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November 16, 2011

VIA UNITED PARCEL SERVICE

U.S. Environmental Protection Agency
Clerk of the Board, Environmental Appeals Board
1314 G Street, N.W., Suite 600
Washington, D.C. 20005

RE: Bacardi Corporation
NPDES Permit No. PR0000591

Dear Sirs:

Enclosed for filing please find original and one copy of Petition for Review in the case of reference. I will appreciate if you can return the enclosed additional copy, without exhibits, stamped filed in the enclosed addressed envelope.

Cordially,

Eduardo Negrón Navas

Enclosure

c: Ms. Barbara McGarry, Chief
Compliance Assistance and Program Support Branch
U.S. Environmental Protection Agency, Region II

BEFORE THE ENVIRONMENTAL APPEALS BOARD
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.

In re:	)
Bacardi Corporation	)
NPDES Permit No. PR0000591	)

COPY

PETITION FOR REVIEW

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INTRODUCTION

Pursuant to Title 40, Part 124, Section 19 of the *Code of Federal Regulations* (40 C.F.R. § 124.19) Bacardi Corporation (the "Petitioner" or "Bacardi") petitions for review of certain conditions of National Pollutant Discharge Elimination System ("NPDES") Permit No. PR000059 (the "Permit"). The Permit was signed on September 27, 2011, and mailed on October 18, 2011, certified mail-return receipt requested, by the U.S. Environmental Protection Agency ("EPA"). Petitioner contends those conditions are based on clearly erroneous findings of facts and conclusions of law and involved an exercise of discretion and important policy consideration that warrants review by the Environmental Appeals Board ("EAB"). Specifically, Petitioner challenges the following permit conditions:

1. the limitations set forth in Special Condition 17(b) of the Permit for Enterococci and Fecal Coliforms; and
2. Special Condition 18(b) of the Permit.

THRESHOLD PROCEDURAL REQUIREMENTS

Petitioner has standing to petition for review under 40 C.F.R. Part 124 because it participated in the comment period. *See* 40 C.F.R. § 124.19(a). A copy of the written comments submitted by Petitioner is attached hereto as **Exhibit A**. The issues raised by Petitioner in this Petition were raised during the public comment period, and therefore were preserved for review.

STATEMENT OF FACTS

1. On April 14, 2010, the Puerto Rico Environmental Quality Board ("EQB") issued a draft Water Quality Certificate ("WQC"). (See **Exhibit B**.)

2. The draft WQC defined and authorized a Mixing Zone ("MZ") pursuant to Article 5 of the Puerto Rico Water Quality Standards Regulation ("PRWQSR"). Special Condition 17(b) of the draft WQC defined an MZ for various parameters, including Enterococci and Fecal Coliforms, for which the following limitations were defined: Enterococci (col/100 mL) – 382,602; and Fecal Coliforms (col/100 mL) – 803,378.

3. The draft WQC established a requirement to conduct definitive acute and chronic toxicity tests pursuant to the PRWQSR and the *Mixing Zone and Bioassay Guidelines*. Special Conditions 17(c, d, e, f, g, and h) of the draft WQC established the EQB requirements to comply with toxicity tests and assure compliance with the PRWQSR.

4. EPA was notified that the draft WQC was available for review and had the opportunity to comment on the draft WQC during the WQC comment process and before EQB issued the final WQC. To Bacardi's knowledge, EPA submitted no comments and, thus, consented to the draft WQC and the WQC process. Bacardi—and, based on information and belief, EQB—reasonably relied upon EPA's consent to the draft WQC and the WQC process.

5. On June 3, 2010, EQB issued a final WQC that includes the provisions described in paragraphs 2 and 3 above. (See **Exhibit C**.)

6. On July 1, 2011, EPA issued a draft NPDES permit. The draft NPDES permit significantly modified the final WQC. The draft NPDES permit imposes significantly more stringent and onerous limitations for Enterococci and Fecal Coliforms than those imposed by EQB in Special Condition 17(b) of the final WQC. The draft NPDES permit also imposed a new

Special Condition 18 (Whole Effluent Toxicity Requirements) with significantly more stringent conditions/limitations than those imposed in the final WQC, the PRWQSR, the *Mixing Zone and Bioassay Guidelines*, and the current NPDES permit. (See **Exhibit D**.)

4. On August 12, 2011, Petitioner commented on the draft NPDES permit, in part, that EPA had wrongly modified the final WQC provisions, as described in paragraph 6 above. (See **Exhibit A**.)

5. On September 27, 2011, EPA issued a final NPDES permit. EPA denied Petitioner's comment that EPA had wrongly modified the final WQC provisions, as described in paragraph 6 above. (See **Exhibit E**.)

PETITION

EPA significantly modified, and failed to incorporate into the NPDES permit, certain conditions that were imposed by EQB in the final WQC. In those respects, the NPDES permit and the conditions therein set forth below are based on clearly erroneous findings of facts and conclusions of law and involved an exercise of discretion and important policy consideration that warrants review by the EAB. The Petitioner requests this Board to grant review of this case and order EPA to revise the NPDES Permit to:

1. Include the limitations defined in Special Condition 17(b) of the final WQC for Enterococci and Fecal Coliforms; and
2. Modify Special Condition 18(b) of the NPDES permit so that it is consistent with the previous NPDES permit, the final WQC for the new Permit, the PRWQSR, and the *Mixing Zone and Bioassay Guidelines* with respect to the numeric limitations for toxicity that are stipulated in the *Mixing Zone and Bioassay Guidelines* and incorporated by reference in the PRWQSR. More specifically,

EPA must set the effluent Chronic Toxicity Criterion ("TUc") at 102 instead of 83.2 and use the 25 percent Inhibition Concentration ("IC_{25}") as the compliance measurement to be applied to whole effluent toxicity ("WET") test results, instead of the No Observed Effects Concentration ("NOEC").

The Petitioner submits that Special Condition 17(b) of the Permit should not be stayed pending review. Such an overly expansive stay would have the improper effect of totally staying the MZ for Enterococci and Fecal Coliforms. Petitioner is not contesting the MZ for Enterococci and Fecal Coliforms, but rather EPA's unilateral and improper modification to the EQB-defined MZ.

Also, the United States and Bacardi have agreed to modify the CWA Consent Decree for the facility to extend and/or amend the interim effluent limitations for, inter alia, Enterococci and Fecal Coliforms at Outfall 001, subject to court approval.[1] Such interim limitations will also effectuate the MZ for Enterococci and Fecal Coliform pending the outcome of this appeal.

ARGUMENT

I. EPA's SIGNIFICANT MODIFICATION OF THE EQB FINAL WQC SPECIAL CONDITION 17(B) DEFINITION OF MZ LIMITATIONS FOR ENTEROCOCCI (col/100 ml) – 382,602 AND FECAL COLIFORMS (col/100 ml) – 803,378, IS PREMISED ON PARTIALLY INCORRECT FACTS.

EPA acknowledges that the proposed effluent limitations are more stringent than those included in the EQB WQC, and attempts to justify the more stringent limitations on two partially

[1] Bacardi anticipates that the Consent Decree modification will be lodged with the U.S. District Court in the very near future (if it has not been lodged as of the date of this appeal).

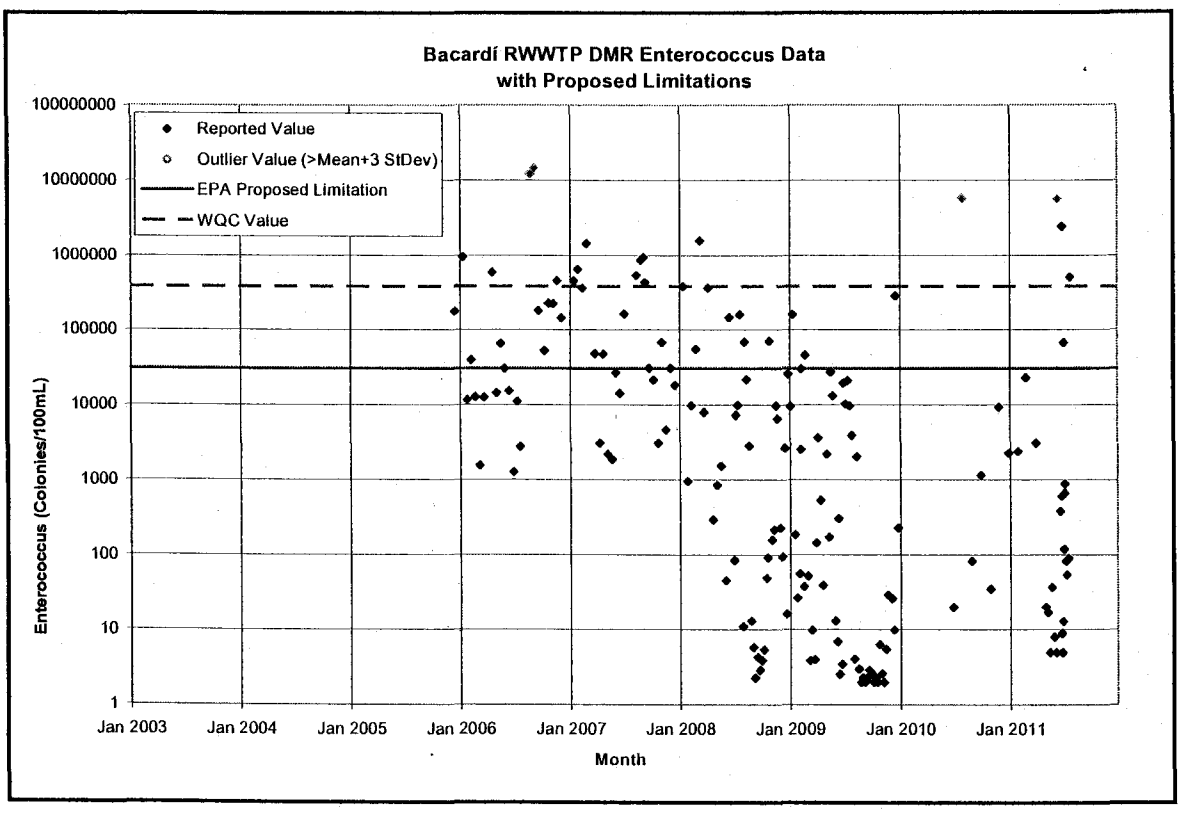
incorrect premises: 1) that those more stringent limitations are achievable by the Petitioner during normal operational conditions; and 2) that dischargers should be held to the level of discharge achievable through treatment rather than assume all assimilative capacity of the receiving water, particularly for bacterial parameters.

The first premise is partially incorrect. 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 Bacardi wastewater treatment system ("WWTS") are not consistently achievable based on recent Discharge Monitoring Report ("DMR") sampling results. (See Figures 1 and 2.)

The second premise also is partially incorrect. Bacardi generally agrees that the entire assimilative capacity of a receiving water should not be used to avoid technology and other control methods to achieve compliance. However, that is not the case of Bacardi or of this receiving water body. The EQB approved the WQC, and EPA did not oppose the granting of the WQC, because, in pertinent part: 1) Bacardi implemented aggressive operational controls and source reduction; 2) the operational controls and source reduction implemented by Bacardi resulted in a significant reduction of regulated bacteria in the effluent at the 001 discharge point; 3) Bacardi upgraded its WWTS 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 WWTS implemented by Bacardi significantly reduced the bacteria levels and, when combined with a

conventional bacterial mixing zone ("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.

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

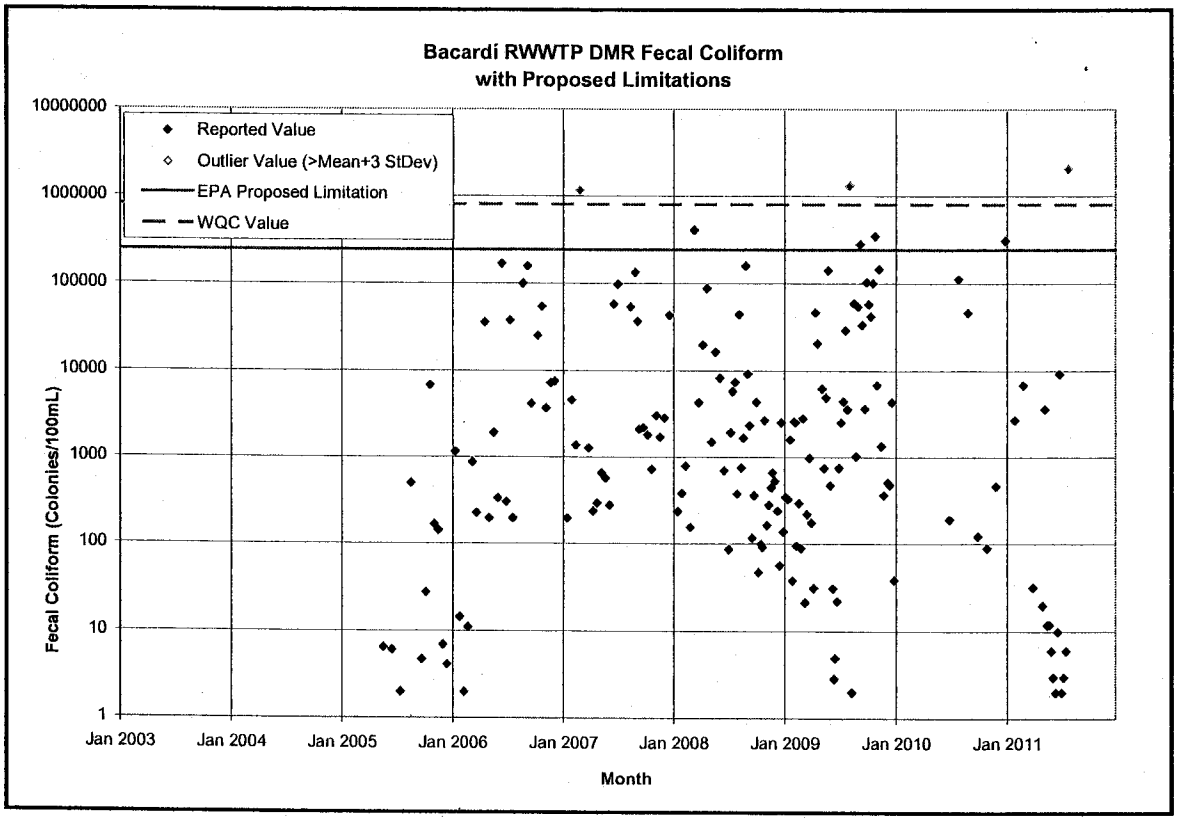


In addition, the receiving waters in the discharge area are not used for human contact or shellfish harvesting, which is a major factor in the EQB decision to approve a small mixing zone for bacteria in its final WQC of identical size and consistent with the mixing zones approved by both EQB and EPA for water quality-based toxic parameters.

Further, the Enterococci and Fecal Coliform concentrations provided by the final WQC were based on a documented BMZ study, with the bacterial limitation request based on

Reasonable Potential Analysis calculations performed according to EPA guidance documents. By contrast, the technical basis for the bacterial limitations provided by EPA in the Permit is not clear, nor was it provided in EPA's Responsiveness Summary to Bacardi and Puerto Rico Aqueduct and Sewer Authority ("PRASA") comments on the draft Permit.

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



The BMZ application and WQC chronology is as follows:

- On January 21, 2009, Bacardi met with EQB to present technical findings and discuss the feasibility of defining a BMZ. EQB indicated that there was no objection to the BMZ concept, if it incorporated EQB's conventional technical approach to defining a mixing zone and if EPA and PRASA concurred with the approach.

- On January 27, 2009, Bacardi submitted a formal BMZ application to EQB, with copies provided to EPA.
- On March 12, 2009, Bacardi met with EPA, EQB, and PRASA to discuss the feasibility and permitting schedule for a BMZ and to determine EPA and PRASA concurrence. EPA stated that it generally concurred with the concept, providing Bacardi employed source reduction. EPA further stated that the approval of a BMZ was under EQB's jurisdiction. For its part, PRASA had no objection to EQB defining a BMZ for Bacardi based on PRASA maintaining end-of-pipe ("EOP") bacterial limitations for the Bayamón and Puerto Nuevo Regional Wastewater Treatment Plants ("RWWTPs"), which share a combined outfall discharge with the Bacardi WWTS.
- On March 19, 2009, Bacardi met with EQB to further discuss the schedule for defining a BMZ. EQB restated its position that a BMZ defined via the conventional mixing zone approach was approvable. EQB further stated that the fall-back, fail-safe alternative (enhanced pasteurization of the effluent) identified by Bacardi after years of process modification/disinfection studies was not an environmentally desirable alternative.
- On April 3, 2009, Bacardi via letter to EQB requested (in part) a formal response from EQB confirming that a BMZ application based on conventional mixing zone definition techniques would be approvable and that the enhanced effluent pasteurization alternative would not be environmentally desirable.
- On April 22, 2009, Bacardi received a letter from EQB (EPA was copied) indicating that it believed that a BMZ application should be approvable and

noting that, in principle, although not having received an environmental impact document concerning the enhanced pasteurization alternative, it was EQB's preliminary understanding that the BMZ would be an environmentally superior alternative because of the energy consumption associated with enhanced effluent pasteurization.

- On April 14, 2010, EQB issued a draft WQC incorporating the concept of a BMZ based on the technical analyses provided by Bacardi.
- On June 3, 2010, EQB issued a final WQC based on those same technical analyses.

It is clear that EPA initially concluded that the BMZ was under EQB's jurisdiction and that EPA did not oppose the concept, provided that source control measures were undertaken. EQB subsequently provided for a bacterial mixing zone for Enterococci and Fecal Coliform in its final WQC. In support of that action, Bacardi undertook the following source control initiatives:

- Inspected (camera study) the sanitary sewer system to identify potential interconnections and/or infiltrations.
- Improved water quality at cooling towers to eliminate the counts of regulated bacteria.
- Replaced wastewater collection pumping system infrastructure at the Fermentation Plant to reduce the wastewater retention time and minimize regulated bacteria from reaching the Anaerobic Filter ("AF") holding tank.
- Repaired drainage system (trenches) and installed new epoxy floor treatment.

- Modified the drainage system to reduce the amount of non-contaminated storm water (Distillery & Equipment D, Barrel Cleaning Area, Molasses Unloading Area and Fermentation Building) entering the WWTS.
- Segregated low biochemical oxygen demand ("BOD")/total suspended solids ("TSS") wastewaters and treat them in the new activated sludge unit (Outfall 003) to minimize the potential of regulated bacteria reaching the AFs.
- Provided disinfection treatment (ultraviolet ["UV"]) to untreated non-process effluent.
- Hired a contractor (Biothane/Veolia) to conduct a pilot study using Anaerobic Continuous Stirred Tank Reactors ("CSTR") to evaluate the difference between this technology (based on a suspended sludge blanket) and Bacardi's technology (fixed film/plastic media) with respect to controlling regulated bacteria. The study concluded that finding an anaerobic biomass void of regulated bacteria is virtually impossible.
- Installed a new activated sludge unit, followed by UV disinfection and multi-media filters, to treat and reuse all the sanitary wastewater.
- Installed a new boiler to reduce the amount of wastewater and associated blowdown generated during the shutdown/ startup period. In addition to the reduction in hydraulic load to the treatment systems, it also helps to avoid issues with the effluent temperature limitation.
- Replaced the old fiberglass-reinforced plastic ("FRP") pipe with a new aboveground effluent pipeline equipped with a means to readily clean and scour the pipe's interior to prevent future build-up of bio-film.

- Relocated the existing Outfall 001 sampling station upstream, closer to the point of effluent generation to improve the representativeness of the samples taken.

What is not clear is why EPA chose to take mixing zone jurisdiction from EQB and to impose numerical bacterial limitations which, if implemented, will force Bacardi to employ the enhanced pasteurization alternative that does not protect either human health or the environment and in fact, runs counter to EPA's nationwide and growing focus on environmental sustainability.

II. EPA's SIGNIFICANT MODIFICATION OF THE EQB FINAL WQC SPECIAL CONDITION 17(b) DEFINITION OF MZ LIMITATIONS FOR ENTEROCOCCI (col/100 ml) – 382,602 AND FECAL COLIFORMS (col/100 ml) – 803,378, IS PREMISED ON AN INCORRECT INTERPRETATION OF EPA's REGION 2 ANTIBACKSLIDING POLICY

Petitioner generally agrees that the entire assimilative capacity of a receiving water should not be used to avoid technology and other control methods to achieve compliance. However, that is not the case of Petitioner and the receiving water body. The EQB approved the WQC, and EPA did not oppose the granting of the WQC, because of the following: 1) Petitioner implemented aggressive operational controls and source reduction; 2) the operational controls and source reduction implemented resulted in a significant reduction of regulated bacteria in the effluent at the 001 discharge point; 3) Petitioner upgraded its WWTS and added a disinfection system; 4) the alternative of an enhanced pasteurization system would likely be unnecessary, and possibly environmentally counter-productive; 5) the operational controls, source reduction, and

upgrade of the WWTS implemented by Petitioner significantly reduced the bacteria levels and, when combined with a conventional MZ, assure compliance with the final limitations.

In further support of its position, Petitioner re-alleges and restates its Argument I, above.

III. EPA's SIGNIFICANT MODIFICATION OF THE EQB FINAL WQC SPECIAL CONDITION 17(b) DEFINITION OF MZ LIMITATIONS FOR ENTEROCOCCI (col/100 ml) – 382,602 AND FECAL COLIFORMS (col/100 ml) – 803,378, IS PREMISED ON AN INCORRECT APPLICATION OF EPA's AUTHORITY UNDER 40 C.F.R. § 122.44(d) TO THE FACTS OF THE CASE.

The discharge of pollutants into coastal waters is regulated by the Public Policy Environmental Act[2] ("Act No. 416"), the Water Quality Standards Regulation[3] (the "Water Regulation"), as well as by the federal Clean Water Act[4] ("CWA"), and the regulations promulgated there under.

Act No. 416 grants EQB the authority to establish water quality standards, and to promulgate regulations to control the discharge of pollutants into bodies of water. The CWA requires that NPDES permits include the contaminant limitations and conditions required to comply with state[5] water quality standards ("WQS").[6] EPA, as part of the NPDES permitting process, requests the state to certify whether any water-quality-based limitations should be

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2 Act No. 416 of September 22, 2004, 12 L.P.R.A. §§ 1121, *et seq.*

3 Water Quality Standards Regulation of March 31, 2010, Dep't of State Regulation No. 7837.

4 33 U.S.C. §§ 1251, *et seq.*

5 The term ''State'' is defined to include "the Commonwealth of Puerto Rico." CWA § 502(3), 33 U.S.C. § 1362(3).

6 33 U.S.C. § 1341(a).

included in the permit.[7] Certification by the state is carried out through the issuance of a WQC. EPA may not issue an NPDES permit unless the state has either issued a certification or waived the right to certify. EPA must incorporate into the permit any additional conditions or limitations imposed by the state in the WQC.[8]

On June 3, 2010, EQB certified that it had received and reviewed the Bacardi application for an NPDES permit. In addition, the EQB on June 3, 2010 specifically certified as follows:

> Pursuant to Section 401(a)(1) of the Act [CWA], after due consideration of the applicable provisions established in the PRWQSR [Water Regulation] and in Sections 208(e), 301, 302, 303, 304(e), 306 and 307 of the Act [CWA], **it is certified that there is reasonable assurance as determined by the Environmental Quality Board (EQB) that the alluded discharge will not cause violations to the applicable water quality standards at the receiving water body, if the limitations and monitoring requirements on Table A-1, are met. The conditions specified in the aforementioned tables shall be incorporated into the NPDES permit in order to satisfy the provisions of Section 301(b)(1)(C) of the Act.** [Emphasis added.]

In other words, EQB certified that there is reasonable assurance that a Bacardi discharge that comports with the limitations and monitoring requirements on Table A-1 in the final WQC will not cause violations of WQS. Further, EQB required that the conditions in Table A-1 must be included in the NPDES permit to satisfy the provisions of the CWA.

EQB required that the conditions in Table A-1 must be included in the NPDES permit to satisfy the provisions of the CWA. EPA's CWA NPDES permitting regulations require the same. For example, 40 C.F.R. § 124.55 provides in pertinent part:

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7 *Id.*

8 *Id.*

Sec. 124.55 Effect of State certification.

(a) When certification is required under CWA section 401(a)(1) **no final permit shall be issued:**

* * *

(2) **Unless the final permit incorporates the requirements specified in the certification under Sec. 124.53(e).**

In other words, EPA's own regulations provide that the permit EPA issues must incorporate the requirements specified in the EQB WQC, including Special Condition 17 and Table A-1 of the final WQC issued EQB.

EPA guidance supports Bacardi's position that EPA cannot independently interpret and unilaterally apply its own interpretation of a state WQS. For example, in the August 6, 1996, *EPA Guidance on Application of State Mixing Zone Policies in EPA-Issued NPDES Permits*, EPA discusses the strict limits of EPA's authority to second-guess a state's interpretation of its own WQS and a state's determination as to what permit limitation is necessary to meet the WQS, as follows:

> [I]n the absence of a state certification under CWA § 401 (i.e., where certification is waived), EPA's interpretation of what constitutes a limitation necessary to meet the state's water quality standard will be upheld if it is "reasonable." *In re American Cyanamid Co. v. Santa Rosa Plant, et al.*, 4 E.A.D. 790, 801 (E.A.B. 1993). If the state does certify a permit under CWA § 401, its interpretation of its own water quality standards generally is controlling. ... In addition, if the state informs EPA in its CWA § 401 certification that a less stringent effluent limitation is all that is necessary to meet its water quality standards (e.g., a mixing zone should be included), **EPA must defer to the state's interpretation unless it is clearly wrong**. *In re Ina Road Water Pollution Control Facility, Pima County, Arizona*, NPDES Appeal

84-12 (Nov. 6, 1985) at 3; *see also American Paper Inst. v. EPA*, 996 F.2d 346, 352 (D.C. Cir. 1993).

> ... EPA's inclusion of a mixing zone in an NPDES permit constitutes an interpretation of the state WQS, which much therefore be "reasonable" if the state does not certify to the permit under CWA § 401. *American Cyanamid, supra.* August 6, 1996 EPA GUIDANCE, at 3. (Emphasis added.)

In fact, the "reasonable" standard in the above-quoted passage actually understates the hurdle EPA faces as articulated in *American Cyanamid.* A footnote in that decision states that EPA needs a "**compelling reason**" for rejecting a state's interpretation of its own WQS:

> "[W]hen a State certification specifically prescribes a permit condition or limitation that interprets one of the State's water quality standards less strictly than the [EPA] Region might prefer, * * *, the Region would have to provide a **compelling reason** for rejecting the State's interpretation of the standard." *In re American Cyanamid Co.*, 4 E.A.D. 790, 801 n.12 (1993). (Emphasis added.)

EPA has not demonstrated a "**compelling reason**" for rejecting the Commonwealth's interpretation of its own WQS.

IV. THE NEWLY EPA IMPOSED SPECIAL CONDITION 18(b) (WHOLE EFFLUENT TOXICITY REQUIREMENTS) WRONGLY FAILS TO CONSIDER THAT THE PRWQSR INCORPORATES BY REFERENCE THE NUMERICAL TUc LIMITATION DEFINED IN THE EQB MIXING ZONE AND BIOASSAY GUIDELINES

Special Condition 18(b) states that "No test result for any species or effect in the combined discharge shall be greater than 83.32 TUc." There are two concerns with this limitation:

1. EPA should have calculated the TUc as 102, not 83.32, based on the EQB *Mixing Zone and Bioassay Guidelines* requirement and the critical initial dilution ("CID").

2. EPA does not list the WET test measure to be applied in determining compliance with the permit limitation, but has stated that it will use the NOEC instead of the IC_{25} that was applied in the previous permit.

EPA's Inappropriate TUc Calculation

The TUc value calculated by EPA is based on the premise in its Fact Sheet that the PRWQSR does not have a numerical TUc limitation (included by reference to EQB's *Mixing Zone and Bioassay Guidelines*), and that EPA, therefore, would need to establish one by making its own calculation. However, the PRWQSR does have a numerical limitation for toxicity. In the case where a mixing zone is granted for discharge to marine waters, Rule 1305.4 (D.2 and D.3) requires that the acute toxicity units do not exceed the criteria maximum concentration ("CMC") and the chronic toxicity units do not exceed the criteria continuous concentration ("CCC") at the boundaries of the mixing zone after CID. The numerical values of the CMC and CCC are provided in EQB's *Mixing Zone and Bioassay Guidelines*, which is included by reference as a part of the PRWQSR.

Further, in making its own calculation to establish an appropriate numerical limitation for TUc, EPA failed to take into account the procedures that EQB applied to developing numerical limitations for parameters that require—and are eligible for—mixing zones, which include effluent toxicity. Specifically, EQB applied the CID to the criterion for each parameter approved for a mixing zone and established an effluent limitation based on that calculation. EPA accepted the limitations for all of the parameters requiring a mixing zone except for whole effluent

toxicity. However, because the PRWQSR does have a numerical limitation for toxicity, that limitation should be treated in the same manner as all other limitations listed in Table A-1 that are subject to a mixing zone. This is clearly the intent of the EQB WQC and is the procedure specified by EQB as demonstrated in Appendix A (example calculations) in the EQB *Mixing Zone and Bioassay Guidelines*. The field-validated CID for this outfall is 102, which, when coupled with the EQB approach to setting effluent toxicity limitations, results in a TUc of 102. The appropriate value is 102 TUc, not 83.32 TUc.

Problems with Use of the NOEC to Evaluate Effluent Toxicity for Arbacia

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 problems with the use of NOEC stem 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," even when the results instead may lie within the range of the normal biological variability that is considered to be acceptable for the control replicates.

The key issues of concern to Bacardi are as follows:

- The NOEC is an inappropriate measure by which to evaluate compliance with effluent chronic toxicity criteria for *Arbacia*.
- There is no demonstrable (and no good) reason for EPA to have changed from the IC_{25} used in the previous permit for these compliance evaluations.
- Using the NOEC will result in false positive reporting problems that will cause excessive expenditure of time and effort where none is logically required

General Discussion

The EPA *Technical Support Document for Water Quality-Based Toxics Control* ("TSD")[9] and another subsequent EPA document that addresses statistical variability, WET test analysis methodology, and NPDES compliance reporting,[10] 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, the aforementioned EPA WET test evaluation guidance consistently recommends point estimation methods in preference to statistical hypothesis testing (concluding, "For the above reasons, if possible, the IC_{25} is the preferred statistical method for determining the NOEC."), as does similar guidance from a number of states including for example Oregon, New Jersey,[11] New York, and Washington.[12]

The NOEC is an Inappropriate Measure of Toxicity for *Arbacia*

The NOEC is based on determining whether there is a statistical difference in the measured effect between control and experimental populations. In the case of *Arbacia*, the measured effect is fertilization success. The test protocols employ high sperm-to-egg ratios and thereby often result in extremely high fertilization and low variability among the control population replicates. Thus, even a very small change (for example, a statistically significant change of 1 percent) between the test series and the control fertilization success is interpreted as a toxic effect and the test is reported as a "failure" to comply with toxicity criteria. This is true

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9 EPA. *Technical Support Document For Water Quality-based Toxics Control.* March 1991. p. 6.

10 EPA. *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.

11 New Jersey Administrative Code 7:14A-13.14.

12 Washington Department of Ecology. *Laboratory Guidance and Whole Effluent Toxicity Test Review Criteria.* Publication No. WQ-R-95-80. 2008.

even though the basis for "success" within the control population according to the EPA WET test protocol includes fertilization rates as low as 70 percent.

In other words, a 1-percent difference between the test series fertilization success and that of the control population can result in a "failure" even though a 30-percent difference within the control population is rated as a "success" for that portion of the testing. The consequence is often the reporting of false positive results that indicate "toxicity" according to the evaluation protocol, even though there is not a biologically meaningful result.

For this reason, both EPA and various state toxicity testing guidance documents recommend that the NOEC should not be used to evaluate test results when the control population variability is low. Instead, this guidance points to use of the IC_{25}, or some other established estimate of biological significance representing a point along an established dose-response curve based on all the available test data that indicates where biologically meaningful responses (toxic effects) begin to occur within the test series dilutions.

In addition, the Percent Minimum Significant Difference (PMSD) "... represents the smallest difference between the control mean and a treatment mean that leads to the statistical rejection of the null hypothesis (i.e., no toxicity) ...".[13] EPA[14] recommends that regulatory authorities implement both the lower and upper PMSD bound approach to minimize within-test variability when using hypothesis testing approaches to report a NOEC. This is done in part to avoid penalizing laboratories that achieve unusually high precision. Lower PMSD bounds represent a practical limit to the sensitivity of the test method that few laboratories are able to

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13 U.S. Environmental Protection Agency. *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.

14 U.S. Environmental Protection Agency. *Method Guidance and Recommendations for Whole Effluent Toxicity (WET) Testing* (40 CFR Part 136). Office of Water. EPA 821-B-00-004. July 2000.

achieve, and below which NOECs or LOECs are not be considered toxic (i.e., significantly different from the control). For inland silverside minnows (*Menidia beryllina*) and mysid shrimp (*Mysidopsis bahia*), for example, the lower bound of the PMSDs established via the EPA interlaboratory testing program was 11 percent. PMSD upper and lower bounds were not established by EPA for *Arbacia*. However, it is reasonable to adopt a PMSD equal to the most sensitive value determined for another invertebrate WET test species, such as the 11 percent lower PMSD for mysid shrimp when evaluating *Arbacia* WET test data.

There is no Demonstrable Reason for EPA to have Changed to the NOEC

After considerable correspondence with EPA and EQB concerning the appropriate compliance measure to use for *Arbacia*, in a June 22, 2007, meeting between Bacardi and EPA staff and their respective consultants and attorneys, it was agreed that the IC_{25} calculation would be applied to flow proportionally blended samples from the Bacardi, Bayamón, and Puerto Nuevo effluent streams to assess chronic effluent toxicity compliance for *Arbacia* per the conditions of the upcoming permit. However, EPA indicated that it would require bioassays in each of the individual effluent streams, and that toxicity identification evaluation/toxicity reduction evaluation ("TIE/TRE") action would be initiated if the blended compliance sample failed and the individual samples demonstrated unacceptable toxicity.

All WET test results reported to EPA and EQB by Bacardi and PRASA under the conditions of the previous permits for the three facilities include a presentation of NOEC, LOEC, IC_{25}, and TUc calculations. Figure 3 shows a typical summary of quarterly test results from the August 2011 WET compliance testing report.

To date, there have been no failures of the combined effluent to meet chronic toxicity criteria for *Arbacia* when applying the IC_{25} and using the appropriate TUc of 102. Further, after

more than a decade of intensive and extensive sampling around the joint outfall, it has been clearly and repeatedly demonstrated that there are no harmful effect associated with this discharge in the vicinity of the outfall on:

- Fish or benthic invertebrate populations;
- Water column concentrations of toxic organic or inorganic constituents;
- Fish tissue accumulations of toxic organic or inorganic constituents;
- Sediment accumulations of toxic organic or inorganic constituents; and
- Phytoplankton concentrations.

Figure 3. Typical Chronic WET Test Results Summary

Chronic Definitive Bioassays Using the Sea Urchin (*Arbacia punctulata*)

Introduction

Hydrosphere Research[1] conducted chronic definitive whole effluent toxicity (WET) tests using the sea urchin (*Arbacia punctulata*) for the Bacardi Corporation wastewater treatment plant (WWTP) as well as for the Puerto Rico Aqueduct and Sewer Authority (PRASA) Bayamón and Puerto Nuevo Regional WWTPs. The tests were conducted on samples from each facility individually and also on a salinity-adjusted, flow-proportioned composite sample from the effluent of each of the three plants. The tests were conducted on August 25, 2011.

Summary of Test Results

Exhibit 1 summarizes the test results. Test data and further discussion are provided in the Results and Discussion section.

EXHIBIT 1
Summary of Chronic Test Results

Species	Sample ID	NOEC	LOEC	IC_{26}	TUc
Arbacia punctulata	Combined discharge	27.0%	9.0%	35.9%	2.79
Arbacia punctulata	Bacardí WWTP	0.27%	0.09%	1.11%	90.1
Arbacia punctulata	Bayamón RWWTP	8.1%	0.09%	>24.3%	<4.12
Arbacia punctulata	Puerto Nuevo RWWTP	48.6%	>48.6%	>48.6%	<2.06

Notes:
NOEC=no observed effect concentration
LOEC=lowest observed effect concentration
IC_{25}=inhibition concentration (estimate of the concentration that would cause a 25-percent reduction in test organism growth or fecundity)
TUc=toxic unit chronic ($100\%/IC_{25}$)

The current National Pollutant Discharge Elimination System (NPDES) permits for the Bayamón, Puerto Nuevo, and Bacardí wastewater treatment plants stipulate that **"No single IC25 test result for any species or effect in the combined discharge shall be less than 1.00%."** The combined discharge clearly meets that condition for this series of bioassay tests.

Methods and Materials

Test Methods

All chronic tests were performed according to: *Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms*, Third Edition (2002); EPA 821-R-02-014.

Additional guidance was provided by:

- *Understanding and Accounting for Method Variability in Whole Effluent Toxicity Applications Under the National Pollutant Discharge Elimination System Program*, (EPA June 2000), EPA 833-R-00-003.
- *Method Guidance and Recommendations for Whole Effluent Toxicity (WET) Testing* (40 CFR Part 136), (EPA July 2000), EPA 821-B-00-004.

[1]The results and methodology from the Hydrosphere Research sea urchin test are summarized in this report. However, more details from this testing are provided in the Hydrosphere Research report (see Appendix A).

In other words, in more than 10 years of intensive monitoring, there has been no measureable ecological response to this discharge. This further validates the toxicity conclusions based on the biologically relevant IC_{25} evaluation of effluent toxicity to the most sensitive stage in an organism's life cycle (i.e., fertilization).

The previous permits for each of the three facilities incorporated this logic and specified the toxicity effluent limitation as follows:

> b. *Effluent Limitation:*
>
> ***No single IC25 test result for any species or effect in the combined discharge shall be less than 1.00%.***
>
> *Results shall be reported as the IC25 percentage effluent of the combined discharge. This permit requires additional toxicity testing if a chronic toxicity effluent limit is violated. The permittee shall notify EPA in writing within fourteen days of the permittee's receipt of results violating this effluent limitation.*

Nonetheless, on September 27, 2011, Bacardi and PRASA received renewed final NPDES permits for all three facilities.[15] In each permit, the effluent limitation for toxicity was changed to read as follows:

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

The 2011 permit is not clear as to why 83.32 was used as the TUc limit when the EQB *Bioassay and Mixing Zone Guidelines,* coupled with the CID for this outfall supports a TUc of 102. Further, although the permit dos not state the specific measure to be applied to determine compliance with WET limitations for any of the test species, subsequent conversations with the

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15 All three facilities have an effective date of permit ("EDP") of December 1, 2011.

EPA permit writer[16] have indicated that, under the new permits, the NOEC rather than the IC_{25} will be used to evaluate compliance with effluent toxicity criteria.

It is not clear why EPA changed both the effluent limitation for TUc and the compliance evaluation protocol, but in the process also apparently failed to take into account—or even acknowledge—the following compelling facts:

- A mixing zone for effluent toxicity can be granted under the PRWQSR based on the numerical results of WET test calculations and the verified CID[17] of the effluent as it rises through the water column. Using this approach, and the data and reports available to EPA, the TUc should be stated as 102, not 83.32.
- The results of the previous white paper[18] clearly indicate the problems associated with applying the NOEC to the *Arbacia* to calculate a TUc.
- There is specific EPA guidance that recommends using a point estimate such as the IC_{25} to evaluate toxicity where [as here] the NOEC fails to adequately address biologically significant responses to potential toxicants.
- The agreement reached in the June 22, 2007, meeting on the basis of the arguments put forward in the previous (2007) white paper that the IC_{25} is an appropriate criterion by which to evaluate effluent chronic effluent toxicity for *Arbacia*.

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16 Julio Torruella/Bacardi telephone conversation with Karen O'Brien/EPA on October 14, 2011.

17 The CID is the lowest postulated initial dilution based on very conservative model inputs. Actual field-verified initial dilutions generally exceed the CID by a factor of at least 2 or 3.

18 CH2M HILL. *White Paper Discussion and Recommendations Related to Arbacia punctulata Whole Effluent Toxicity Testing Using Combined Effluent from the Bayamón, Puerto Nuevo and Bacardi Wastewater Treatment Plants*. Prepared for Bacardi Corporation. May 2007. Attached to Bacardi's comments on the draft NPDES permit. (See **Exhibit A** hereto.)

- Both EPA and EQB accepted both the IC_{25} as the basis for evaluating effluent toxicity for *Arbacia* and the concept of a TUc of 102 in relation to the WET test reporting as done under the previous permits.

Application of the NOEC will Result in Excessive and Unnecessary Effort

Under the effluent toxicity limitations provided in the previous NPDES permits for the Bacardi and PRASA facilities, application of the IC_{25} for compliance evaluations led to the conclusion that the toxicity of the combined effluent consistently complied with PRWQSR criteria for all three test species. There were only two toxicity "failures" of the combined effluent under the IC_{25} evaluation protocol, the most recent being in May 2007 (Table 1). None of the test failures was related to *Arbacia* test results. However, as discussed above, applying the NOEC to evaluate the effluent toxicity compliance would have resulted in false positives and reporting of unacceptable toxicity where there were actually no meaningful biological responses to the effluent concentrations tested.

This was pointed out in the following tables (excerpted from the Bacardi comments on the July 2011 draft NPDES permit, Appendix B), which demonstrate that using the inappropriate NOEC as the chronic toxicity compliance measure and a TUc of 83.32 would have resulted in "failures" in many of the samples tested, and of those "failures" would have been related to misleading *Arbacia* test results.

TABLE 1

Bioassay Test Results for the Bayamón/Puerto Nuevo/Bacardi Flow-weighted Effluent Composite

Comments on the Draft NPDES Permit WET 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

TABLE 1

Bioassay Test Results for the Bayamón/Puerto Nuevo/Bacardi Flow-weighted Effluent Composite

Comments on the Draft NPDES Permit WET Limitation for the Bacardi WWTS

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*
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*

TABLE 1

Bioassay Test Results for the Bayamón/Puerto Nuevo/Bacardi Flow-weighted Effluent Composite

Comments on the Draft NPDES Permit WET Limitation for the Bacardi WWTS

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.

These matters are discussed at greater length in the white paper on *Arbacia punctulata* WET testing, which was attached to Bacardi's comments on the draft NPDES permit. (See **Exhibit A** hereto.) An update to the toxicity white paper is provided as **Exhibit F**.

CONCLUSION

For the foregoing reasons, the failure to include in the NPDES permit the limitations defined in Special Condition 17(b) of the final WQC for Enterococci and Fecal Coliforms, and the inclusion of a new Special Condition 18, as proposed by EPA, are based on clearly erroneous findings of facts and conclusions of law, contrary to the final WQC, the PRWQSR, and the *Mixing Zone and Bioassay Guidelines*, and arbitrary, capricious, and otherwise not in accordance with law, and involve an exercise of discretion and important policy consideration that warrants review by the EAB. Petitioner requests this Board to grant review of this case and order EPA to: 1) include in the NPDES permit the limitations defined in Special Condition 17(b) of the final WQC for Enterococci and Fecal Coliforms; and 2) modify Special Condition 18 of the NPDES permit so that it is consistent with the final WQC, the PRWQSR, and the *Mixing Zone and Bioassay Guidelines*.

Respectfully submitted,

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Date: November 16, 2011

List of Exhibits

Exhibit A – Comments submitted by Petitioner on Draft NPDES Permit

Exhibit B – Draft Water Quality Certificate

Exhibit C – Final Water Quality Certificate

Exhibit D – Draft NPDES Permit

Exhibit E – Final NPDES Permit

Exhibit F – Toxicity White Paper Update