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June 9, 2011

File Ref: W9777.290

Ms. Stephanie Sanzone
Designated Federal Officer
EPA Science Advisory Board (1400R)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE: Science Advisory Board Staff Office Notification of a Public Teleconference of the Chartered Science Advisory Board [FRL-9310-5]

Dear Ms. Sanzone and Committee Members:

The Marine Invasive Species Program Staff of the California State Lands Commission (Commission) appreciates the opportunity to provide comment to the chartered Science Advisory Board on the near-final report, "Efficacy of ballast water treatment systems; A Report by the EPA Science Advisory Board (May 2011 Draft)."

Since 1999, California has been and remains a national and world leader in the development of effective science-based management strategies for preventing species introductions through vessel vectors. The Commission's Marine Invasive Species Program (MISP) pursues aggressive strategies to limit the introduction and spread of nonindigenous species (NIS), including recently establishing strict performance standards for the discharge of ballast water. California's performance standards serve to force the regulated industry to develop technology-based strategies to manage NIS in ballast water discharges.

California works cooperatively with the United States Coast Guard (USCG) and the EPA in order to advance a consistent, strong, enforceable, funded, national program that pushes technology and the science of vessel vector management forward, while ensuring that the state's existing, world-leading programs be allowed to continue. Based upon the MISP's extensive experience in the management and regulation of vessel vectors, Staff offers the following comments on the May 2011 Draft of the Science Advisory Board (SAB) report on ballast water treatment systems.

General Comments

Overall, the May 2011 draft of the ballast water treatment report is an improvement over the March draft. Many of the specific comments noted in the Commission staff's March 14, 2011 letter to the SAB were addressed by the current version of the report. However, staff remains concerned that several key concepts discussed in our first comment letter are still not fully addressed by the May draft of the report.

Comment 1 – Measurability does not necessarily equate to system performance limitations

The report frequently confuses *measurability* (e.g. detection limits) with the *performance ability of BWMSs*. If the detection limits of current measurement methods are not sufficient to measure to standards stricter than the IMO D-2, conclusions should not be made about the ability or inability of systems to meet those standards, as the system's full potential cannot be known. Specifically, the report at times indicates that the detection limits of current testing methods precludes the ability to evaluate if systems can meet stricter standards, but then the report goes on to make conclusions that the stricter standards cannot be met. These two opposing statements will create substantial confusion for regulators and stakeholders.

Comment 2 – Limited availability of system performance data

The report makes broad conclusions about the ability and availability of ballast water treatment systems to meet a variety of ballast water treatment systems. These conclusions are based on a small subset of the available data on ballast water treatment performance. Out of 51 treatment systems identified as under development or available for purchase, only 9 reliable data sets were collected by the EPA, and only 8 data sets are for systems still on the market. As of May, 2011, sixteen ballast water treatment technologies have received Type Approval according to the IMO G8 Guidelines. An additional two or three systems have completed all land-based and shipboard testing and are awaiting review for Type Approval from their respective administrations. Therefore, the SAB report includes data for only half of the most advanced treatment technologies. Whole categories of treatment systems under development were not reviewed for this report. Therefore this report cannot be considered a comprehensive review of the current and foreseeable progress toward meeting ballast water discharge standards more stringent than IMO.

Specific Comments

Pg 14, Table 2.1 –The California interim standard for organisms greater than 50 microns is "no detectable living organisms." There is no volumetric requirement associated with this standard. The standard is not "no detectable living organisms" per cubic meter. Similarly the California Final Standard is set as "zero detectable living organisms for all organism size classes." There is no volume or organism concentration associated with this standard.

Pg 19, line 8 – Recommend replacing "hull fouling" with "vessel fouling" or "biofouling." Fouling organisms may be found on many wetted surfaces other than the hull (e.g. propeller, stabilizers…).

Pg 41, lines 37, 40-41 – What does a "decrease in total bacteria" vs. a "significant reduction" in total bacteria mean. These terms are ambiguous.

Pg 42, line 41-43 – The reviewers gave systems a 'D' if "any living organisms in any size class were found following treatment." The 100x and 1000x standards are not set as "no detectable," for all organism size classes, and therefore it seems inappropriate to state that any organisms in any size class warrants a 'D' for that system. As stated in lines 38-39, "current testing methods do not provide the resolution required to conclude that the 10x standards can be met." Therefore it would seem appropriate to state that current testing methods also cannot conclude that the 10X standard (as well as the 100x and 1000x standards) cannot be met. The current methods and detection limits do not allow for conclusive statements either way at this time.

Pg 44-45, Table 4.1 – Recommend adding that the information used to develop Table 4.1 is referenced in Appendix A.

Pg 46, line 10 – The report frequently states that 9 systems had reliable data for performance assessment. However, the panel only reviewed 8 of those data sets (see Table 4.1) because one system has been removed from the market. Therefore the report should be adjusted to note that the conclusions drawn were based on 8 data sets and not 9.

Pg 47, lines 25-33 – There is no note of whether or not the panel reviewed the ability of treatment systems to meet standards for human health indicator species. These species are important components of the IMO and CA standards and should be included in the analysis for this report.

Pg 47, line 38-39.- Given that only 8 of 51 systems were assessed for compliance with any of the existing or proposed standards, it seems a bit of a reach to say that "no current BWMS types can meet a 100x or 1000x discharge standard." The authors have noted that "current testing methods do not provide the resolution required to conclude that the 10x standards [and presumably anything more stringent than the 10x standards] can be met." Therefore, the best that can be said is that based on the data available for 8 ballast water treatment systems, the lower performance limit does not appear to indicate that the 100x and 1000x standards can be met. However, methods are not available and insufficient testing of systems has been conducted to verify this statement at this time.
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Pg 78, lines 13-14 – The California standards are not "suggested", they are established in statute. Additionally the California standards were not implemented through the Clean Water Act Section 401 certification process. They were enacted in separate California statute and then implemented via California regulation.

Pg 96, lines 1-21 -This is the only section in the report that addresses any aspects of the cost of treating ballast water. While we agree that a comprehensive comparison of the cost of onshore facilities vs. shipboard treatment systems is necessary, we recommend that this information be included in a separate white paper and not in this report, unless, discussions are included in other parts of the report to address costs associated with the different types of ballast water treatment systems and costs associated with testing, etc. This section would be improved if it focused solely on effectiveness.

Pg 102, lines 4-36 – We believe the main body of the report should reflect the majority opinion of the panel. The appendix could be used as an avenue to present competing opinions, but since this document will be utilized by many government regulators, researchers, and

stakeholders as the best available assessment of treatment systems, the panel should agree upon one thesis/set of statements for the main body of the report.

Pg 110, Section 6.7 – This section includes no summary of the information gathered from the review of system performance data. Instead it jumps from a summary of what is wrong with available data to alternatives to shipboard treatment. There is no recognition of the fact that great strides have been made in the development of shipboard ballast water treatment technologies. While only limited data was available for this analysis, it is still clear that shipboard treatment is substantially and significantly reducing the numbers of aquatic organisms in ballast water. This will result in a reduction in the number of organisms being discharged into US waters and will likely result in a decrease in the introductions of new species. This success should be celebrated.

Additionally, this section seems to have been hastily assembled. There are duplicative bullet points, and the charge questions – the reason for development of this report - are not referred to nor answered.

Pg 111, lines 19-28– It is inappropriate to focus on cost in this summary statement given that actual cost numbers are presented in the text, and no economic information is provided for shipboard systems in comparison to reception facilities. Additionally, the cost data that is presented in the text is out-of-date.

Thank you for consideration of these comments. If you have any questions, please do not hesitate to contact me.

Sincerely,

Maurya B. Falkner
Marine Invasive Species Program Manager
Marine Facilities Division

CC: Kevin Mercier, Acting Chief, Marine Facilities Division

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Joe Martens
Commissioner

June 9, 2011

SENT BY PDF AND REGULAR MAIL

Ms. Stephanie Sanzone
Designated Federal Officer (DFO)
EPA Science Advisory Board (1400R)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW.
Washington, DC 20460

Re: Scientific Advisory Board Draft Report dated 5/31/11

Dear Ms. Sanzone:

This letter provides New York State's additional written comments on the Scientific Advisory Board (SAB) Draft Report. (SAB Report)

We request that the following three letters, which contained New York's previous comments on the content of the SAB Report and analogous comments from California, be included as an appendix in the SAB report when the report is finalized and issued:

- Our 21-page letter dated March 11, 2011
- The California State Lands Commission's 10-page letter dated March 14, 2011
- Our 3-page letter dated March 25, 2011

The comments and issues raised in these three letters are still of great concern to New York and we continue to ask that the points raised in those three letters be addressed.

Thank you for the opportunity to comment, and please let me know if you have any questions about this matter.

Sincerely yours,

Scott Crisafulli, Chief
Water Bureau, OGC

EDMS#401324

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Joe Martens
Commissioner

March 11, 2011

SENT BY PDF AND REGULAR MAIL

Ms. Iris Goodman
Designated Federal Officer (DFO)
EPA Science Advisory Board (1400F)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW.
Washington, DC 20460

Re: Scientific Advisory Board Draft Report dated March 3, 2011 for EPEC Ballast Water Review: New York's comments

Dear Ms. Goodman:

Enclosed please find New York State's written comments on the Scientific Advisory Board Draft Report dated March 3, 2011 for EPEC Ballast Water Review Draft Scientific Advisory Board Report on Ballast Water Treatment Systems. The State's comments consist of 7 pages of comments, plus 13 pages of attachments, totaling 20 pages. As you know, Raymond Vaughan submitted an unsigned version of these comments on March 10, 2011.

Please let me know if you have any questions about this matter. Thank you.

Sincerely yours,

Scott Crisafulli, Chief
Water Bureau, OGC

EDMS#394060

NEW YORK COMMENTS TO SAB, March 15, 2011
(comments submitted March 10, 2011)

We appreciate this opportunity to address the Committee and offer herewith a combination of written and oral comments on behalf of New York's ballast water management team which is coordinated by the Department of Environmental Conservation.

My name is Dr. Raymond Vaughan. I am an Environmental Scientist with the New York State Attorney General's Office, and a member of New York's ballast water management team. These comments are too extensive to deliver in full as oral comments on March 15 and/or March 17, and we therefore ask that the entire set of comments be treated by the SAB as written comments. We submit these comments (replacing less detailed comments that we submitted March 7) a few days after the March 7 comment deadline set forth in the Federal Register (76 FR 11245-46, March 1, 2011) based on a time extension granted by email by Iris Goodman (EPA DFO) on March 8. A time extension was needed because of the short time given to us and the general public to review the near-final SAB report on ballast water treatment technologies on which comments are solicited. That report was posted online either late in the evening of Thursday March 3 or early in the morning of Friday March 4, 2011, and was not available for review prior to that time.

We make the following comments on the near-final SAB report on ballast water treatment technologies (also known as the "SAB Draft Report dated March 3, 2011 for EPEC Ballast Water Review"):

1. The report suffers from two major interrelated deficiencies. First, its claims that 100x IMO ballast water treatment is unachievable (or very unlikely to be achievable) with existing technology are entirely conclusory and unsubstantiated. Second, the report shows no awareness of the several sets of substantive comments we have submitted to date to the SAB (copies attached), and it likewise shows no awareness of New York's more recent vessel extension letter dated February 7, 2011 (copy attached). In combination, these two deficiencies are very serious. Given the fact that our previous comments are largely directed to the SAB's unsubstantiated claims that 100x IMO ballast water treatment is unachievable or very unlikely to be achievable with existing technology, and given the presumption that substantive public comment under FACA is not a mere exercise in futility but deserves substantive attention, the SAB cannot properly proceed without addressing the issues we have raised. New York's February 7 vessel extension letter, widely publicized but not heretofore submitted formally to the SAB, is likewise pertinent.

2. Chapter 3 of the report, entitled Statistics and interpretation, contributes to the report's deficiencies by failing to provide a clear and straightforward statistical basis. This failure was pointed out previously in our oral comments dated November 4, 2010, and has not been resolved.

3. Assuming a Poisson distribution, the necessary and sufficient statistical relationship involves the *concentration limit or standard*, the *sample volume*, and the *statistical confidence*. Chapter 3 (page 24, lines 22-23) indicates that the Poisson distribution "will be the focus here" but fails to focus on it. The chapter does not focus on the necessary and sufficient Poisson relationship (involving the *concentration limit or standard*, *sample volume*, and *statistical confidence*) but

engages primarily in long discussions of other statistical measures such as coefficient of variation, other (non-Poisson-based) testing criteria such as ETV, and issues of secondary relevance such as the ability to discriminate between 10 and 12 organisms per unit volume. These discussions, while of theoretical interest, tend to obscure the necessary relationship (involving the *concentration limit or standard*, *sample volume*, and *statistical confidence*) for regulating ballast water based on a Poisson distribution.

4. Assuming a Poisson distribution, New York has stated that the minimum total sample volume needed to demonstrate compliance at 95% confidence with a 100x IMO standard is 30 m^3 for organisms >50 μm and 30 ml for organisms 10-50 μm. New York recognizes that larger volumes may be preferable but finds that these are the minimum sample volumes needed under a Poisson distribution. The SAB report neither disagrees with nor clearly acknowledges these minimum sample volumes for the two aforementioned organism classes. The report should either agree or disagree with these minimum sample volumes (30 m^3 and 30 ml, respectively) and should clearly explain why. If the SAB finds that some type of qualification is necessary, that should also be clearly expressed.

5. As indicated in Chapter 3, a Poisson distribution cannot be assumed when samples are collected from a larger tank in which organisms are aggregated rather than randomly distributed. New York agrees. However, as indicated in our oral comments dated November 4, 2010, and described in more detail in our oral comments dated January 25, 2011, the issue of aggregated organisms can be avoided by an appropriate sampling strategy similar to that routinely used for testing wastewater discharges. As we described in those prior comments, a *representative sample* can be continually collected during either landbased or shipboard testing of a ballast water treatment system, and the *entire volume* of this representative sample can be concentrated and tested without regard to whether organisms in the sample are aggregated or randomly distributed. Using this type of sampling strategy, known as composite sampling in the wastewater industry, aggregation becomes a non-issue, and the Poisson distribution can be used regardless of whether organisms in the sample are aggregated or randomly distributed. The SAB report fails to acknowledge or address our comments on this point; it should do so. In doing so, the SAB needs to understand the point we have made. A distinction needs to be made between sample collection from a larger tank already filled with treated ballast water in which organisms are aggregated (in which case aggregation is an issue) and collection of the entire contents of a dedicated sample tank which has been continually and representatively filled with treated ballast water as the treatment system operates (in which case aggregation is a non-issue because 100% of the sample tank will be tested).

6. Alternatively, if for some reason the sampling strategy of the preceding paragraph is not used, the applicability of a Poisson distribution cannot be known beforehand; it must be determined from test results. Specifically, if testing shows that the variance of the samples tested is equal to the mean of the samples tested, then a Poisson distribution can be assumed and the aforementioned relationships (involving the *concentration limit or standard*, *sample volume*, and *statistical confidence*) are applicable. Alternatively, if testing shows that the variance of the samples tested exceeds the mean of the samples tested, then the Poisson distribution cannot be assumed; another distribution such as the negative binomial is needed. In either case, the comparison of variance to mean is closely related to the coefficient of variation (CV) discussed at length in Chapter 3 of the SAB report, but the report needs to explain more clearly that the

value of the CV *is obtained from testing* and thereby serves as an indicator of whether organisms are distributed randomly (Poisson) or aggregated (negative binomial or other distribution).

7. If, for example, thirty 1-m^3 samples totaling 30 m^3 are tested for organisms >50 μm, a mean and a variance can be calculated from the thirty organism counts. Similarly, if thirty 1-ml samples totaling 30 ml are tested for organisms 10-50 μm, a mean and a variance can be calculated from the thirty organism counts. Other numbers can be used in these examples, but the point is that the degree of randomness or degree of aggregation can be determined from the ratio of the variance to the mean.

8. The following statement on page 24, lines 31-34, is either misleading or not true as stated:

> Since the Poisson distribution pools the data to improve measurement precision, sample replication is unnecessary if one subsample is continuously taken on a time-averaged basis and is therefore representative of the sample (as is required in the EPA Environmental Technology Verification (ETV) Generic Protocol for the Verification of Ballast Water Treatment Technology; U.S. EPA 2010).

Specifically, there is no inherent requirement for a "time-averaged basis" when dealing with a Poisson distribution. The numbers of occurrences in any two disjoint intervals are independent, regardless of whether the intervals are time-averaged or not. Thus, when dealing with a Poisson distribution, *any* combination of samples can be pooled to obtain the necessary sample volume for a given confidence level.

9. The ETV protocol that is discussed at length in Chapter 3 and elsewhere in the report is *not* a strictly Poisson process; it contains other unstated assumptions. Those assumptions should be clearly identified, to the extent that the report relies on the ETV protocol. Alternatively, the report needs to explain the very substantial differences (e.g., in necessary test volume) that exist between Poisson-based and ETV-based conclusions.

10. The report's approach to organisms >50 μm appears arbitrary and inconsistent. The report says on page 23, line 24, that the statistical discussion will focus on those (zooplankton-sized) organisms, yet the need for testing and statistically evaluating the organisms in this size class would essentially disappear or be greatly diminished if they could be reliably removed and/or killed by filtration during ballast uptake. The report (p. 7, lines 23-24) indicates that the technology exists to "remove all or nearly all" such organisms. However, on page 57, lines 16-33, the reports relies inappropriately on two manufacturers' statements to conclude that such removal does not exceed about 90% and that "it is not reasonable to expect incremental improvements" in such removal. This logic is weak. First, the question involves not just removal but filter-induced mortality, which is said on page 85, lines 14-32, to be high. Second, such an important point (i.e., whether organisms >50 μm present the primary obstacle to attaining 100x or 1000x IMO) should not be judged entirely on two manufacturers' statements; it should be determined by testing. Third, if such testing has not already provided a reliable answer for a range of mesh sizes and filter designs, it should be a top priority in the additional testing that the SAB authors recommend.

11. The SAB authors consider onshore treatment to be promising. We agree (for example, see pp. 17-21 of our letter dated May 7, 2005 in docket USCG-2004-19842) but believe that the SAB

report is inconsistent in implying that compliance with a given standard such as 100x IMO could not readily be verified for shipboard systems (or landbased testing thereof) but could be readily verified for onshore treatment. The same statistics, Poisson or otherwise, apply in both cases.

12. We are concerned, as stated above, about the SAB report's conclusory and unsubstantiated claims that 100x IMO ballast water treatment is unachievable (or very unlikely to be achievable) with existing technology. Our concerns about these claims are reviewed in more detail in the next several comments.

13. An example of such claims can be found in the report's draft cover letter (from line 38 of page 1 to line 2 of page 2 of the letter), where the basis for the claim is said to be "technological, logistical, and personnel constraints imposed by shipboard operations." Granted, one can imagine many endeavors that would face challenges due to "technological, logistical, and personnel constraints imposed by shipboard operations," but this generalization fails to explain how the SAB authors have drawn a distinction between the achievability of IMO ballast water treatment and the alleged unachievability of 100x IMO ballast water treatment with existing treatment technology. The same claim, based on the same broad generalization, can be found in the report's executive summary (p. 1, lines 36-39).

14. Another example of such claims can be found in the executive summary (p. 3, lines 22-34), where the basis for the claim is not what it purports to be. The paragraph in question begins with a discussion of discharge standards that are "currently measurable," then raises a generalized concern about the volumes of water required to "achieve" a 1000x IMO standard, and finally makes the unsubstantiated claim that "it seems unlikely, for the reasons mentioned above," that a 100x IMO standard can be "achieved." The problem with this logic is that the SAB authors are improperly confusing the *achievability* of a standard (i.e., the ability of a given treatment system to meet a given standard) with the question of whether the achievement of a given standard is *currently measurable*. We recognize that the concepts of being achievable and being measurable are closely related, yet they are distinct concepts and need to be properly distinguished by the SAB. We made this point in our written comments dated October 19, 2010 (especially the first paragraph therein) and in our oral comments dated October 26, 2010:

> As the Committee moves forward, we encourage each member to distinguish the *availability and use of testing protocols* from the *efficacy of individual treatment systems as determined by independent testing facilities*. As it happens, *actual performance* of treatment systems does not depend on whether a particular test protocol is fully developed.... (emphasis in original)

Equally importantly, as we have described in our prior comments and elsewhere, the achievement of a 100x IMO standard is currently and readily measurable; there should be no question about this.

15. Another example of such claims can be found in the executive summary (p. 5, line 36), where the SAB authors address the question of reasonable changes/additions that could improve the performance of treatment systems. After stating that "tweaking" of existing technologies "will only result in incremental improvements," they claim that "New technologies will be needed for 100x and 1000x regulations." The surrounding text offers no basis for this claim.

16. Another example of such claims can be found in the executive summary (p. 6, lines 11-13), where the SAB authors assert that "The complexity of the systems and the difficulties associated with counting live organisms, particularly the smaller size classes, combine to limit our ability to measure improvements to levels 100x and 1000x IMO." System complexity tends to be an unavoidable fact of modern life; it cannot be viewed as an automatic or inherent barrier to achieving or measuring 100x IMO. The "difficulties associated with counting live organisms, particularly the smaller size classes" is likewise not a valid basis for the authors' contentions about being able to measure improvements to levels 100x and 1000x IMO. We addressed this concern, at least in part, in the second paragraph of our written comments dated October 19, 2010, where we said: "The relevant discussion may need to consider, for example, whether the time to conduct biological analyses would necessarily increase when testing larger volumes, given the tendency for organism concentrations to be lower in samples that meet a more stringent standard." In a broader sense, the statement about "difficulties associated with counting live organisms" is a generalization that fails to explain how the SAB authors have concluded that something is possible at the IMO level but substantially less possible (i.e., limited) at the 100x level.

17. Another example of such claims (page 36, lines 19-28) starts with an unsubstantiated premise (available methodologies are "at or near analytic detection limits" with respect to IMO compliance) and builds a series of unsubstantiated conclusions upon that premise:

> Available methodologies to test IMO D-2/Phase 1 compliance are presently at or near analytic detection limits for the two largest organism size classes. While the IMO D-2/Phase 1 performance standards are measureable at present based on land-based and shipboard testing approaches, new or improved methodologies will be required in order to increase detection limits. Due to the logistics of collecting, reducing, and counting organisms in all size classes within the volumes of water required to detect achievement of a standard 1000x more stringent than the IMO D-2/Phase 1 performance standard, measuring to a 1000x more stringent standard is impracticable. Detecting achievement of a standard 10x more stringent may be possible, but it seems unlikely for the reasons mentioned above that detecting achievement of a 100x more stringent standard is possible.

The problem here, from the initial premise onward, stems from a failure to express and apply the necessary Poisson relationship (involving the *concentration limit or standard*, *sample volume*, and *statistical confidence*). Alternatively, the SAB authors might conceivably express and apply some other statistical relationship that they consider more appropriate than a relationship based on the Poisson distribution – but they would need to clearly identify, justify, and quantify any such relationship, which they have not done in this report.

18. Another example of such claims, or more precisely an example of how such claims are arbitrarily applied without justification, is found on page 40, lines 22-28, where the SAB's criteria for assigning a score of 'D' to treatment systems are described. The report asserts that a 'D' score "indicates that it is extremely unlikely (or perhaps impossible) the BWMS could meet a stricter standard, again because the detection limit of the test methods used provide resolution to D-2/Phase 1, at best." This statement, coupled with the report's assignment of a 'D' score to treatment systems in the "Filtration + chlorine dioxide" category (see Table 4.1), is contradicted by information we have already provided to the SAB in the third and fifth paragraphs of our

written comments dated October 19, 2010, and also in our oral comments dated October 26, 2010. Specifically, the report's claim that "the detection limit of the test methods used provide resolution to D-2/Phase 1, at best" is either a false generalization or a conditionally true claim that depends on one or more unstated conditions. If the latter, the SAB authors need to provide a clear statement of the conditions that would make the claim true. Otherwise the authors should delete this claim and the conclusions they draw from it.

19. A related example of such claims is found on page 45, lines 32-36, where the report claims that "Given the data available, it is highly unlikely that any of the systems listed in Table 4.1 could provide organism removal to the level of 100x or 1000x the standard because all systems showed at least one observation of a living organism within the sample volumes as specified in IMO D-2 guidelines, thus clearly exceeding these more stringent standards." This claim, analogous to the one discussed above, is either a false generalization or a conditionally true claim that depends on one or more unstated conditions. If the latter, the SAB authors need to provide a clear statement of the conditions that would make the claim true. Otherwise the authors should delete this claim and the conclusions they draw from it.

20. Another example of such claims (page 66, lines 34-37) is problematic in several ways. First, the report implicitly links the attainment of 100x or 1000x IMO to the achievability of "zero live organisms in the discharge." These should not be linked or confused with each other, as we pointed out on page 3 of our oral comments dated January 5, 2011. Second, the report does not clearly distinguish the question of whether a given standard is *achievable* from the question of whether such achievement is *currently measurable*. As we note above in our comment 14 and previously noted our written comments dated October 19, 2010 and oral comments dated October 26, 2010, the concepts of being achievable and being measurable are closely related, yet they are distinct concepts and need to be properly distinguished by the SAB. Equally importantly, as we have described on various occasions, the achievement of a 100x IMO standard is currently and readily measurable; there should be no question about this. Third, the report inappropriately claims that "The complexity of the systems and the difficulties associated with counting live organisms, particularly the smaller size classes, combine to limit our ability to measure improvements to levels 100X and 1000X IMO." We have already commented on similar wording from the report. See our comment 16 above, where we noted that system complexity is an unavoidable fact of modern life that cannot be portrayed as an automatic or inherent barrier to achieving or measuring 100x IMO. Similarly, the "difficulties associated with counting live organisms, particularly the smaller size classes" cannot be viewed as an automatic or inherent barrier to being able to measure improvements to levels 100x and 1000x IMO. See especially the second paragraph of our written comments dated October 19, 2010. Finally, the report's claim about "difficulties associated with counting live organisms" is a generalization that fails to explain how the SAB authors have concluded that something is possible at the IMO level but substantially less possible (i.e., limited) at the 100x level.

21. Table 4.1 on page 60 of the report apparently needs to be redesignated Table 5.1. There is already a Table 4.1 in Chapter 4, and the table in question is in Chapter 5.

22. Table 2.1 (pp. 14-15) shows several of the concentration-based limits that have been proposed or adopted for organisms in ballast water, but it does not show the 100x IMO limits. These limits fit the table's criteria (proposed or adopted) and have received wide attention, not

only in the current context of New York's VGP certification Condition 2 but in the prior context of Congressional bill H.R. 2830. Is there any reason not to include these limits in Table 2.1?

23. In general, the SAB report does not provide a reliable and useful overview of either the challenge of, or current and foreseeable progress toward, meeting ballast water discharge standards more stringent than the IMO D-2 standard. The IMO D-2 standard can be viewed as the status quo around which formal testing protocols have been built, and in that sense any questions about achievability are more conveniently answered for the IMO standard than for the more stringent standards that some states have found necessary to protect their water quality. However, the SAB charge questions asked for guidance, essentially a progress report, on the current and foreseeable achievability of more stringent standards. The report has not provided this in any reliable or useful way. It properly recognizes the value of formal test protocols but does not adequately recognize the developmental pathway (from concept to preliminary, pilot, and increasingly standardized testing) that necessarily precedes the adoption of a formal test protocol. Of equal or greater importance, the report does not recognize the documented progress already achieved by certain treatment systems, and it therefore does not start from an appropriate vantage point in looking ahead at foreseeable improvements. Part of the difficulty is the lack of a consistent and straightforward statistical approach (as detailed in our comments above), and another part can be traced to the report's lack of clarity in sorting out the different components of progress and the remaining impediments thereto. In combination, these problems prevent the report from being a trustworthy assessment of the current and foreseeable achievability of ballast water discharge standards more stringent than the IMO D-2 standard.

Thank you for this opportunity to address the Committee.

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Alexander B. Grannis
Commissioner

October 19, 2010

US EPA Science Advisory Board
Ecological Processes and Effects Committee
Augmented for Ballast Water
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Ballast Water Treatment Technology: Verification Issues

Dear Ms. Vu and Committee Members:

Thank you for the opportunity to address the Ecological Processes and Effects Committee Augmented for Ballast Water. As the Committee members begin to formulate preliminary advice to EPA pertaining to ballast water treatment technology, we encourage each member to carefully distinguish the differences between available testing protocols and the use of such, versus the efficacy of individual treatment systems as determined by independent testing facilities. While in the ideal world one would develop acceptable protocols for each of the proposed ballast water discharge standards (i.e. IMO, 100x IMO, 1000x IMO) the actual performance of systems is not dependent on such. As explained in more detail below, we believe that tests conducted using the widely available IMO testing protocols will allow testing facilities to determine the efficacy of treatment systems to at least an order of magnitude greater than the IMO D-2 discharge standard and multiple tests evaluating at least 30 m^3 of water cumulatively can be used to determine, with statistical rigor, if systems exceed the 100x IMO discharge standard.

Existing land-based facilities have been designed to test the ability of BWTS to achieve the IMO D-2 discharge standard following the guidelines of the IMO G8 and G9 documents. While it is generally recognized that use of larger sample volumes and additional replicate trials make it possible for facilities to test systems to more stringent standards, such as Condition 2 (100x IMO) of the NYS Certification to the EPA VGP, these approaches are still being studied. We see the development of such protocols as a logical extension of the formal testing protocols presently available to verify system performance to the IMO D-2 standard. Some test facility managers have claimed that testing to a more stringent discharge standard by sampling and analyzing larger volumes of water may be confounded by testing errors, i.e. representativeness will decline as time to conduct the biological analyses increases. This concern merits consideration but should not be viewed as an automatic barrier that halts all further discussion. The relevant discussion may need to consider, for example, whether the time to conduct biological analyses would necessarily increase when testing larger volumes, given the tendency for organism concentrations to be lower in samples that meet a more stringent standard.

A recent publication *Density Matters: Review of Approaches to Setting Organism-Based Ballast Water Discharge Standards* provides a good basis on which to develop more formal protocols for verifying to the 100x IMO and/ or 1000x IMO discharge standards, requiring smaller test volumes than previously deemed necessary. Of particular interest is chapter 10 *Statistical Considerations in Estimating the Concentrations of Organisms in Ballast Water Discharge* which states that "The probability of detecting an exceedance depends on: 1) the volume of ballast that is sampled; 2) the stringency of the discharge standard; and 3) the magnitude of the exceedance." and "When the true concentration of organisms is 0.1 m^{-3} [100x IMO] approximately 30 $m^3$of ballast water must be sampled." Figure 11B on page 81 provides a graphic in which the white regions of the plot indicate a >95% probability of detecting the exceedance.

It is important to note, that the values presented in the above referenced document are probably optimistic due to the fact that the calculations assume that organisms are randomly distributed. Most organisms, though, demonstrate at least some aggregation and for aggregated populations larger volumes must be sampled to obtain good estimates of concentrations. While aggregation is a particular form of non-uniform distribution of organisms, we note that concerns about non-uniform distribution are already partially addressed by existing procedures that are intended to ensure representativeness. Various testing protocols can and usually are utilized to ensure that test samples are representative of the total ballast discharge volume. If testing facilities follow the IMO G8 guidelines, this is accomplished by collecting three replicate samples of discharge treated water collected at each of three times during the period of discharge.

At least one technology developer, Ecochlor, appears to have met the minimum volume requirement suggested for determining if discharge from a treatment system exceeds the 100x IMO discharge standard. This was accomplished by batching individual 3 m^3 test runs (#7-16) conducted by NIOZ utilizing 5 mg/L active substance (vs. 4 mg/L for earlier tests) until a volume of 30 m^3 was reached. NIOZ staff detected 2 organisms >50 um in the 30 m^3 test samples, thus demonstrating compliance with the 100x IMO discharge standard for organisms >50um with about 58% confidence. Additional ship-board testing completed this past summer brought the total test volume to 39 m^3, with the number of organisms detected >50 um remaining at 2 resulting in an increased confidence level of approximately 75%. If this particular ballast water treatment system continues to operate with similar performance, additional testing will likely only increase statistical confidence levels. Two additional technology developers, Quindao Headway Tech and Techcross, may be able to demonstrate similar treatment performance.

Therefore, we conclude that ballast water treatment technology with the potential to comply with the more stringent ballast water discharge/ performance standards set by New York and Wisconsin (100x IMO) has been developed, has demonstrated reasonably high statistical confidence, and is commercially available. We encourage the Committee to carefully consider the information and concepts presented above, and to review the relevant land based and ship-board testing data for the three ballast water treatment systems noted.

We also take this opportunity to forward to you the latest listing of ballast water management systems that make use of Active Substances which received Basic and Final Approval from IMO and Type Approval Certification by their Administration. As noted by California State Lands

Commission staff in the report, *2010 Assessment of the Efficacy, Availability and Environmental Impacts of Ballast Water Treatment Systems for Use in California Waters*, at least eight of these treatment systems have demonstrated the potential to comply with the Commission's performance standards. Three of the eight systems show the potential to meet California's performance standards under more rigorous evaluation criteria. Given the extensive number of systems identified, we are confident that the number of systems capable of meeting more stringent discharge standards, such as 100x IMO or 1000x IMO, will increase in the very near future.

We thank you for the opportunity to present the aforementioned information to the Committee and look forward to hearing the remaining discussions of the various members and interested parties.

Sincerely,

Koon S. Tang, P.E.
Acting Director
Bureau of Water Permits

New York State Oral Comments to US EPA Science Advisory Board
Ecological Processes and Effects Committee Augmented for Ballast Water
October 26, 2010

Good afternoon, and thank you for the opportunity to address the Committee.

My name is Dr. Raymond Vaughan. I am an Environmental Scientist with the New York State Attorney General's Office, and a member of New York's ballast water management team which is coordinated by the Department of Environmental Conservation.

As the Committee moves forward, we encourage each member to distinguish the *availability and use of testing protocols* from the *efficacy of individual treatment systems as determined by independent testing facilities*. As it happens, *actual performance* of treatment systems does not depend on whether a particular test protocol is fully developed. Formal protocols are ultimately needed, but, in the context of the Committee's charge, we note that tests conducted under existing IMO protocols already allow testing facilities to determine treatment efficacy to *at least an order of magnitude greater* than the IMO D-2 standard. *Multiple* tests, evaluating 30 m^3 of water cumulatively, can show *with statistical rigor* whether systems meet a discharge standard 100x more stringent than the IMO standard. The basis for the 30 m^3 volume, which we would be happy to discuss further, can be found in the recent *Density Matters* report. We would also be happy to discuss the issues of aggregation and clustering that the ballast water community is now starting to address.

Using additional trials and larger sample volumes to verify compliance beyond the IMO standard remains a work in progress, but, in general, the *development of formal protocols* is a logical extension of the protocols presently available to verify

compliance with the IMO D-2 standard. With respect to current status, at least one technology developer appears to have met the 30 m^3 volume requirement indicated in the *Density Matters* report. In tests done for Ecochlor, *individual 3-m^3 test runs* were batched until a volume of 30 m^3 was reached. Two organisms >50 um were detected in this total volume, demonstrating compliance with the 100x IMO standard for this size class at about 58% confidence. Recent ship-board testing has brought the total test volume to 39 m^3, with the number of organisms remaining at 2, thus raising the confidence to about 75%. Assuming performance remains high for the Ecochlor system, *additional testing* would provide even better statistical confidence. Other technology developers may be capable of similar performance.

We conclude that *ballast water treatment technology with the potential to comply* with the 100x IMO discharge standards set by New York and Wisconsin *has been* developed, *has demonstrated* reasonably high statistical confidence, and *is* commercially available. On this basis, augmented by the *California State Lands Commission's* latest report, we are confident that the number of systems capable of meeting more stringent discharge standards – such as 100 or 1000x IMO – will increase in the very near future.

Thank you for the opportunity to present this information, both orally and in our written submission. We look forward to the remaining discussions in today's meeting.

NEW YORK ORAL COMMENTS TO SAB, 11/4/2010

We appreciate this opportunity to address the Committee.

My name is Dr. Raymond Vaughan. I am an Environmental Scientist with the New York State Attorney General's Office, and a member of New York's ballast water management team which is coordinated by the Department of Environmental Conservation.

We have two main comments that are intended to be constructive:

First, it looks like the Committee is not consistently posing the right statistical questions, meaning you're not yet being precise or succinct enough in framing the relevant questions and applying the appropriate statistical methods. In the SAB's draft response to its charge question 4, for example, the material on pp. 8-12 appears largely inconsistent with the material on pp. 30-39. There's also a lot of material that's illustrative of statistical concepts in general but appears to be tangential to the questions at hand.

As a starting point, the idealized Poisson requirements for sample volume are very straightforward. Lee et al. describe these requirements well. Granted, you can't just assume an idealized Poisson model, but the Committee needs to parse out and quantify the *quality control issues*, the *effects of volume concentration procedures*, and the *effects of aggregation or clustering*. Each of these can and should be distinguished from the Poisson volume requirements. In particular, you can't just assume overwhelming human and equipment error; you need data to identify the bounds on such error. You can't just assume overwhelming effects from aggregation or clustering; you need data to identify the bounds on such effects.

Our second comment is an apparently new and important one. It involves the following question:

In looking at aggregation and clustering, is the purpose to assess *ballast water treatment system performance* or *tank performance*? In other words, are we more interested in whether organisms are clustered in a ballast water discharge stream due to a momentary malfunction or hiccup of the treatment system, or due to clustering that occurs afterward in the ballast tank? These are separate issues. Assuming that we're all more interested in ballast water treatment system performance, the *uncertainties about aggregation and clustering can be largely eliminated by filling a tank with the required Poisson volume* − for example, 30 m^3 − of water from the outlet of the ballast water treatment system, *and testing 100% of that volume*. Such a test procedure would directly measure treatment system performance and would keep such performance distinct from any subsequent complication of clustering in the ballast tank. Questions of clustering in tanks can't be ignored but need to be assessed separately. Any clustering that occurs in tanks is not necessarily related to treatment-system performance. More importantly, any clustering that occurs in a ballast tank − whether related to treatment-system performance or not − does not affect the measurement of treatment-system performance if 100% of the tank volume is tested.

Thank you.

NEW YORK COMMENTS TO SAB, January 25, 2011, as revised for presentation

We appreciate this opportunity to address the Committee.

My name is Dr. Raymond Vaughan. I am an Environmental Scientist with the New York State Attorney General's Office, and a member of New York's ballast water management team which is coordinated by the Department of Environmental Conservation.

In our comments to the SAB's third meeting last November, we explained briefly how the uncertainty associated with aggregation can be avoided by testing the entire contents of a relatively small but representative ballast tank. Our initial comments today are on this same topic.

Such a tank, which I'll call a "sample tank," can be used for land-based testing, shipboard testing, or compliance monitoring. The sample tank, shown schematically in red in the diagram below, should be configured as a separate ballast tank. Its volume should be either the volume needed to demonstrate compliance for a Poisson distribution, or some fraction thereof. The sample tank should be "partnered" with one of the main ballast tanks, and should be routinely filled or discharged whenever the main ballast tank is filled or discharged (so that both tanks remain equally full on a percent basis).

On uptake, part of the treated flow going into the "partnered" main tank from the ballast water treatment (BWT) system should be diverted isokinetically into the sample tank. On discharge, ballast water should be discharged from the sample tank into the "partnered" tank whenever the "partnered" tank is being discharged. Both tanks should remain the same percentage full at all times, and any backflow should be avoided. This procedure will keep a representative sample of ballast water within the sample tank at all times.[1]

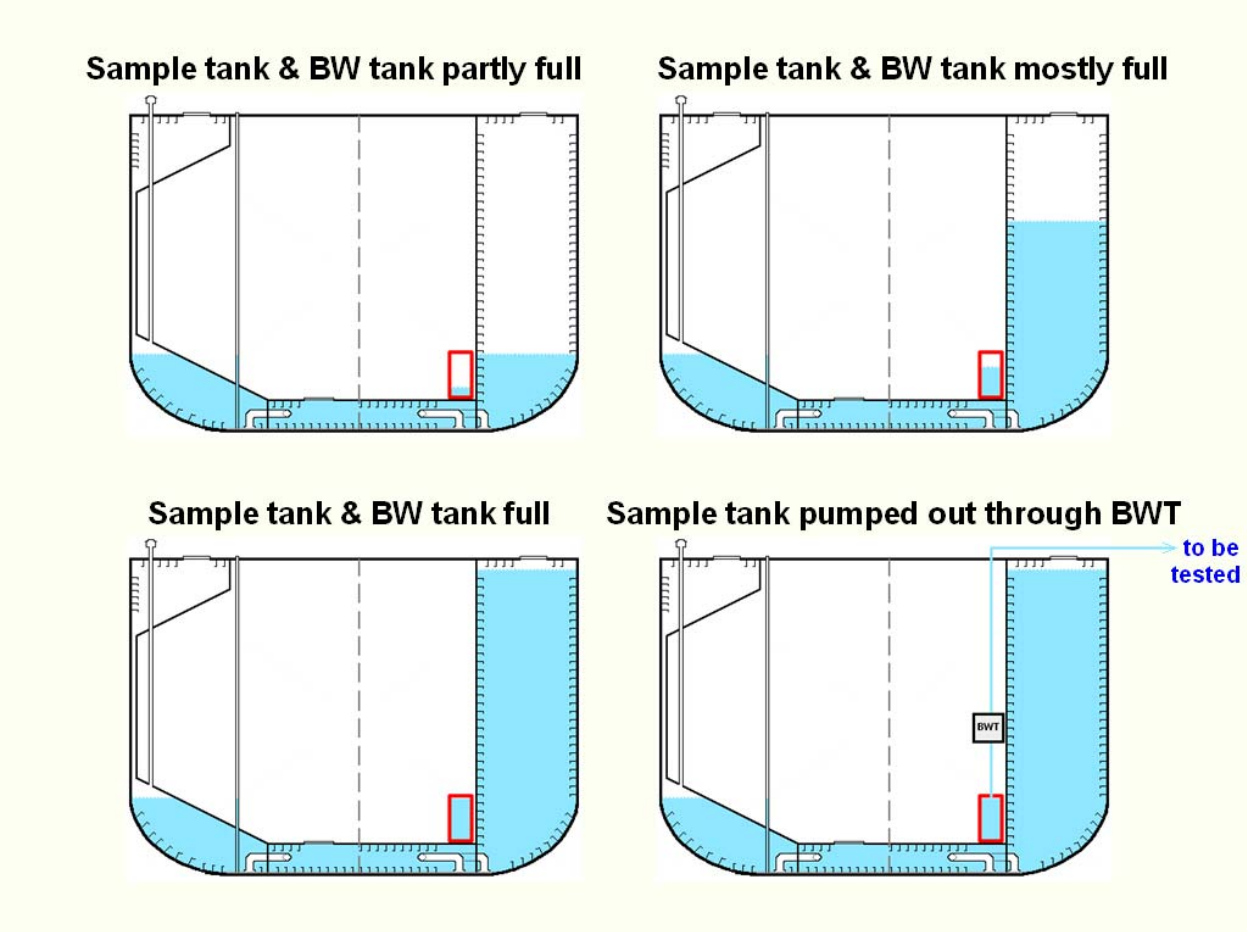
A sample can be collected for testing by discharging the entire contents of the sample tank through the ballast water treatment system (assuming that ballast discharge normally goes through BWT). By testing the entire contents of the sample tank, any uncertainty introduced by aggregation of organisms within the tank will be eliminated.

The size of the sample tank – whether it is the full volume needed to demonstrate compliance for a Poisson distribution, or some fraction thereof – will depend on testing constraints. The tank should not be larger than the volume that can be routinely tested in a single test session. As needed, multiple samples can be collected over time until the full Poisson volume has been reached.

This procedure effectively eliminates the statistical uncertainties that would otherwise be introduced by aggregation of organisms within ballast tanks. A rough analogy can be drawn to the composite samplers that are widely used to collect representative samples in land-based applications (e.g., Isco wastewater samplers).

[1] In effect, the task of collecting a time-averaged sample is shifted to the time when ballasting operations are done. The procedure thus differs from current practice where a time-averaged sample is collected from a ballast tank as an initial step when testing is done.

One comment we've received on this procedure suggests that there may be differences – for example, in surface-to-volume ratio – that would make the contents of the sample tank different from the contents of the partnered main tank. If such an effect indeed exists, it's important to determine whether it affects organism *mortality* or *regrowth* within the tank, or merely the distribution of organisms within the tank. If the latter, the effect makes little or no difference since this procedure essentially eliminates the issue of distributional differences for purposes of testing. On the other hand, if tank properties such as surface-to-volume ratio are in fact contributing significantly to either in-tank mortality or in-tank regrowth, this is something that the ballast water community in general needs to be aware of; it's not just an issue for this sampling procedure.



Our remaining five comments are on the January 11th SAB draft:

First, as noted in our previous comments in November, the SAB's treatment of statistics and interpretations needs to be substantially clearer and more focused. I don't see much improvement in Section 2 of the current draft. Section 2 needs to focus on the central relationship which links statistical confidence to the sample volume and discharge standard for both Poisson and negative binomial distributions. Auxiliary measures such as statistical power are worthy of discussion but need to be recognized as secondary. Any assertions about extraneous sources of error need to be presented as numerical parameters that are clearly defined, quantified within reasonable limits, and capable of being brought into the larger statistical framework.

Second, we see no defensible basis for the SAB's draft conclusions that attainment of a 100x IMO standard is "extremely unlikely" or "perhaps impossible" (p. 31) and that current ballast water treatment systems "are unlikely to ever meet" a 100x IMO standard (p. 36). These claims appear to be leaps of faith, not science.

Third, following up on what I just said, consider the SAB's draft conclusion that existing systems, or combinations of systems, are capable of removing or killing all or nearly all organisms >50 μm in minimum dimension (p. 62). This, combined with the statistical validation methods we've been discussing, clearly contradicts the view that attainment of a 100x IMO standard is extremely unlikely or impossible in the foreseeable future for organisms >50 μm. Let's look then at the remaining components of the 100x IMO standard: organisms in the 10-50 μm size class and indicator microorganisms. For the latter, there should be no question about attainment because there's not much difference between the IMO and the so-called 100x IMO standards for these indicator microorganisms.[2] That leaves only organisms in the 10-50 μm size class as a possible impediment to attaining 100x IMO. However, since the minimum volume needed to demonstrate compliance at 95% confidence based on a Poisson distribution is only thirty milliliters (30 ml), and since existing test data show promising results, there's no reasonable basis for thinking that 100x IMO can't be attained for organisms in the 10-50 μm size class. In reality, it is advisable to test more than the 30 ml minimum Poisson volume for this size class – partly to achieve better statistical power and partly to deal with organism populations that are likely to be aggregated – yet neither the test volumes nor the test results to date are indicative of any serious problem in meeting 100x IMO for this size class. In short, there is no identified problem in meeting 100x IMO.

Fourth, it is important not to confuse 100x IMO with the achievement of a "zero or near zero discharge." For a vessel that complies with 100x IMO, the ballast discharge[3] may allowably contain up to 1000 or more organisms >50 μm, and up to 1 billion or more organisms in the 10-50 μm size class. These are not zero or near-zero numbers.

Fifth, if there are significant concerns about biological contamination in the piping aboard "imperfect ships" (pp. 62-63), this may be an additional reason to implement the combination of ballast water treatment and ballast water exchange that has been advocated in recent months. Mid-ocean exchange or flushing will reduce any such contamination lurking in pipes, and will also provide a relatively uniform and organism-sparse flow of water into ballast water treatment systems, thereby reducing the log-reduction task needed from ballast water treatment.[4]

Thank you.

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[2] Using Condition 2 of New York's 401 certification as the example of a 100x IMO standard, the *vibrio cholera* limit is the same as the IMO limit (<1 cfu per 100 ml in both cases), the *e. coli* limit differs from IMO by about a factor of 2 (<126 cfu as compared to <250 cfu per 100 ml), and the intestinal enterococci limit differs from IMO by about a factor of 3 (<100 cfu as compared to <33 cfu per 100 ml).

[3] "Ballast discharge" refers to the discharge from a fully ballasted vessel, where oceangoing vessels entering the Great Lakes may carry up to 10,000 m^3 or more, and other vessels may be considerably larger (or smaller).

[4] In particular, mid-ocean water will have sparse populations of the organisms that are typically of concern for receiving ports and ecosystems. In general, please note the "shorthand" terminology used throughout the oral presentation: terms such as "organisms >50 μm" should properly refer to ≥50 μm and "living" or "viable" organisms, etc., etc.

New York State Department of Environmental Conservation
Assistant Commissioner
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Joe Martens
Acting Commissioner

FEB 0 7 2011

Re: New York State DEC Division of Water
EPA VGP CWA 401 Certification Conditions
Vessel Extension Letter
Condition 2 Ballast Water

Dear Sir or Madam:

The New York State Department of Environmental Conservation (Department) has received your request for an extension to the implementation date for Condition 2 of New York's Clean Water Act 401 Water Quality Certification (WQC) to the Environmental Protection Agency's (EPA's) Vessel General Permit (VGP). New York's WQC is incorporated herein by reference. As noted in the text of Condition 2 of the WQC, "No extensions will be made to this implementation date, unless an entity covered under the permit makes a request for an extension to the Department and can provide sufficient justification for such a request." This letter answers your request for a time extension to Condition 2 of the WQC for your vessel(s), meaning the vessel(s) listed in your request for extension, and/or vessels for which you have filed, or may file, a Notice of Intent (NOI) to be covered under the VGP.

After a review of the request for extension filed under your name, the Department has determined that the information you provided demonstrated that:

1.) There is a shortage in supply of the technology necessary to meet the limits set forth in the certificate, or a vessel-specific engineering constraint, or other factor related to the availability and installation of technology beyond the vessel owner/operator's control, that delays the technology being available and installed in time to comply with this standard; and/or

2.) The unavailability of supply or installation constraint is the only reason the January 1, 2012 date cannot be met; and/or

3.) The vessel has exhausted all other options to comply with this standard. *The Department has also determined that ballast water treatment technology capable of meeting the discharge criteria in Condition 2 of WQC has been developed as further explained in the Addendum attached to this letter.* Furthermore, the Department has determined that ballast water treatment technology continues to advance rapidly (as summarized in reports issued by Lloyd's Register and others, and illustrated by test results released by vendors such as Ecochlor: see Addendum), and that the extension offered herein will provide adequate time for the installation of a ballast water treatment system on your vessel(s) to meet New York's water quality standards.

The Department continues to be concerned about the economic and ecological impacts of aquatic invasive species, including their negative impacts on the fish and wildlife resources of New York and other states. Consistent with its December 17, 2008 statement in the WQC the Department finds an ongoing need for discharge standards that will reduce these ecological and economic impacts in a way that meets the requirements of federal and state law, including state water quality standards. The economic disruption to communities just from the zebra mussel alone has already cost billions of dollars. The effects of other invasive species such as the round goby, spiny flea and Asian shore crab continue to threaten the economic vitality of the fishing and recreational waters of New York and the Great Lakes.

By copy of this letter, the Department extends the implementation date for your vessel(s), and all other similarly situated vessels, to comply with Condition 2 of New York's WQC to midnight August 1, 2013. In granting the extension, the Department expects you to play an active role in ensuring the timely availability of the technology needed to comply with Condition 2, and in installing compliant treatment system(s) on your vessel(s) by August 1, 2013. In the event that EPA issues a new VGP prior to midnight August 1, 2013, the Department reserves the right to incorporate the August 1, 2013 compliance deadline in a new Clean Water Act 401 Water Quality Certification.

If a ballast water treatment system that meets the discharge criteria in Condition 2 of the WQC is not installed on your vessel(s) by August 1, 2013, then such vessel(s) operating in New York waters will be deemed out of compliance with New York's WQC to the EPA's VGP.

Additional requests for extensions to the implementation date for Condition 2 of New York's WQC may be considered on a case-by-case basis. In considering such requests, the Department will look more favorably on cases where substantial effort and progress have been demonstrated by documentation which must:

1.) Provide a record of your progress over time in identifying and installing the necessary technology on your vessel(s), including descriptions of steps you have taken at intervals no more than nine months apart, and also including current information which covers the most recent three months or other reasonable time period preceding the date of your request;

2.) List each ballast water treatment system you have evaluated that is reasonably capable of installation on your vessel;

3.) Describe, for each ballast water system you have listed, its potential to meet the requirements of Condition 2 of New York's WQC;

4.) Explain, for each ballast water system you have described, how you reached a conclusion about its potential to meet the requirements of Condition 2 of New York's WQC;

5.) Determine, for each ballast water system you have described, its availability for installation on your vessel(s); and

6.) Describe the active efforts you took to ensure that ballast water system(s) capable of meeting the requirements of Condition 2 of New York's WQC would be

installed on your vessel(s) by August 1, 2013, including reference to vessel-specific plans prepared by a qualified engineer or naval architect that show installation details of the work in progress on your vessel(s). In the event you have not already begun to install such system(s) onboard your vessel(s) as of the date of your extension request, you must provide clear and substantial justification that shows how an additional extension will serve the purpose of bringing your vessel(s) into compliance within a short additional period of time.

In considering such requests, the Department reserves the right to apply a more flexible extension policy to vessels enrolled in the U.S. Coast Guard's Shipboard Technology Evaluation Program (STEP) and equivalent technology demonstration programs than to other vessels. Other conditions of New York's WQC relating to graywater and bilge water remain unchanged unless extensions are provided by separate letter.

Sincerely,

James M. Tierney
Assistant Commissioner

Addendum: Comparison of Ecochlor data to requirements of New York Condition 2

The New York State Department of Environmental Conservation has determined that Ecochlor's land-based test report for runs 7-16 (see Final Report issued February 2009 by NIOZ at www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480b130b5) shows results that are at or near the confidence level needed to demonstrate compliance with New York's Condition 2, as discussed below. Condition 2 is part of New York's Water Quality Certification (WQC) to EPA's Vessel General Permit (VGP). New York's WQC, incorporated herein by reference, can be found starting on p. 82 of EPA's VGP which is online at www.epa.gov/npdes/pubs/vessel_vgp_permit.pdf. Confidence level calculations are based on a Poisson distribution (see Lee et al., *Density Matters*, EPA/600/R-10/031, 2010) and based on the assumption that living organisms are randomly distributed.

1. *Zooplankton.* Statistical confidence that Ecochlor's system meets the 0.1 per m^3 living organism limit for organisms >50 μm (corresponding generally to zooplankton) is 57.68%, based on run 7-16 test results in which 2 living organisms were counted in a total sample volume of 30 m^3. In this and following paragraphs, "total sample volume" refers to total sample volume prior to concentration. Runs 7-16 are those in which the Ecochlor system operated in its standard configuration (including filter) at a 5 mg/liter concentration of chlorine dioxide. See Table 8 of the NIOZ report.

2. *Phytoplankton.* Statistical confidence that Ecochlor's system meets the 0.1 per ml living organism limit for organisms 10-50 μm (corresponding generally to phytoplankton) is in the range of 83.64% to 100.00%, based on run 7-16 test results in which total sample volume was 100 liters, and depending on how the "E-T5*" results reported in Table 9 as "<0.1 cell/ml" are interpreted. If the E-T5* results listed as "<0.1 cell/ml" are conservatively interpreted to mean ≤0.099 cell/ml, then the 0.1 per ml living organism limit is met with a statistical confidence of 83.64%. Alternatively, if the E-T5* results listed as "<0.1 cell/ml" are interpreted to mean ≤0.096 cell/ml, then the limit is met with a statistical confidence of 100.00%.

3. *Indicator microorganisms.* Statistical confidence that Ecochlor's system meets the 126 cfu per 100 ml limit for *E. coli* is 100.00%, based on run 8-16 test results in which <0.1 count/ml was reported for the 5.4-liter total sample volume obtained from the nine test runs. See p. 22 and Table 12 of the NIOZ report. (No *E. coli* data are reported for run 7.) Statistical confidence that the 33 cfu per 100 ml limit will be met for intestinal enterococci cannot be readily determined from Table 12 because the detection limit for the reported data is too high (all ten runs are reported as "<1 count/ml"), but compliance is expected to be routinely achievable for this microorganism based on the known effectiveness of chlorine dioxide and based on the fact that the 33 cfu per 100 ml limit is also the U.S. federal primary recreational water quality criterion which is routinely measured and met. This limit differs from the IMO limit for intestinal enterococci by only a factor of three. For *vibrio cholera*, the NIOZ report lists no test results in Table 12, apparently because *vibrio cholera* was not present in the intake water at the test facility. Page 38 of the NIOZ report refers to studies that show the effectiveness of chlorine dioxide against *vibrio cholera*. Compliance with the New York limit for this microorganism is expected to be routinely achievable, partly for the above reasons and partly because the New York limit is the same as the IMO standard for *vibrio cholera*.

As noted, these results are at or near the confidence level needed to demonstrate compliance with New York's Condition 2. Other technologies may also currently exist that comply with Condition 2, and it is expected that more technologies will be developed to comply with Condition 2 in the near future.

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March 14, 2011

File Ref: W9777.290

Ms. Iris Goodman
Designated Federal Officer
EPA Science Advisory Board (1400F)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE: Science Advisory Board Staff Office; Notification of Two Public Teleconferences of the Science Advisory Board Ecological Processes and Effects Committee Augmented for Ballast Water

Dear Ms. Goodman and Committee Members:

The Marine Invasive Species Program of the California State Lands Commission (Commission) appreciates the opportunity to provide comment to the Science Advisory Board Ecological Processes and Effects Committee Augmented for Ballast Water (SAB) on the near-final report on ballast water treatment technology, also known as the "SAB Draft Report dated March 3, 2011 for EPEP Ballast Water Review."

Since 1999, California has been and remains a national and world leader in the development of effective science-based management strategies for preventing species introductions through vessel vectors. The Commission's Marine Invasive Species Program (MISP) pursues aggressive strategies to limit the introduction and spread of nonindigenous species (NIS), including recently establishing strict performance standards for the discharge of ballast water. California's performance standards serve to force the regulated industry to develop technology-based strategies to manage NIS in ballast water discharges.

California works cooperatively with the United States Coast Guard (USCG) and the EPA in order to advance a consistent, strong, enforceable, funded, national program that pushes technology and the science of vessel vector management forward, while ensuring that the state's existing, world-leading programs be allowed to continue. Based upon the MISP's extensive experience in the management and regulation of vessel vectors, Staff offers the following comments on the near-final SAB report on ballast water treatment technologies.

General Comments

Comment 1 – Measurability does not necessarily equate to system performance limitations

The report frequently confuses *measurability* (e.g. detection limits) with the *performance ability of BWMSs*. If the detection limits of current measurement methods are not sufficient to measure to standards stricter than the IMO D-2, conclusions should not be made about the ability or inability of systems to meet those standards, as the system's full potential cannot be known.

Specifically, the report at times indicates that the detection limits of current testing methods precludes the ability to evaluate if systems can meet stricter standards. At other times, the report concludes that BWMSs will never meet the stringent proposed USCG Phase II standards. For example:

> *Page 44, line 7-8 suggests evaluation to stricter standards cannot be done:* "The detection limits for currently available test methods and approaches prevent a complete statistical assessment of whether BWMS can meet any stricter discharge standards."
>
> *Yet, page 44, line 10-12, concludes that standards cannot be met:* "Available data also indicates that no current BWMS can meet the USCG Phase 2 standard, particularly for categories such as total bacteria."
>
> *Page 44, line 13-15 goes back to indicating that system performance cannot be known:* "Because the only reliable data available to the Panel were on BWMSs that were able to meet D-2 standards, it is not possible to identify types or categories that will be unable to reliably reach any or all of the other discharge standards."
>
> *Similarly, page 36, lines 21-28 states that it is currently not possible to detect the achievement of a BWMS to 100x more stringent standard to the IMO D-2/USCG Phase 1 standard*.

Given these facts there is no support for the conclusion included in the Executive Summary (p. 4, lines 11-15) that, "…five BWMS types may be able to reach 10x D-2/Phase 1 for the > 50 µm and 10 – 50 µm size classes sometime in the near future, if both treatment performance and testing approaches improve." If current BWMS performance is not known, projections about improvements to technologies and their future abilities should not be made. Similarly, the statement that, "…wholly new treatment systems need to be developed in order to meet more stringent proposed standards (i.e., standards that are 38 100x, or 1000x more stringent than D-2/Phase 1)," (p. 1, lines 37-39) is not supported.

Comment 2 - Development of novel treatment systems

The conclusion that, "… due to technological, *logistical, and personnel constraints* imposed by shipboard operations, the Panel also concluded that wholly new treatment systems need to be developed in order to meet more stringent proposed standards (i.e., standards that are 100 x, or 1000 x more stringent than D-2/Phase 1)," (Executive Summary, p. 1, lines 37-39) is not supported by the information supplied in the report. There is no description related to specifically which logistical & personnel constraints are limiting (e.g. training? number of staff? time in port? time at sea?), and no evaluation of existing BWMS on how well they do or do not address the undefined constraints.

Comment 3 – Omission of smaller organism size classes
The report contains little information, statistics, measurability and system performance for organism size classes ≤10 µm, including information for microbial indicator species (*E. coli*, Intestinal Enteroccoci, *V. cholerae* O1 & O139). This is true, even though these organism classes represent a majority of the IMO performance standards (4 out of 6 total). Further, chapters 3 and 4 do not clarify if information on these organism classes is accounted for in those evaluations. Information for ***all*** classes of organisms should be included for a complete evaluation. The focus of the report should not only be the >50 µm size class.

Comment 4 – Onshore treatment
The authors consider onshore treatment to be promising. We agree, but believe that the report makes unsubstantiated statements about the ability of onshore Facilities to reach higher ballast water treatment standards than shipboard systems. No data has been presented to support this statement. Unless the report can include performance data side-by-side between shipboard treatment systems and onshore Facilities, these statement should be removed.

Comment 5 – Limited availability of system performance data
The report makes broad conclusions about the ability and availability of ballast water treatment systems to meet a variety of ballast water treatment systems. These conclusions are based on a small subset of the available data on ballast water treatment performance. Only 9 reliable data sets were collected, however 51 treatment systems were identified as under development or available for purchase. Whole categories of treatment systems were not reviewed for this report. Therefore this report cannot be considered a comprehensive review of the current and foreseeable progress toward meeting ballast water discharge standards more stringent than IMO.

Comment 6 – Failure to recognize successes
Ultimately the goal of all ballast water treatment systems is to kill organisms entrained in ballast water and prevent or reduce the introduction of species into recipient environments. Although only a small amount of data is available for this report, there is no recognition of the fact that significant progress has been made in reducing organism concentrations in treated ballast water discharges. A useful overview of treatment systems should not only point out deficiencies and areas needing improvement, but should also highlight successes that have been achieved in both system development and testing.

Specific Comments
Pg 1, line 20 – The statement that information was compiled on 51 treatment systems is misleading. 51 treatments may have been initially examined, but data packages were received for only 15 systems, and only 9 of those were considered reliable. Nowhere in the executive summary is it stated that all the conclusions about the availability of treatment systems are based on this small sample of data.

Pg 7, lines 36-39 - There is not adequate supporting evidence for the conclusion, “Meeting increasingly stringent performance standards will require that BWMS perform nearly perfectly, nearly all of the time. Existing ship ballast water management systems and practices do not support this level of control or performance; a fundamental shift in system design and operational practices would be needed.” Inadequate information is provided indicating how the performance of control systems or system design for BWMSs were evaluated, thus it is

unknown how or why such elements are currently inadequate. No information is clearly provided indicating how "operational practices" hinder BWMS performance. Further, earlier claims indicating that the performance of BWMSs to stricter performance standards cannot be evaluated, suggest that such conclusions cannot be made.

Pg 13, lines 15-36 – The Federal overview provided is inadequate. The section does not sufficiently describe the dual regulation of ballast water by EPA and USCG. The reader needs further information to understand how ballast water treatment systems may be evaluated/approved similarly or differently by EPA and USCG and how this may play into the availability and use of treatment systems by vessels operating in US waters.

Pg 13, Section 2.3.1, beginning line 41 – U.S. States may establish standard either through Section 401 processes or as separate laws. USCG laws (NANCPA and NISA) do not limit states rights. This section needs clarification. It would be useful to provide examples of state standards that are set in law (such as those in California).

Pg 14, Table 2.1 –The California interim standard for organisms greater than 50 microns is "no detectable living organisms." There is no volumetric requirement associated with this standard. The standard is not "no detectable living organisms" per cubic meter. Similarly the California Final Standard is set as "zero detectable living organisms for all organism size classes." There is no volume associated with this standard.

Pg 15, Section 2.3.2 – This section may be a better fit if included in Section 6.6 (pg 108). The charge questions clearly delineate that this report will focus on a review of ballast water treatment systems. The risk management section begins to discuss other sub-vectors associated with vessel movement (i.e. fouling). This may serve to confuse the focus of the report. This section would be better suited towards the end of the report, after the charge questions are addressed, to point out that while the focus of the report is on ballast water treatment that the management of vessels as a whole is essential to reduce the risk of species introductions.

Pg 18, lines 28-30 – This section seems out of context. There has been no discussion of onshore or land-based treatment options thus far. Clarify or remove.

Pg 19, line 7 – Recommend replacing "hull fouling" with "vessel fouling" or "biofouling." Fouling organisms may be found on many wetted surfaces other than hull (e.g. propeller, stabilizers…).

Pg 19, lines 29-38 – The authors should clarify that these are water quality issues. Not all systems that use active substances include the use of decontamination agents. Systems that create low oxygen environments or change the pH can also impact receiving waters.

Pg 23, lines 21-31 – As written, this section seems to indicate that the only way to do credible system testing is to focus on zooplankton-sized organisms. In reality standards encompass a variety of size classes. The bacterial indicator species standards can be tested for without much difficulty based on well-established, standardized tests. The volumes for the 10-50 micron size classes are much more practical to handle even though scientists are still developing tests to easily determine viability. The report's focus on zooplankton detracts from the success occurring at treating and detecting treatment performance for the other size classes. The section needs to

break out what is involved in credible testing, and then it should discuss how zooplankton create a particularly challenging statistical situation.

Pg 37, lines 12-18 – The statement that it is impracticable to measure for the 1000x standard may be correct for the greater than 50 micron size standard due to sampling volumes, but is not necessarily correct for smaller organism size classes. This caveat needs to be added to the text.

Pg 38, Section 4.3 – The methods of analysis for this entire section are not clear. It would be very difficult for anyone to replicate the analysis presented in this report based on the information provided. We recommend adding additional text, or perhaps an example in the appendix, to describe how data were analyzed in order to come up with the rankings provided in Table 4.1.

Pg 40, lines 19-20 – As previously discussed in the General Comment, it is important not to confuse technical ability of the system to meet a standard with our ability to measure compliance with the standard. This statement will confuse readers and needs clarification.

Pg 40, line 37 – Reference should be to California State Lands Commission 2010, not Dobroski et al. 2010.

Pg 41, Table 4.1 – No citations are provided for the information presented in this table. It makes it extremely difficult for anyone to conduct a similar evaluation of the available data if the authors do not provide references to the reports examined for this analysis. Also, it is not clear if the reviewers focused on data for all organism size classes or whether the focus was on data for the greater than 50 micron size class. The authors should have conducted the review of data for all organism size classes. This information needs to be included.

Pg 41, lines 9-13 – There seems to be confusion about whether systems cannot actually meet more stringent standards or if we don't have methods to determine if they can meet the standards. Scientists have no methods to account for total viable bacteria at this point (although the authors fail to make this point in the text), so it seems difficult to make a statement that the standard cannot be met. Please provide reasoning.

Pg 45, lines 32- 36 – Given the fact that only 9 systems have reliable data, it seems a bit of a reach to say that "it is highly unlikely that any of the systems listed in Table 4.1 could provide organism removal to the level of 100x or 1000x…" The authors may be able to make this conclusion for the systems that have provided data, but the extrapolation to all systems listed in the report is unwarranted and misleading.

Pg 46, lines 5-14 – The argument for why systems cannot meet higher standards is not supported based on the information provided. The authors noted that systems have not been tested for the higher standards and that limits of existing assessment methods inhibit our ability to determine if systems have reached the higher standards. This does not mean they the systems cannot meet the standards; we just don't have the capability to test for it at this time. A more open ended conclusion is appropriate based on the information presented.

Pg 47, Table 4.2 – Are the considerations presented in Table 4.2 the opinion of the reviewers or based on information presented in reports and in the available data? If reports were used to

guide these considerations, please cite accordingly. Or clarify if the considerations are the opinion of the reviewers.

Pg 48, lines 3-6 – Again, information not supported by citations or references. What is the source of information for the statement, “deoxygenation, if operated properly, can dramatically reduce uniform corrosion rates, but alternatively may results in increased corrosion rates due to either the cycling hypoxic…” Is this statement based on existing data?

Pg 46, Section 4.8 – This section does not appear to address concerns related to the water quality of treated ballast water discharges. While the issues discussed in this section may not impact the performance of the system, water quality issues are highly relevant to the applicability of systems (as brought up in the conclusion statement for this section). Almost everything can be killed in ballast water if sufficiently high levels of biocides are employed, but impacts to the receiving environment are too great to ever consider using such a highly toxic system. This section largely ignores that water quality standards in receiving waters may impact which systems can be used by vessels operating in selected waters. We do not expect this panel to review all available water quality standards, but the report should acknowledge that this will be an issue when determining system availability. Already one system has been pulled from the market because, while it was highly effective at treating ballast water, it had the potential to be toxic in freshwater and very cold environments.

Pg 51, lines 7-8 – The authors note that “Combinations of some systems above may results in improved performance, and we recommend that trials be conducted to determine optimum combinations.” The authors fail to note that some of the existing 51 systems listed in Table 4.1 are combinations of such technologies. The data on these systems was not made available for this report, but it is possible that existing technologies have achieved some levels of improved performance over those few discussed in detail in this report.

Pg 51, lines 10-11 – Insufficient evidence is presented to support that statement that altogether new technologies will be needed for 100X and 1000X IMO regulations. The report makes it clear that: 1) data has been examined for only a small subset of existing technologies, 2) data collected thus far has only been from testing conducted for the IMO standards, and 3) existing methods of evaluation are insufficient (levels of detection are not low enough) to determine if systems can meet standards of 100X or 1000X IMO. The statements make it clear that a significant amount of additional testing is necessary and that we need to continue to develop new and enhanced methods of quantifying organisms in ballast water discharge, but the authors fail to make a clear argument as to why new technologies are necessary.

Pg 53, line 17-19 – The information on numbers of systems that have Type Approval is not provided for other treatment methods discussed (such as filtration + UV or oxidant-based systems). We recommend standardizing the approach to presenting this information for all types of systems. Also, only one deoxygenation system provided reliable data for this report. Which type of deoxygenation method was used by that system?

Pg 58, lines 15-16 – See comment for pg 51, lines 10-11.

Pg 58, lines 18-26 –This information is not highlighted sufficiently in the executive summary or other portions of the report. As written, the report appears to say that the challenge of meeting more stringent discharge standards is not only a function of the design of ballast water

treatment systems but also the design of piping and plumbing of existing and new vessels. Thus vessels as a whole may need some plumbing designs into order to increase efficacy of treatment. This information has not received much, if any, public attention but should be emphasized here.

Pg 58-61, “Perspective on More Stringent Standards” – While this information is useful and provides valuable information and perspective for those reading the report, the detail presented may cause confusion when it comes to understanding the direct answers to the charge questions. This section may be better suited for the appendix.

Pg 61, lines 16-20 – Although this information is not technology-based, it does play into a risk management strategy, and should be brought up and discussed in Section 2.3.2.

Pg 62, “Idealized shore-side plant” – The authors should also consider presenting an idealized shipboard facility or an idealized barge-mounted facility. There are additional options for treatment other than shipboard treatment, but the authors focus here solely on shore-side treatment and do not provide evidence as to why an idealized shore-based facility would be superior to something such as an idealized shipboard or barge-mounted facility.

Pg 63, lines 9-10 – This broad statement is not backed by any information cited in the text. What are the capabilities of existing onshore water treatment facilities? Are the methods of treatment at these facilities equally effective in freshwater vs. saltwater environments? Will these systems be effective for the virus and total bacteria standards in the USCG Phase-2 standards? This conclusion statement has no basis without this type of additional information.

Pg 63, “Concepts for Meeting a More Stringent Ballast Water Standard” – Similar to our comments for “Pg 58-61, Perspective on More Stringent Standards” – this information is useful and provides a level of consideration of approaches not discussed in other reports or publications. However, the level of detail may be more appropriate for an appendix that the body of the report.

Pg 66, lines 1-2 – The summary states that the conceptual treatment system “is presented solely to assist in the evaluation of how more stringent treatment standards might impact vessel arrangements, operations, and costs.” Yet, lines 22-24 (pg 63) state that the conceptual system neither estimated “capital nor operating costs.” Thus, the conclusion that this concept provides information relative to costs is inappropriate.

Pg 66, lines 34-37 – This bullet point confuses two important issues – the performance of the treatment system and the ability to detect and measure organism concentrations in ballast. As discussed throughout the comments, these issues must be addressed separately when considering whether or not systems will be available to meeting ballast water standards.

Pg 68. lines 10-12 – We are not aware of, nor has the report indicated the availability of, any shore-based treatment facilities that exist for treating segregated ballast water [Note: we are aware of at least one facility in Alaska geared towards treating un-segregated (dirty) ballast]. Therefore it is confusing to read this statement that shipboard constraints need to be considered relative to “potential increased usage of shore-based treatment facilities.” It would be more appropriate to say that shipboard constraints should be considered relative to the development and construction of shore-based facilities.

Pg 68, lines 23-28 – Please provide references for this information.

Pg 68, lines 29-31 – What is the reasoning behind the statement that "Pragmatically, it may be best to focus on eliminating larger organisms in ballast water…then assessing the extent to which smaller organisms (e.g. bacteria, viruses) survive the treatment…" Are these larger organisms more invasive than smaller organisms? If the goal is to prevent or reduce species introductions, then the focus should first be on the size class that is most invasive, but this information is not provided to the reader. Certainly it is more difficult to detect if systems have reached standards for this larger size class because of the small numbers present in treated ballast and the large volumes of water that must be sampled to determine performance at treating this size class.

Pg 71, line 18 – The statement that "there is no formal environmental assessment approval program for BWMSs" is confusing. Are the authors referring to approval for water quality/toxicological purposes or approval of a system for biological efficacy relative to a performance standard? This paragraph is comparing two different types of standards. The first sentence of the paragraph refers to biological performance while the rest appears to discuss water quality issues. As the federal government (EPA and USCG) has not yet adopted performance standards, obviously no treatment systems have yet been federally approved to meet biological performance standards. Additionally, at this time there are no approval programs in place for water quality purposes (unless a biocide needs registration under FIFRA). Vessel discharges must meet applicable water quality standards. This paragraph needs clarification to separate out approvals for biological efficacy vs. approvals for water quality.

Pg 76, line 5 – The California standards are not suggested, they are established in statute. Additionally the California standards were not implemented through the Clean Water Act Section 401 certification process. They were enacted in separate California statute and then implemented via California regulation.

Pg 80, lines 2-17 – This approach could have major implications for causing "false positives" for failure to comply with performance standards. UV systems are a major subset of available treatment systems, and many organisms treated by this approach may not display destruction of cellular components. Thus these organisms may be scored as "viable when collected" when they are actually dead or dying. Unless the committee can provide evidence that these "false positives" would not frequently occur, it seems premature to recommend preserving samples immediately.

Pg 90, lines 20-24 – This summary is not necessary. The rest of the report does not use this type of summary paragraph.

Pg 91, "Transfer and Reception" – This section fails to discuss that transfer and reception connections must be standardized. If the vessel's connecting pipe doesn't match up with the reception facility, then transfer will not be possible. This standardization will require world-wide effort to ensure that as vessels travel from country to country that there are no problems with the ability of vessel to hook up to necessary reception facilities.

Pg 92, line 18 – Are port-based vessel Facilities less effective or suitable that on-shore facilities? Why are they not included in the discussion? A report by McMullin et al. (2008)

addressed the feasibility of facilities at the Port of Milwaukee and found that the most cost-effective and practical approach to treatment involved the discharge of ballast to a barge to store or treat the ballast before possible further treatment onshore.

Pg 94, lines 21-27 – Unless studies have been performed to compare ballast water treatment performance between shipboard and onshore facilities, there is no basis for the assertion that onshore facilities are more effective than shipboard facilities. Please include this data.

Pg 94, "Comparison of cost of on-shore facilities to shipboard BWMS" – This is the only section in the report that addresses cost of treating ballast water. While we agree that a comprehensive comparison of the cost of onshore facilities is necessary, we recommend that this information be included in a separate white paper and not in this report, unless, discussions are included in other parts of the report to address costs associated with the different types of ballast water treatment systems and costs associated with testing etc… It seems inappropriate to only discuss economics in this section, when it will clearly be a deciding factor in regards to all aspects of system purchase, installation, testing and compliance enforcement.

Pg 94, lines 38-39 – Is the screening-level analysis referred to in this sentence the 1993 AQIS report discussed in the Appendix? The citation should be clearly made in this section. The AQIS report, while useful as a historical reference, does not seem appropriate for analysis of current-day costs of either onshore or shipboard ballast water treatment. This analysis was conducted prior to the development of any international, federal or state ballast water management laws and before the development of any current ballast water treatment systems. Simply adapting the costs presented in the AQIS report to 2010 dollars does not take into account the large changes in technologies, and presumably the cost with development and purchase of such technologies, that has occurred during the last 17-18 years.

Pg 98, lines 2-4 – What are the costs of treatment installations? Unless this report presents up-to-date numbers for the installation of various treatment systems, this statement has no data to support it.

Pg 101, Figure 6.8, Number of Installations – All vessels will not necessarily need to install treatment systems. Vessels that are able to use permanent ballast tanks or move ballast among tanks may be able to avoid the need to discharge ballast. Some vessel may also use municipal water as ballast and therefore not need to treat before discharging. Finally, there has been some movement to develop ballast-less ships and these vessels would not require a treatment system.

Pg 103, lines 2-3 – We see no evidence in Section 6.4 that Facilities will be able to reach higher ballast water treatment standards than shipboard systems. No data has been presented to support this statement. Unless the report can include performance data side-by-side between shipboard treatment systems and Facilities, this statement should be removed.

Pg 105, lines 1-2 – Current law requires coastal vessels operating on the US West Coast, that intend to discharge ballast water, conduct a ballast water exchange more than 50 nm from shore. California, Oregon and Washington have high compliance rates with coastal ballast water management requirements. Other countries, such as Canada, are looking very closely at requiring exchange in addition to treatment to ensure that stringent ballast water standards are

met (as discussed later in this report). This section of the report does not give this potentially valuable management strategy sufficient weight.

Pg 107, Section 6.5.5 – This section seems to be tucked in at the end, when in fact, it describes important ways of potentially increasing the efficacy of ballast water treatment systems. This information should be included earlier in the report when methods of improving system performance are discussed.

Pg 108, Section 6.6 – We recommend taking the information presented in Section 2.3.2 and including it in this section. Section 2.3.2 seems out of place and disrupts the flow of the initial portions of the report.

Pg 111, Section 6.7 – This section includes no summary of the information gathered from the review of system performance data. Instead it jumps from a summary of what is wrong with available data to alternatives to shipboard treatment. There is no recognition of the fact that great strides have been made in the development of shipboard ballast water treatment technologies. While only limited data was available for this analysis, it is still clear that the shipboard treatment is substantially and significantly reducing the numbers of aquatic organisms in ballast water. This will result in a reduction in the number of organisms being discharged into US waters and will likely result in a decrease in the introductions of new species. This success should be celebrated.

Additionally, this section seems to have been hastily assembled. There are duplicative bullet points, and the charge questions – the reason for development of this report - are not referred to nor answered.

Pg 112, line 29-30 – Be more specific about how onshore treatment will be more adaptable than shipboard treatment. It not clear based on the information presented.

<u>References Cited in Comments</u>

McMullin, J., V. Loete, R. Larson, S. Sylvester, and D. Drew. 2008. Port of Milwaukee Onshore Ballast Water Treatment. 17 pp.

Thank you for consideration of these comments. If you have any questions, please do not hesitate to contact me.

Sincerely,

Maurya B. Falkner
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Marine Facilities Division

CC: Kevin Mercier, Acting Chief, Marine Facilities Division

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Joe Martens
Commissioner

March 25, 2011

SENT BY PDF AND REGULAR MAIL

Ms. Iris Goodman
Designated Federal Officer (DFO)
EPA Science Advisory Board (1400F)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW.
Washington, DC 20460

Re: Scientific Advisory Board Draft Report and SAB discussion during March 15 and March 17 teleconferences: New York's comments

Dear Ms. Goodman:

This letter provides New York State's additional written comments on the Scientific Advisory Board (SAB) Draft Report, and on the SAB's discussion of that report during its March 15 and March 17 teleconferences. The comments have been prepared primarily by Dr. Raymond Vaughan of the New York Attorney General's Office, and are submitted on behalf of New York's ballast water management team which is coordinated by our Department. We understand from your March 17, 2011 email that comments may still be submitted at this point in time.

1. During the March 15 teleconference, the SAB expressed a preference for using a 95% confidence level as a criterion for ballast water treatment system performance. While we agree that a relatively high confidence such as 95% is preferable, the SAB should be willing and able to compute the full range of confidence levels, including those lower than 95% that can be calculated from current and ongoing test data. In reviewing treatment-system performance, the SAB needs to be able to *express* and *assess* the progress being made toward a desired goal such as 95%. It should not deprive itself of this ability by converting numeric data into a less informative "pass/fail" format at a premature stage that hinders scientific inquiry.

2. As stated in comment 4 of our recent comments (submitted with our cover letter dated March 11, 2011), 30 milliliters is the minimum sample volume that needs to be collected in order to demonstrate compliance at 95% confidence with a 100x IMO standard for organisms in the 10-50 μm size class, assuming a Poisson distribution. Specifically, the standard is met at 95% confidence if the organism count shows zero living organisms within the collected sample volume of 30 ml. Compliance at 95% confidence can also be demonstrated when non-zero numbers of living organisms are counted within larger volumes of collected sample, but for a count of zero the necessary sample volume is 30 ml. Judging from the draft report and March 17 teleconference discussion, the SAB does not recognize this important statistical relationship. This distinction must be so recognized.

3. As noted, the 30-ml minimum sample volume has not been acknowledged in the SAB's teleconference discussions or in its draft report and there appears to be no evidence that the correct relationship is being applied in the following important sections of the draft report:

> For the most stringent standards, 100x and 1000x more stringent than D-2/Phase 1, if any living organisms in any size class were found following treatment, the BWMS earned a 'D'. This score indicates that it is extremely unlikely (or perhaps impossible) the BWMS could meet a stricter standard, again because the detection limit of the test methods used provide resolution to D-2/Phase 1, at best. (SAB draft report dated March 3, 2011, page 40, lines 22-26.)

> Given the data available, it is highly unlikely that any of the systems listed in Table 4.1 could provide organism removal to the level of 100x or 1000x the standard because all systems showed at least one observation of a living organism within the sample volumes as specified in IMO D-2 guidelines, thus clearly exceeding these more stringent standards. No BWMS reported zero living organism in all samples analyzed following treatment. (SAB draft report dated March 3, 2011, page 45, lines 32-37.)

Our specific concern here involves organisms in the 10-50 μm size class. When using a living organism count of zero to demonstrate 100x IMO compliance at 95% confidence in this size class, the necessary sample volume is 30 ml, assuming a Poisson distribution. If using a *non-zero* living organism count for this purpose in this size class, the necessary sample volume and/or the confidence level would be different, in which case the SAB would need to provide a clear explanation. If the SAB is assuming a non-Poisson distribution, it needs to specify clearly which distribution is being used.

4. In assigning scores and otherwise assessing ballast water treatment systems, the SAB needs to deal separately and explicitly with the different organism size classes. For the 100x IMO standard, the five different organism classes include organisms >50 μm, organisms 10-50 μm, and three different microorganisms. All of these need to be assessed and reported separately because there are differences in how easily the standard is met for each class, and also differences in the existing and foreseeable technical options for meeting each standard. For example, the standard for organisms >50 μm is typically considered the most difficult to meet, yet the organisms in this size class can be largely eliminated by filtration. Even though a 50-μm filter cannot remove all organisms larger than this size, it remains generally true that a progressively smaller mesh size will catch or kill an increasingly large number of the organisms >50 micrometers, thus minimizing the number of organisms in this size class that pass through as living organisms. As another example, the so-called 100x IMO standards for the indicator microorganism classes are expected to be routinely achievable because they are already used as U.S. public health standards and are also substantially similar to the IMO standards for those classes. The *vibrio cholera* limit is the same as the IMO limit (<1 cfu per 100 ml in both cases); the *e. coli* limit differs from IMO by about a factor of 2 (<126 cfu as compared to <250 cfu per 100 ml); and the intestinal enterococci limit differs from IMO by about a factor of 3 (<33 cfu as compared to <100 cfu per 100 ml). See also page 3 of our comments dated January 25, 2011.

5. The SAB presents a poorly defined argument that "imperfect ships" are a substantial impediment to achieving standards more stringent than the IMO standard. While we recognize the nature of the concern, the SAB's portrayal of the problem is too general and appears to be exaggerated with respect to standards such as 100x IMO. Our previous comments have addressed this in two different ways. *First*, as noted on page 3 of our comments dated January 25, 2011, the SAB should not equate the 100x IMO discharge standard with a "zero or near zero discharge" standard. The ballast discharge from a vessel complying with 100x IMO may allowably contain up to 1000 or more organisms >50 μm, and up to 1 billion or more organisms in the 10-50 μm size class. These are not zero or near-zero numbers, yet the SAB continues to imply that the 100x standard is unachievable because some unspecified number of living organisms remain untreated – because they are harbored in discharge pipes and orifices – and are routinely discharged along with the treated ballast. If the SAB believes that the number of harbored organisms will inevitably prevent the achievement of the 100 x IMO standards, it needs to support this view with reasonably quantitative logic and data. *Second*, as also noted on page 3 of our comments dated January 25, 2011, any concerns about biological contamination in the piping aboard "imperfect ships" can be substantially alleviated by employing a combination of ballast water treatment and ballast water exchange. Mid-ocean exchange or flushing will reduce any such contamination lurking in pipes. In addition, it will also provide a relatively uniform and organism-sparse flow of water into ballast water treatment systems, thereby reducing the log-reduction task needed from ballast water treatment.

6. In general, the SAB should more clearly identify the benefits of combining ballast water exchange with ballast water treatment. The benefits are acknowledged near the end of the draft report dated March 3, 2011 (pp. 103-107) but should also be acknowledged, for example, in response to charge question 3a ("For those systems identified in questions 1 a. and 2, are there reasonable changes or additions to their treatment processes which can be made to the systems to improve performance?"). Performing ballast water exchange in combination with ballast water treatment falls within the scope of "reasonable changes or additions" to treatment processes.

Thank you for the opportunity to comment, and please let me know if you have any questions about this matter.

Sincerely yours,

Scott Crisafulli, Chief
Water Bureau, OGC

EDMS#395001