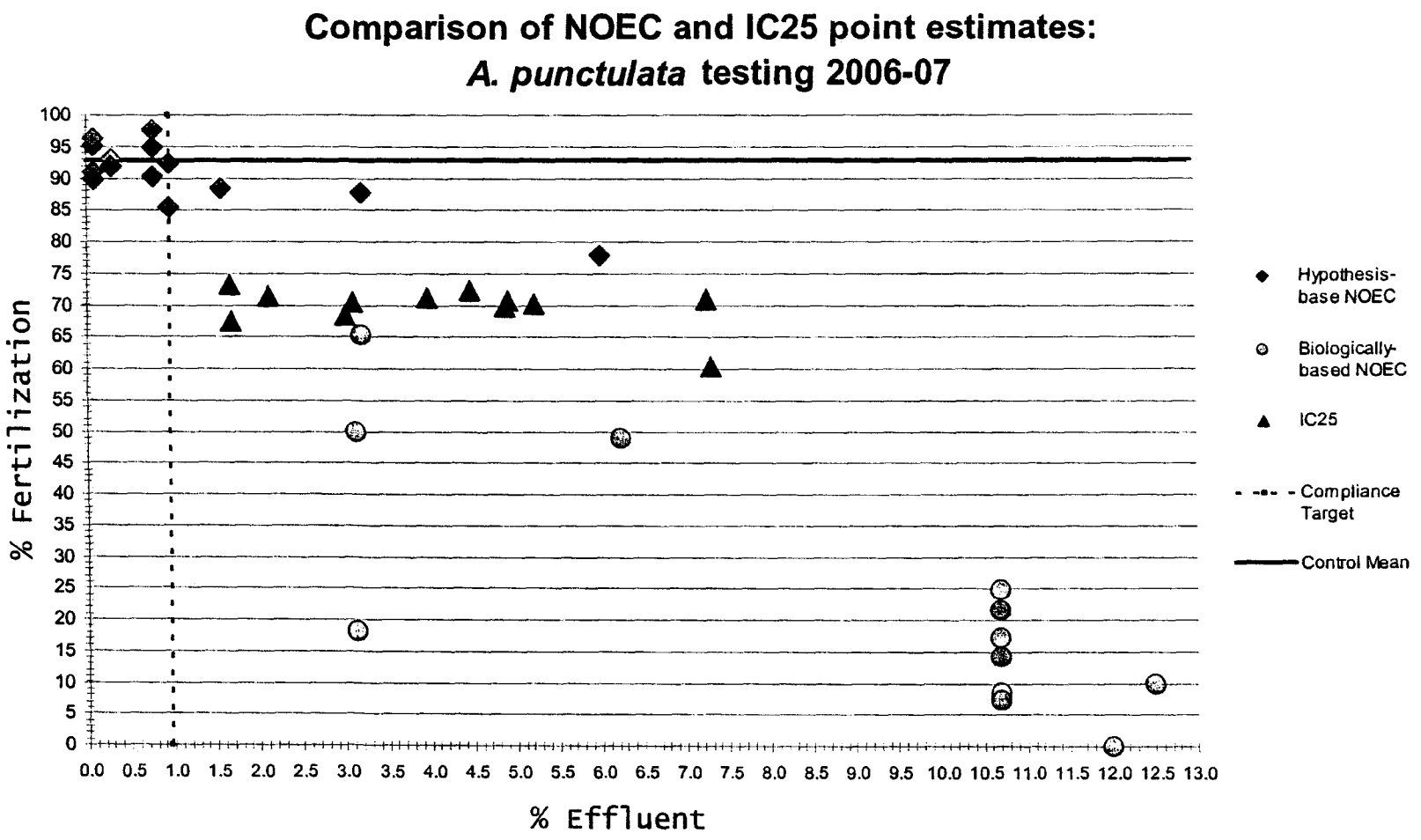
EXHIBIT 1
Summary of *Arbacia* Bioassay Tests Conducted to Date with Combined Bacardi/Bayamon/Puerto Nuevo Effluent, showing Comparison of NOECs with IC25 Point Estimates of Chronic Toxicity

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".8 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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[8] 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.[9] 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.

[9] 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*.

Attachment 4
Request for Pinch Valve Inclusion

ATTACHMENT 4

Request for Pinch Valve Inclusion

Inclusion of Pinch Valves in the Final NPDES Permit

The Puerto Nuevo RWWTP collection system includes two emergency structures designed to discharge only during extreme conditions (such as Puerto Nuevo RWWTP shutdowns) or during circumstances in which their use would be necessary to protect the public from contact with untreated sewage and associated health risks. The two pinch valves are referred to as the Plaza Las Américas and Constitution Bridge pinch valves. Along with five other locations, these structures were identified as CSO outfalls in the CWA-02-2008-3155 administrative order (AO) signed on September 5, 2008.

The draft NPDES permit includes all CSO outfalls identified in the CWA-02-2008-3155 AO except for the two pinch valves. It is recommended that each pinch valve outfall be classified as an Emergency Wastewater Exit (EWWE) in the final permit. The requirements for the EWWEs would be similar to the requirements for a bypass, except the EWWEs are not located at the treatment plant. As an example, the Milwaukee Metropolitan Sewerage District (MSD) has a permit for sanitary sewer outfall structures in which sanitary sewer overflow (SSO) discharge points are listed, but not permitted to discharge. See Exhibit 4-1 for a copy of the Milwaukee MSD permit page that lists the SSO requirements. Taking a similar approach would allow PRASA to propose a means by which EPA could formally identify and permit the structures.

The suggested language modification to the draft permit's Attachment 1, C.13, that would address both bypasses and the EWWEs are presented below.

13. Bypass or Emergency Wastewater Exit (EWWE)

a. Bypass or EWWE overflow not exceeding limitations. The permittee may allow any bypass to occur that does not cause effluent limitations to be exceeded, but only if it also is for essential maintenance to assure efficient operation or necessary to protect the public from contact with untreated sewage and associated health risks. These bypasses are not subject to the provisions of paragraphs 13.b. and 13.c of Part II.B.

b. Notice.

(1) Anticipated bypass or EWWE overflow. If the permittee knows in advance of the need for a bypass or EWWE overflow, it shall submit prior notice, if possible at least ten days before the date of the bypass or EWWE overflow.

(2) Unanticipated bypass or EWWE overflow. The permittee shall submit notice of an unanticipated bypass as required in paragraph 12.f of Part II.B (24-hour reporting).

c. Prohibition of bypass or EWWE overflow.

(1) Bypass or EWWE overflow is prohibited, and the Director may take enforcement action against the permittee for bypass or EWWE overflow, unless:

(a) Bypass or EWWE overflow was unavoidable to prevent loss of life, personal injury, or severe property damage;

(b) There were no feasible alternatives to the bypass or EWWE overflow, such as the use of auxiliary treatment facilities, retention of untreated wastes, or maintenance during normal periods of equipment downtime. This condition is not satisfied if adequate back-up equipment should have been installed in the exercise of reasonable engineering judgment to prevent a bypass that occurred during normal periods of equipment downtime or preventive maintenance; and

(c) The permittee submitted notices as required under paragraph 13.b of Attachment I.B.

(2) The Director may approve an anticipated bypass or EWWE overflow, after considering its adverse effects, if the Director determines that it will meet the three conditions listed above in paragraph 13.b.(1) of Attachment I.B.

d. The two structures listed below are constructed as potential EWWE overflow locations. Controlled overflow at these locations is subject to the restrictions in paragraph 13.b of Part II.B.

Constructed Potential Emergency Wastewater Exits

ID No.	Name	Identification	
		Latitude	Longitude
201	Pinch Valve 1 (near Constitution Bridge)	18°26'23.17"N	66°04'54.17"W
202	Pinch Valve 2 (near Plaza Las Americas)	18°26'33.09"N	66°04'43.04"W

EXHIBIT 4-1
Example Page from Milwaukee MSD NPDES Permit Regarding SSO Discharge Points

4 Separate Sewer Overflow (SSO) Requirements

Beginning on the effective date of this permit and lasting until March 31, 2008, the permittee shall provide quarterly bypass reports for the SSOs listed below, and comply with the following conditions.

4.1 Bypass Reports

The permittee shall submit to the Department a discharge report describing the bypasses during the previous three month period. This requirement is in addition to the Standard Requirements for Unscheduled Bypassing herein (see Standard Requirements, subsection System Operating Requirements). Quarterly reports shall be filed within 45 days from the end of each calendar quarter. The report shall include all sanitary sewer overflows and bypasses, including the discharge points listed in the "SSO Points" table below. All discharges which take place during each quarter shall be reported. The report shall contain a description of each discharge event, including the approximate duration, an estimate of the average volume per incident, and the reasons why discharge occurred. When caused by precipitation, the amount of precipitation, as recorded by the nearest MMSD rain gauge, shall be reported.

4.2 Inspection of Bypass/Overflow Structures

Within 24 hours of the conclusion of each rainfall and/or snow melt event which totals 3/4 inch or greater in a 24 hour period, the permittee shall inspect each permanently installed automatic bypass/overflow structure within its sanitary sewerage system which is not equipped with a manually-activated gate or valve for evidence of any bypass or overflow occurrence.

4.3 Bypasses and Overflows Prohibited

Bypasses and overflows of wastewater from the permittee's sanitary sewage system are prohibited and are not authorized by this permit, the Department my initiate legal action regarding such occurrences as authorized by s. 283.89, Wis. Stats.

4.4 SSO Monitoring Requirements

Take a grab sample from three SSO locations listed below during a wet weather event in 2003, 2004 and 2005. The grab samples shall be analyzed for BOD, TSS, Total Phosphorus, fecal coliform and E. coli. Results of this analysis shall be submitted to the Department's Southeast Region office in the quarterly report due within 45 days of the end of the quarter during which the wet weather event occurred.

4.5 SSO Point(s)

Sampling Point Designation	
Sampling Point Number	**Sampling Point Location**
206	Easement 500' south of Milwaukee-Ozaukee Co. line and 200' west of Waverly Road
205	W. Roosevelt Drive and W. Scranton Place
207	N. 31st St. and W. Fairmont Avenue
208	N. 31st St. extended on north side of Lincoln Creek
209	N. 27th St. and W. Silver Spring Drive
212	W. Hampton Ave and N. Green Bay Road, west side
213	W. Hampton Ave and N. Green Bay Road, East side
214	W. Hampton Ave at N. Lydell Ave
220	S. Howell Ave at E. Grange Ave