March 2, 2015

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The Honorable Regina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Correcting an erroneous conclusion in "Efficacy of Ballast Water Treatment Systems," a report by the EPA Science Advisory Board (EPA-SAB-11-009)

Dear Administrator McCarthy,

We, the undersigned, were members of the 2010/11 Science Advisory Board Panel that drafted the referenced report on ballast water treatment technology. We prepared the referenced report at the request of the EPA Office of Water and the U.S. Coast Guard, who used it to develop the Coast Guard's ballast water discharge standards implementing the National Invasive Species Act (*Federal Register* March 23, 2012) and the EPA's ballast water discharge standards in the Vessel General Permit implementing the Clean Water Act (*Federal Register* April 12, 2013).

We are writing to inform you that one of our report's main conclusions is incorrect. Our report concluded, based on available test data, that five types of shipboard treatment had demonstrated the ability to meet a set of ballast water discharge standards known as the IMO D-2 standards (also referred to as the USCG Phase 1 standards), but that no types of shipboard treatment had demonstrated the ability to meet standards 10 times more stringent. However, we recently re-examined the test data on which this conclusion was based, and using the method of assessment described in the report found, to the contrary, that some treatment types had demonstrated the ability to meet discharge standards that are at least 10 times, and in some cases nearly 100 times, more stringent than the IMO D-2 standards.

This finding is important because in adopting discharge standards identical to the IMO D-2 standards, both the Coast Guard and the EPA cited the Science Advisory Board report as the basis for their conclusion that these "represent the most stringent standards" that ballast water treatment can "currently safely, effectively, credibly, and reliably meet."[1]

We have attached a description of the changes needed to correct these errors in our report; and a summary of the relevant test data reviewed by the SAB Panel in 2010/11, which show three treatment systems met a standard 10 times more stringent than IMO D-2.

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[1] U.S. Coast Guard, "Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters: Final Rule." *Federal Register* 77(57): 17256 (March 23, 2012). U.S. Environmental Protection Agency, 2013 *Final Issuance of National Pollutant Discharge Elimination System (NPDES) Vessel General Permit (VGP) for Discharges Incidental to the Normal Operation of Vessels: Fact Sheet*, pp. 74-75. Also see *Fact Sheet*, p. 76, and U.S. Environmental Protection Agency, *2013 VGP: EPA's Response to Public Comments*, p. 551.

Sincerely,

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Corrections to the Report, and Relevant Test Data

1. Corrections Needed

The Science Advisory Board Report "Efficacy of Ballast Water Treatment Systems" incorrectly concluded that five types of shipboard treatment had demonstrated the ability to meet the IMO D-2 standard, but that no type of treatment had demonstrated the ability to meet a standard 10 times more stringent than the IMO D-2 standard. This conclusion is contradicted by the test data summarized below, which show that three treatment systems representing three different treatment types produced organism concentrations in treated discharges that consistently were at least 10 times lower than the concentrations allowed by the IMO D-2 standard.

The incorrect conclusion is stated, in part or in whole, twice in the Report's Cover Letter (on page 2), and 12 times in the Report (on pages 4, 5, 36-39, 41, 43, 50, 56 and 57). These statements should be corrected or deleted. In addition, the treatment system evaluations in *Table 4-1. Performance of Ballast Water Management Systems* (pages 34-35) should be changed to show that three treatment types (Filtration+chlorine dioxide, Filtration+electrochlorination, and Hydrocyclone+filtration+peracetic acid) demonstrated the ability to meet a standard 10 times more stringent than IMO D-2.

In addition, there are nine statements in the Report that assert or imply that it is impossible to determine from the available test data whether or not any of the treatment types have demonstrated the ability to meet a standard 10 times more stringent than IMO D-2 (on pages 3, 25, 28, 29 and 36-37 in the Report, and pages 1, 2 and 4 in Appendix C). It is unclear what assumptions underlie these assertions, since no supporting data, citation, or explanation is given. Most of these assertions are made within the Report's statistical discussion in Chapter 3 and Appendix C. This discussion draws largely on similar discussions in two other EPA documents, Report #EPA/600/R-10/031 ("Density Matters") and Report #EPA/600/R-10/146 ("ETV Protocol"), but the assertions themselves do not appear in these EPA source documents. In any event, these assertions do not apply to the analyses conducted by the Panel, since the available data, when analyzed by the methods described in the Report, show that three treatment systems yielded organism concentrations in treated discharges that were consistently more than 10 times lower than the IMO D-2 standard. The assertions either should be clarified by stating the assumptions that underlie them, or should be deleted from the Report.

Another point: The Report gives two different definitions for standards described as 10 times, 100 times and 1,000 times more stringent than IMO D-2. One definition, in the Report's introductory chapter, was in all of the drafts reviewed by the Panel members save the last one. The other definition was inserted into the Report's fourth chapter in the final "concurrence" draft, which the Panel members had only 72 hours to review before submitting their concurrence or non-concurrence. We believe this second definition should be deleted and the first definition, which Panel members had worked with for months, should be retained. However, by either definition the Report's current conclusion (that five treatment types met the IMO D-2 standard but none met a standard 10 times as stringent) is incorrect.

Finally, as a smaller point, the Report found that the test data for the PeraClean treatment system were reliable, but did not evaluate that particular treatment system or the treatment type it represented because (as explained in a footnote to a table) the manufacturer had withdrawn the system from the market. However, since nothing in the methods described in the Report required exclusion of the PeraClean treatment system and its test data, we include it in our data summary below. We note, however, regardless of whether PeraClean is included in the analyses, the Report's current conclusion (that five treatment types met the IMO D-2 standard but none met a standard 10 times as stringent) is incorrect.

2. Summary of Relevant Test Data

The SAB Report assessed the treatment system test data against the following concentration limits for the group of organisms that are at least 50 microns in minimum dimension (hereafter, ≥50 µm group), and for the group of organisms that are between 10 and 50 microns in minimum dimension (hereafter, 10-50 µm group):

Table 1. Concentration limits in IMO D-2, and 10x, 100x and 1000x IMO D-2.

Organism group	Standard			
	IMO D-2	10x IMO D-2	100x IMO D-2	1000x IMO D-2
≥50 µm	$10/m^3$	$1/m^3$	$0.1/m^3$	$0.01/m^3$
10-50 µm	10/mL	1/mL	0.1/mL	0.01/mL

The SAB Report scored treatment systems relative to these standards in two ways: systems were scored "A" for a standard if they had been "demonstrated to meet this standard in accordance with the approach suggested in the IMO G8 guidelines," and "B" if they were "likely to meet this standard if the more detailed ETV Protocol" was used (SAB Report, page 31). The IMO G8 guidelines require treatment systems to meet the IMO standard in 10 land-based trials and 3 consecutive shipboard trials.[1] The ETV Protocol requires 6 land-based trials and doesn't address shipboard trials.[2] For some of the treatment systems assessed, the Panel had no data on shipboard trials, or had data on fewer than 10 land-based trials. In those cases the Panel based its assessment on the data that were available.

The following pages provide the test data that the Panel reviewed for three treatment systems. The data show that these systems met the 10x IMO D-2 standards, contrary to the conclusion in the SAB Report that no treatment systems met the 10x IMO D-2 standards.

[1] Resolution MEPC.174(58). *Guidelines for Approval of Ballast Water Management Systems (G8), Annex Part 2: Test and Performance Specifications for Approval of Ballast Water Management Systems*, §§2.2.2.4, 2.2.2.8, 2.3.17 and 2.3.18.
[2] *Generic Protocol for the Verification of Ballast Water Treatment Technology* (Version 5.1, Sept. 2010), EPA/600/R-10/146, pages 30, 33 and 35.

Ecochlor treatment system: ≥50 μm organisms

Ecochlor was the only treatment system in the "Filtration+chlorine dioxide" category reviewed by the SAB Panel, and was reported as meeting IMO D-2, but not meeting 10x IMO D-2 and not capable, even with improvements, of meeting 100x IMO D-2. The Panel reviewed one land-based test report,[3] which gave the following results for the ≥50 μm group.

Table 2. Concentrations of ≥50 μm organisms in discharges from the Ecochlor treatment system. Land-based test data, from Table 8 in NIOZ 2009.

Trial	Used a Filter?	Chlorine dioxide dose (mg/L)	Viable ≥50 μm organisms per m^3
1	No	5	3.0
2	No	5	81.0
3	No	5	25.3
4	No	5	no data
5	No	5	no data
6	Yes	4	3.7
7	Yes	5	0.0
8	Yes	5	0.3
9	Yes	5	0.3
10	Yes	5	0.0
11	Yes	5	0.0
12	Yes	5	0.0
13	Yes	5	0.0
14	Yes	5	0.0
15	Yes	5	0.0
16	Yes	5	0.0

This test series combined testing for Research and Development purposes with type approval testing. Trials 1-5 were conducted without a filter, and did not meet the IMO D-2 standard; Trial 6 was then conducted with a filter, but with a lower than normal dose of chlorine dioxide (4 mg/L); finally, Trials 7-16 (10 trials) were conducted with a filter and with the normal 5 mg/L dose.[4] In those 10 trials, the highest count in the treated discharge was 0.3 organisms/mL, 30 times more stringent than the limit in IMO D-2. It appears from these data that Ecochlor, with a filter and 5 mg/L dose (the configuration that was type approved and has been offered for sale), easily met the 10x IMO D-2 standard for the ≥50 μm group, contrary to what is stated in the SAB Report.

[3] NIOZ. 2009. *Final Report of the Land-based Testing of the Ecochlor®-system, for Type Approval according to Regulation-D2 and the Relevant IMO Guideline (April–July 2008).*

[4] Filter use and dosage in the different trials are discussed in NIOZ 2009 at pages 4, 13, 26-27 and 37.

Ecochlor treatment system: 10-50 µm organisms

Ecochlor's results for the 10-50 µm group were reported as follows:

Table 3. Concentrations of 10-50 µm organisms in discharges from the Ecochlor treatment system. Land-based test data, from Table 9 in NIOZ 2009.

Trial	Used a Filter?	Chlorine dioxide dose (mg/L)	Viable 10-50 µm organisms per mL
6	Yes	4	<0.1
7	Yes	5	<0.1
8	Yes	5	<0.1
9	Yes	5	<0.1
10	Yes	5	<0.1
11	Yes	5	<0.1
12	Yes	5	<0.1
13	Yes	5	<0.1
14	Yes	5	<0.1
15	Yes	5	<0.1
16	Yes	5	<0.1

These data appear to show that Ecochlor met the 100x IMO D-2 standard (<0.1 organisms/mL) for the 10-50 µm group in 10 trials at the normal chlorine dioxide dose and in one trial with a lower dose. However, in each trial the volume analyzed consisted of nine 1-mL samples, so that the detection limit is actually 0.1111.../mL, and the "<0.1" entries in the test report resulted from rounding off. Although Ecochlor came very close to meeting the 100x IMO D-2 limit, the volumes analyzed were not quite large enough to demonstrate that it did meet it. However, the results do show that Ecochlor easily met the 10x IMO D-2 limit, contrary to what is stated in the SAB Report.

BalPure treatment system: ≥50 µm organisms

Severn Trent de Nora's BalPure was one of two treatment systems in the "Filtration+electrochlorination" category that the Panel determined had reliable test data, and was reported as meeting IMO D-2, but not meeting 10x IMO D-2 and not capable, even with improvements, of meeting 100x IMO D-2. The Panel reviewed two test reports on BalPure's treatment performance, a report on 11 land-based trials conducted in April-July 2009,[5] and a report on 5 land-based trials conducted in October-November 2009.[6] The results for the ≥50 µm group were reported as follows:

Table 4. Concentrations of ≥50 µm organisms in discharges from the BalPure treatment system. From Table 9 in NIOZ 2010 and pages 6-16 in MERC 2010.

Trial	Viable ≥50 µm organisms per m^3
NIOZ 2010 (Land-based Tests)	
1	4.3
2	0.3
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0.3
11	1.0
MERC 2010 (Land-based Tests)	
1	1.4
2	0.2
3	0.4
4	0.8
5	0

The IMO G8 protocols for land-based testing require that the discharge limits be met in 10 trials. Because the concentrations in the ≥50 µm group were $1/m^3$ or less in 10 of 11 NIOZ trials (#2-11) and $0.8/m^3$ or less in 4 of 5 MERC trials (#2-5), the BalPure treatment system met the 10x IMO D-2 standard for the ≥50 µm group if assessed in accordance with the IMO G8 protocols,[7] contrary to what is stated in the SAB Report.

[5] NIOZ. 2010. *Final Report of the Land-based Testing of the BalPure®-Ballast Water Treatment System, for Type Approval according to Regulation D-2 and the Relevant IMO Guideline (April–July 2009).*
[6] MERC. 2010. *Land-based Evaluations of the Severn Trent De Nora BalPure™ BP-1000 Ballast Water Management System.*
[7] Since the ETV protocol only requires 6 land-based trials for type approval, BalPure also met the 10x IMO D-2 standard when assessed in accordance with the ETV protocol.

BalPure treatment system: 10-50 µm organisms

BalPure's results for the 10-50 µm group were reported as follows:

Table 5. Concentrations of 10-50 µm organisms in discharges from the BalPure treatment system. From Table 10 in NIOZ 2010 and pages 6-16 in MERC 2010.

Trial	Viable 10-50 µm organisms per mL
NIOZ 2010 (Land-based Tests)	
1	<0.1
2	<0.1
3	<0.1
4	<0.1
5	no data
6	<0.1
7	<0.1
8	<0.1
9	<0.1
10	<0.1
11	<0.1
MERC 2010 (Land-based Tests)	
1	0
2	0
3	0
4	0
5	0

The MERC report doesn't state the detection limit for the viable organism counts in the 10-50 µm category, but the results for the controls at t=0 and t=5 and for treatments at t=0 suggest a detection limit of 1/mL for each replicate; with 5 replicates (MERC 2010, page 3), th s corresponds to a detection limit of 0.2/mL in each trial.

As with the Ecochlor data, the NIOZ data appear to show that BalPure met the 100x IMO D-2 standard, but since the total volume analyzed was 9 mL the detection limit was actually 0.1111.../mL, not 0.1/mL. Thus these data only show that BalPure came very close to meeting the 100x IMO D-2 limit. These results, as well as the MERC results, show that BalPure easily met the 10x IMO D-2 limit.[8] contrary to what is stated in the SAB Report.

[8] As discussed above, a more stringent definition of 10x IMO D-2 was inserted into the fourth chapter in the final "concurrence" draft provided to the Panel. BalPure met the 10x IMO D-2 standard even by this more stringent definition, since it produced discharge concentrations below the 10x IMO D-2 limits for both the ≥50 µm group and 10-50 µm group, and decreased total bacteria in all trials (Table 13 in NIOZ 2010).

PeraClean treatment system: ≥50 µm organisms

SEDNA PeraClean was the only treatment system in the "Hydrocyclone+filtration+peracetic acid" category reviewed by the SAB Panel. As discussed above, although the SAB Panel determined that PeraClean's test data were reliable, the Panel did not score the PeraClean treatment system because the manufacturer withdrew it from the market. The Panel reviewed one report on PeraClean's treatment performance, which included both a land-based test report[9] and a shipboard test report.[10] The results for the ≥50 µm group were reported as follows:

Table 6. Concentrations of ≥50 µm organisms in discharges from the PeraClean treatment system. From Table 8 in NIOZ 2008 and Tables 6-10 in NIOZ/GoConsult 2008.

Trial	Viable ≥50 µm organisms per m^3
NIOZ 2008 (Land-based Tests)	
1	0.7
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0.3
11	0
12	0
NIOZ/GoConsult 2008 (Shipboard Tests)	
1	1.1
2	0
3	0
4	0
5	0

The IMO G8 protocols for land-based testing require that the discharge limits be met in 10 land-based trials and 3 consecutive shipboard trials. Because the concentrations in the ≥50 µm group are $<1/m^3$ in all 12 land-based trials and in 4 consecutive shipboard trials, the PeraClean treatment system met the 10x IMO D-2 standard for the ≥50 µm group if assessed in accordance with the IMO G8 protocols.[11] Had the type of treatment represented by PeraClean been scored by the Panel, the Panel would have found that it met the 10x IMO D-2 standard for the ≥50 µm group, contrary to the conclusion in the SAB Report that no treatment systems met the 10x IMO D-2 standards.

[9] NIOZ. 2008. *Final Report of the Land-based Testing of the SEDNA®-System, for Type Approval according to Regulation D2 and the Relevant IMO Guideline (April–July 2007).*
[10] NIOZ/GoConsult. 2008. *Final Report of the Shipboard Testing of the SEDNA®-System, for Type Approval according to Regulation D2 and the Relevant IMO Guideline (June–December 2007).*
[11] Since the ETV protocol only requires 6 land-based trials for type approval, PeraClean also met the 10x IMO D-2 standard when assessed in accordance with the ETV protocol.

PeraClean treatment system: 10-50 µm organisms

PeraClean's results for the 10-50 µm group were reported as follows:

Table 7. Concentrations of 10-50 µm organisms in discharges from the PeraClean treatment system. From Table 10 in NIOZ 2008 and Tables 6-10 in NIOZ/GoConsult 2008.

Trial	Viable 10-50 µm organisms per mL
NIOZ 2008 (Land-based Tests)	
1	<0.1
2	<0.1
3	<0.1
4	<0.1
5	<0.1
6	<0.1
7	<0.1
8	<0.1
9	<0.1
10	<0.1
11	<0.1
12	<0.1
NIOZ/GoConsult 2008 (Shipboard Tests)	
1	<0.1
2	<0.1
3	<0.1
4	<0.1
5	<0.1

As with the Ecochlor and BalPure data, the PeraClean data appear to show that PeraClean met the 100x IMO D-2 standard, but since the total volume analyzed was 9 mL the detection limit was actually 0.1111.../mL, not 0.1/mL. Thus these data only show that PeraClean came very close to meeting the 100x IMO D-2 limit. Had the type of treatment represented by the PeraClean system been scored by the Panel, the Panel would have found that it easily met the 10x IMO D-2 limit, contrary to the conclusion in the SAB Report that no treatment systems met the 10x IMO D-2 standards.