

MEMORANDUM

TO: Members of the Chartered SAB and SAB Liaisons

FROM: Jeanne M. VanBriesen, Chair, Work Group on Ballast Water Shipboard Treatment Efficacy in the *Efficacy of Ballast Water Treatment Systems: a Report by the Science Advisory Board (EPA-SAB-11-009)*

DATE: October 28, 2016

SUBJECT: Work Group Review of *Efficacy of Ballast Water Treatment Systems: a Report by the Science Advisory Board (EPA-SAB-11-009)*

In response to inquiries from some members of the former Ecological Processes and Effects Committee Augmented for the Ballast Water Advisory and a current SAB member, the SAB convened a Work Group under the auspices of the chartered SAB to review conclusions in the 2011 SAB report, *Efficacy of Ballast Water Treatment Systems: a Report by the Science Advisory Board*, and the information and analyses used to support the conclusions. The SAB did not seek new data regarding ballast water treatment system efficacy, nor was any new data reviewed by the Work Group.

The Work Group was charged with assessing whether the conclusions about shipboard treatment efficacy in the SAB report, *Efficacy of Ballast Water Treatment Systems: a Report by the Science Advisory Board*, were supported by the data that were provided to the panel. The purpose of the Work Group is to assist the SAB in considering whether or not to make a correction to the SAB report.

As this is the first time the SAB has been asked to consider corrections to a final SAB report, the Staff Office drafted a process whereby the SAB may consider whether or not to make a correction to a final SAB report that has been transmitted to the EPA Administrator. The process is intended to be an avenue for correcting a final report that at the time of its release contained a substantial scientific error. The draft process, attached as Appendix A, has been discussed by the SAB but has not been adopted at this time. In the present case, following discussion by the SAB at the March 2016 meeting, the SAB approved creation of the Work Group.

Background

In 2010, the EPA's Office of Water requested the SAB to review technical documents and available data on the efficacy of ballast water treatment systems and to provide advice on improving the performance of such systems. The Ecological Processes and Effects Committee

was augmented with additional experts to form the Ballast Water Advisory Panel, which was convened to conduct the review and develop recommendations through the chartered SAB. The Ballast Water Advisory Panel conducted its work in 2010 and 2011, and its final report, *Efficacy of Ballast Water Treatment Systems: a Report by the EPA Science Advisory Board* (hereafter, the Ballast Water Report), was transmitted to the administrator on July 12, 2011. Having completed its work, the Ballast Water Advisory Panel no longer exists, and its members were released from Federal Advisory Committee Act (FACA) and ethics requirements for this activity at that time.

In late 2014, several members of the former Ballast Water Advisory Panel (hereafter, the former Panel) raised questions about whether the conclusions regarding shipboard ballast water treatment efficacy in the Ballast Water Report were supported by the data reviewed. These concerns were transmitted to the former Panel chair and all the former Panel members. Some members of the former Panel agreed with the concerns, while others did not. Subsequent discussions among former Panel members ensued via phone and email. These email discussions among former Panel members are not the subject of the Work Group's current assessment and the evaluation of such comments is not within the scope of the Work Group's charge.

In March 2015, several members of the former Panel submitted their concerns that the Ballast Water Report should have concluded "some [ballast water] treatment types had demonstrated the ability to meet discharge standards that are at least 10 times and in some cases 100 times more stringent than the IMO D -2 standards¹" in a letter to the administrator of the EPA, with copy to the SAB Staff Office. Additional correspondence between former Panel members and EPA ensued. In early 2016, a member of the chartered SAB sent a letter to the administrator² of the EPA, expressing concerns with the conclusions and the implications of these conclusions. In March 2016, at a meeting of the chartered SAB, the issue was discussed briefly and a decision was made to create a Work Group to assist the SAB in considering whether or not to make a correction to the Ballast Water Report. All correspondence related to this issue received or sent by EPA and the SAB Staff Office was included in the materials available to the Work Group. This correspondence is not the subject of the current assessment; the evaluation of comments contained in the correspondence is not within the scope of the Work Group's charge.

Summary of the Process Used by the SAB Work Group

The SAB Work Group was formed in June 2016 and includes SAB members with broad expertise in scientific and technological topics. The Work Group consists of Drs. Jeanne M VanBriesen (chair), Ingrid Burke, Joel Ducoste, James Mihelcic and Daniel Stram.

The charge to the work group is attached as Appendix B.

¹ March 2, 2015 letter to The Honorable Gina McCarthy. Available at: [https://yosemite.epa.gov/sab/sabproduct.nsf/CE60F52A8FEEAEF285257FFF00705F06/\\$File/Cohen+March+2+2015.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/CE60F52A8FEEAEF285257FFF00705F06/$File/Cohen+March+2+2015.pdf)

² January 26, 2016 letter to The Honorable Gina McCarthy. Available at: [https://yosemite.epa.gov/sab/sabproduct.nsf/F5F201ADB7D6120285257FFF007142FB/\\$File/Burke+letter++jan26.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/F5F201ADB7D6120285257FFF007142FB/$File/Burke+letter++jan26.pdf)

As noted above, the Work Group was charged to review whether the conclusions about shipboard treatment efficacy in the SAB Report, *Efficacy of Ballast Water Treatment Systems, a Report by the Science Advisory Board*, are supported by the data that were provided by the former Panel.

The Work Group received information from the SAB Staff Office and from former members of the Panel. All materials submitted for review are available on the SAB Web site at:

<https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCal/2BF6E4715508B06785257FE9004F819F?OpenDocument> In addition, the Work Group had access to the work of the original SAB

Panel, available on the SAB Web site at:

<https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/9e6c799df254393a8525762c004e60ff!OpenDocument>

The Work Group held a public teleconference on August 12, 2016 from 12:00 p.m. to 1:30 p.m. and the Designated Federal Officer noted that neither the FACA nor EPA policy requires meetings of Work Groups under the auspices of a chartered federal advisory committee to provide notice or conduct public meetings. Public notice of this meeting of the Work Group was provided to assist the Work Group in obtaining public comment from interested parties on the topic under consideration. All members of the former Panel were contacted and invited to be present on the call to provide input and to answer questions from the Work Group. A summary of the public teleconference is provided as Appendix C to this memorandum.

The Work Group members individually reviewed the conclusions of the Ballast Water Report, as well as associated materials and documents. The Work Group held several conference calls to discuss their individual evaluations and to address the charge question regarding the conclusions of the Ballast Water Report. The Work Group drafted this memorandum to summarize the results of this work.

Work Group Assessment

As described in the final report, *Efficacy of Ballast Water Treatment Systems: a Report by the EPA Science Advisory Board*, the former Panel undertook analyses to respond to their charge questions and provide conclusions regarding ballast water management systems (BWMS) efficacy.

The evaluation of effectiveness of a technology incorporates two distinct issues. The primary issue is whether the technology is effective at meeting a specific goal. Basically, does it work? The secondary, but equally important, issue is whether the methods used to assess the efficacy of the technology are adequate to ensure that the conclusion regarding effectiveness is accurate. Basically, can you *judge* whether it works or not? This second issue requires considering the adequacy of several components of the assessment process, including: (1) sampling method

suitability and repeatability; (2) analytical method accuracy and precision; and (3) quality assessment and quality control methods.

If *all* of the components of the assessment method are considered acceptable, a technology effectiveness evaluation can be undertaken by comparison of reported values achieved by the technology with current or proposed numerical limits. In the present case, the relevant numerical limits are contained in the International Maritime Organization (IMO) International Convention for the Control and Management of Ships' Ballast Water and Sediments Section D-2 Ballast Water Performance Standard (IMO-D2)³ and the United States Coast Guard (USCG) Phase 1 Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters (USCG Phase 1)⁴. The IMO-D2 and the USCG Phase 1 standards require that multiple numeric limits (for different size classes of organisms to be removed from ballast water) must all be met in order to consider that a technology is effective. Thus, all components of the assessment method *for each size class* must be considered acceptable *and* the technology must meet the numerical limits *for each size class* in order for the evaluation to conclude that the technology is effective in meeting these standards⁵.

The former Panel considered both the issue of methodological suitability for assessment as well as the issue of demonstrated technology effectiveness in reaching its conclusions. The former Panel describes the state of the knowledge and the state of the available data with respect to both questions in the Ballast Water Report. These issues are described in two different chapters (3 and 4) as well as an Appendix C of the report, and the implications of conclusions from Chapter 3 on the analysis described in Chapter 4 were sometimes difficult to follow in the Report.

In meeting the charge of the present Work Group, we reviewed the analyses described in the Ballast Water Report. Components of the analyses necessary to understand the support for the conclusions are summarized here.

³ International Maritime Organization (IMO) International Convention for the Control and Management of Ships' Ballast Water and Sediments Section D-2 Ballast Water Performance Standard
[http://www.imo.org/en/About/Conventions/ListOfConventions/Pages/International-Convention-for-the-Control-and-Management-of-Ships'-Ballast-Water-and-Sediments-\(BWM\).aspx](http://www.imo.org/en/About/Conventions/ListOfConventions/Pages/International-Convention-for-the-Control-and-Management-of-Ships'-Ballast-Water-and-Sediments-(BWM).aspx)

⁴ The former Panel reviewed the proposed standard [United States Coast Guard. 2004. Mandatory Ballast Water Management Program for U.S. Waters U.S. Federal Register 69(144): 44952-44961 (July 28, 2004)]. The current standard has the same values [United States Coast Guard (USCG) Phase 1 Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters. 74 FR 44632. August 28, 2009.]

⁵ In considering a more stringent standard of 10x, 100x, or 1000x of the concentration limit in current or proposed regulations, the Ballast Water Report notes that this could refer to concentration limits that are 10 times, 100 times or 1000 times smaller than the concentration limits specified for *one or both* of the organism class sizes, thus, a technology *could* be evaluated to meet 10x for one class size but not another. (Ballast Water Report, p. 15) However, in the technology assessment conducted by the former Panel, the system's ability to meet the current or potential standards was based on meeting *all* the class sizes. (Ballast Water Report, p. 31)

Adequacy of Assessment Methods

First, the former Panel considered the adequacy of the assessment methods used to determine if the technologies could meet the performance criteria. As noted by the former Panel, ballast water must be collected and concentrated and analyzed. The suitability of these methods depends upon the capability of the testing facilities to carry out those steps reliably as well as the representativeness of the collected material and the analyzed fraction of the collected material. The sampling necessary to evaluate effectiveness of any Ballast Water Management System (BWMS) is discussed in Chapter 3 and Appendix C of the Ballast Water Report.

As the former panel notes, the size class with the lowest concentration requirement (zooplankton-sized organisms) “represents the most challenging size class in terms of sampling to achieve statistical rigor.”(Ballast Water Report, p.22) Further, “the required sample volumes for these organisms are in the range of five to tens of m^3 .” (Ballast Water Report, p.22)

Sample volumes this large require concentration followed by sub-sampling from the concentrated samples. The high number of sub-samples required and the labor intensity of the analytical methods (i.e., counting via microscopy) may limit the ability of laboratories to conduct these tests. The Ballast Water Report includes as Table 3-1 (p.25) a table from EPA’s Environmental Technology Verification (ETV) program indicating that to meet the IMO D-2 / USCG Phase 1 standard of less than 10 organisms greater than 50 micrometer per $1m^3$, a sample of $12 m^3$ would need to be collected and concentrated to 1L, from which 100 1ml sub-samples would need to be analyzed microscopically. The former Panel noted that the table indicates that “to meet a standard 10 times more stringent than D-2/Phase 1 would require anywhere from 120-600 m^3 of whole water sample volumes.” (Ballast Water Report, p. 26)

Further, the former Panel considered the implications of the sample sizes used in testing according to the IMO D-2 Standard and IMO guidelines for Type Approval testing (G8)⁶, which represented the most common method of assessment of the systems considered in the former Panel’s evaluation. For the size classification of organisms greater than 50 micrometers in minimum dimension, the process involves collection of three $1 m^3$ samples, concentration of each sample using a suitable net, resuspension in a smaller volume (e.g., 100ml to 1 L), staining of live organisms caught in the net, and microscopic counting of live organisms⁷. Given a presumed concentration present in a ballast water tank, the likelihood of detecting organisms in a $1m^3$ sample can be evaluated statistically. The former Panel provided several examples in the Ballast Water Report and in Appendix C of the Ballast Water Report. Most relevant for assessing the suitability of sample size for evaluation of whether a technology meets a given target concentration is that a $1m^3$ sample that was reported to contain zero organisms could “correspond to a true concentration of organisms in the ballast tank of up to ~3.7 organisms per

⁶ International Maritime Organization, 2008. Guidelines for Approval of Ballast Water Management Systems (G8). Marine Environment Protection Committee (MEPC (, Annex 4 Resolution MEPC.174(58).

⁷ Additional concentration steps and sub sampling is used for the filtrate to assess the other size classes.

m³.” (Ballast Water Report, p. 27 and Table C-3, p. C-6) Thus, a reported value of zero organisms in a 1m³ sample in a technology evaluation would indicate the system met the IMO D-2/USCG Phase 1 standard of less than 10 per m³ but could not be used to indicate the system met a more stringent standard of less than 1 organism per m³ (a 10x standard) since the zero detected value could correspond to a true concentration of up to 3.7 organisms/m³ in the water from which the 1 m³ was sampled. Thus, the Panel concluded that “current testing methods do not provide the resolution required to conclude that 10x standards can be met.”(Ballast Water Report, p.32) This is also supported by the analysis presented in Table C-2 (p. C-5), which indicates that for a sample volume of 1 m³, the probability of detecting a true concentration of 10 organisms/m³ (the IMO C-2/USCG Phase 1 standard) is >0.99, while the probability of detecting a true concentration of 1 organism/m³ (the 10x level) is 0.632.

Based on this analysis, no technology performance review using this method that reports lower values than this practical limit would be considered to support the conclusion that lower values can be reached through treatment, since such a report would be based on inadequate sampling methods. Reported concentrations of zero in 1 m³ could not support a conclusion of meeting a standard more stringent than IMO D-2/USCG Phase 1.

Considering the impracticality of concentrating and analyzing volumes of ballast water necessary to meet sampling requirements for evaluation of 10x, 100x or 1000x IMO D2 standards, the Panel concluded that “the available methodologies for testing compliance with the IMO standards for zooplankton-sized organisms⁸ are at or near the analytic detection limits.” (Ballast Water Report, p.25). Similarly, the former Panel concluded “Phase 1 standard (<10 protist-sized⁹ organisms/mL) represents the practical limit that can currently be achieved by testing facilities in the U.S.”(Report p. 25) Thus, while treatment technologies *may be able to achieve* removal of organisms to levels required by a 10x, 100x, or 1000x standard, assessment methodologies to *determine that the technologies are meeting these levels* are inadequate.

In addition to the limitations to conclusions drawn from small samples sizes, several other issues were discussed in terms of adequate sampling. For example, the former Panel discussed the method needed to ensure a *representative* water sample, noting the EPA ETV Generic Protocol for the Verification of Ballast Water Treatment Technology¹⁰ specifies that the sample be collected continuously over the entire discharge of the ballast tank and in an isokinetic manner.” (Ballast Water Report, p.23) None of the reviewed technologies used the ETV protocol for

⁸ Zooplankton-sized organisms are those greater than or equal to 50 micrometers in minimum dimension. The IMO D2/Phase 1 numerical limit for this size class is less than 10 viable organisms per 1m³. (Ballast Water Report, p. 15)

⁹ Protist-sized organisms are those that are less than 50 micrometers in minimum dimension and greater than or equal to 10 micrometers in minimum dimension. The IMO D2/Phase 1 numerical limit for this size class is less than 10 per milliliter. (Ballast Water Report p. 15)

¹⁰ U.S. EPA (2010) Environmental Technology Verification Program (ETV) Draft Generic Protocol for the Verification of Ballast Water Treatment Technologies, Version 4.1.U.S. EPA ETV in cooperation with the U.S. Coast Guard Environmental Standards Division (CG-5224) and the U.S. Naval Research Laboratory, National Sanitation Foundation International, Ann Arbor, MI, 62pp+appendices.

sampling, and thus, none could be determined to meet the USCG Phase 1 standards. Several assessments did use continuous sampling¹¹, and as noted in the next section, the former Panel chose to assess whether the technologies were *likely* to meet the USCG Phase 1 standard if tested using the required sampling protocols for ETV¹².

Evaluation of the Technologies with respect to IMO D-2/ USCG Phase 1

In charge questions 1 and 2, the former Panel was asked “to assess the documented performance of existing Ballast Water Management Systems (BWMS) in terms of quality of the discharged ballast water, and to assess the likely future performance of BWMS based on their design and treatment processes.” (Ballast Water Report, p. 30)

Despite concerns regarding sampling and analysis with current methods (discussed in Chapter 3 and Appendix C and summarized above), which suggested that *documentation* of performance was likely to be inadequate for evaluation beyond the current IMO D-2/USCG Phase 1 levels, the former Panel considered the available data of performance.

The former Panel approached this through an evaluation process described in chapter 4 of the Ballast Water Report. Briefly¹³, a subgroup of the former Panel considered the BWMS technologies. Data packages, reports, publications, certification documents and other available information (listed in Appendix A of the Ballast Water Report), were reviewed independently by three subgroup members, with two other members providing review oversight and quality control. “The three primary reviewers independently scored each package as having ‘reliable’ or ‘unreliable’ data. To earn a ‘reliable’ rating, the data package had to include, at a minimum, methods and results from land-based or shipboard testing.”¹⁴ After this assessment, the packages meeting these minimum criteria were evaluated by the reviewers.

This evaluation included (1) assessment of sampling protocols, including whether adequate sample numbers and size were collected and whether handling of samples was appropriate; (2) assessment of laboratory testing and methods, including whether methods were rigorous and equivalent to a standard, common approach; and (3) assessment of documented quality assurance/quality control procedures, when available. Each of the subgroup members then

¹¹ See for example, 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). P. 19.

¹² See discussion in next section of this memo and Ballast Water Report p. 32.

¹³ The Work Group briefly summarizes the process here. The reader is referred to the Ballast Water Report for full details in Chapter 4, beginning on page 30.

¹⁴ The word ‘reliable’ could have many meanings within scientific discourse, but the Ballast Water Report was explicit about the meaning of ‘reliable.’ Reliable meant there were data and methods that could be evaluated. It did not mean that the data themselves were of particular quality or adequate to support specific conclusions with respect to concentration standards. Most notably, few packages contained adequate quality assurance and quality control documentation. This normally disqualifying characteristic was not used as a filter in the evaluation by the former Panel.

considered the system's ability to meet four standards: IMO D-2 / USCG Phase 1 and 10x, 100x and 1000x more stringent than IMO D-2/USCG Phase 1.¹⁵

Scoring was *qualitative*, with grades of A, B, C, and D assigned by the reviewers independently based on their assessment and the use of the following *interpretations*¹⁶:

A-Demonstrated to meet this standard in accordance with the approach suggested in the IMO G8 guidelines (and G9 guidelines, if the BWMS employs an active substance)

B-Likely to meet this standard if the more detailed ETV Protocol (and corresponding sample volumes) were used¹⁷.

C-May have the potential to meet this standard with reasonable/feasible modifications to the existing BWMS.

D-Unlikely or not possible to meet this standard, even with reasonable/feasible modifications to the existing BWMS.

Thus, each technology evaluated as providing information adequate for assessment, received *four* letter grades, one for each of the four standard levels. The assessment included consideration of what the technology had demonstrated as well as what the reviewer determined to be likely or potentially likely for the technology to achieve under other conditions or with modification.

“After each subgroup member completed his or her individual independent assessments, they discussed their scores collectively. All scores from the three primary reviewers were found to be identical and in complete agreement with the general assessments by the two subgroup oversight members, as well as other members of the entire Panel.”(Ballast Water Report, p. 32)

The former Panel concluded that 5 technologies provided adequate information to support the assertion that they demonstrated an ability to meet the IMO D-2 / USCG Phase 1. These same

¹⁵ Definitions for these terms are on page 31 of the report. Meeting the standard requires meeting all components of the standard, which includes performance for multiple size classes of organisms.

¹⁶ These interpretations are repeated verbatim from page 31 of the Ballast Water Report.

¹⁷ Grade B was necessary since no technology had been tested using the ETV protocol at the time of the evaluation by the Panel. As noted in the Ballast Water Report “The ETV protocol has significantly improved sampling procedures.” (Ballast Water Report, p.32) And, “ETV, and others have demonstrated that a time-integrated sampling approach with larger sample volumes will increase statistical confidence regarding whether zooplankton in sparse populations meet or exceed the IMO D-2/Phase 1 standard.” (Ballast Water Report, p.32) Thus, even though the numerical requirements for each size classification for the ETV standard and the IMO D-2/USCG Phase 1 standard are the same, a grade of A could not be assigned with regard to the ETV standard since no systems *demonstrated* meeting these standards by conducting sampling in accordance with the ETV requirements. The assignment of a grade of B was based on the expert assessment of the reviewers that the technology would perform at the level it had demonstrated with the less stringent testing, and that more stringent ETV testing would confirm that performance level.

five were determined likely to meet that quantitative standard using the more stringent ETV protocols.

These analyses, further detailed in Chapter 4 of the Ballast Water Report, support the conclusion presented in the letter to the Administrator (p.2) and the Executive Summary (p.4), quoted here:

“Based on the information provided, five of 34 categories of assessed BWMS achieved reductions in organism concentrations sufficient to comply with the first standard proposed by the USCG (i.e., the ‘Phase 1’ standard).” (Letter, p.2)

“The Panel concluded that the same five BWMS categories (listed above)¹⁸ have been demonstrated to meet the IMO D-2 discharge standard, when tested under the IMO certification guidelines, and will likely meet USCG Phase 1 standards, if tested under EPA’s more detailed Environmental Technology Verification Protocol.” (Executive Summary, p. 4)

Evaluation of the Technologies with respect to 10x, 100x or 1000x IMO D2/USCG Phase 1

The steps outlined in Chapter 4 of the Ballast Water Report for evaluation of technologies with respect to the IMO D2/USCG Phase 1 standard were also followed for evaluation of technologies with respect to more stringent 10x, 100x, and 1000x levels.

However, as noted by the former Panel in Chapter 3, such evaluation suffers from the limitations of the assessment methods used to generate the data for the evaluation. Because no statistical assessment could be made, the former Panel elected to use a categorical assessment based on the consistency of the data provided demonstrating meeting the IMO D2/USCS Phase 1 standard.

Details of the assessment are given in the Ballast Water Report (beginning on page 36). In brief, the former Panel noted that systems that consistently exceeded current detection limits¹⁹ for all samples and all size classifications of organisms would be impossible to assess with respect to more stringent standards, since the reported zeros could not be used to distinguish if a system is “performing just below the IMO D-2/Phase 1 standards or if it is approaching 10x, 100x, or 1000x.”(Ballast Water Report, p. 37) As noted in the Report in Chapter 3 (and summarized above), reported zeros could represent *up to* 3.7 organisms per m³ and thus, zeros cannot be interpreted to indicate lower concentrations (Ballast Water Report, p. 27 and p. C-6). Since no systems met this level (of all zeros in all tests), the former Panel next considered the question of whether it was *likely* that systems could meet more stringent standards.

¹⁸ Five categories (Executive Summary, p. 3) were (1) Deoxygenation +cavitation; (2) Filtration +chlorine dioxide; (3) Filtration +UV; (4) Filtration + UV + TiO₂; (5) Filtration + electro-chlorination.

¹⁹ Consistently exceeding current detection limits was defined as a BWMS that produced zero or non-detectable in all reported results. (Ballast Water Report p. 37)

Some systems demonstrated mostly zero or non-detect values, indicating they are “operating *near but below* the IMO D-2/Phase 1 standards,” while other systems reported zero or non-detect rarely, indicating they are “operating *only at, or just below,* the IMO D-2/Phase 1 standards.” (Ballast Water Report, p. 37) Based on this assessment, the former Panel concluded that the five types of BWMS that are currently able to reach IMO D-2/USCG Phase 1 standards *may* be able to reach 10x IMO D-2/Phase I standards for the two largest size classes of organisms “in the near future, if both treatment performance and testing approaches improve.” (Ballast Water Report, p. 37)

Because none of the treatment systems consistently exceeded current detection limits (reporting zero or non-detect all the time), the former Panel concluded that actual concentrations if adequate sampling sizes were used were unlikely to be 100x or 1000x below the current detection limits. Thus, the former Panel concluded “no current BWMS types can meet a 100x or 1000x discharge standard.” (Ballast Water Report, p. 37)

These analyses support the conclusions included in the letter to the administrator and the executive summary:

“Although current test methods and detection limits preclude a complete statistical assessment of whether a BWMS meets any standard more stringent than Phase 1, the Panel concluded that none of the assessed BWMS can meet a standard that is 100 or 1000 times more stringent.” (Letter, p.2)

“The detection limits for currently available test methods preclude a complete statistical assessment of whether BWMS can meet standards more stringent than IMO D-2/Phase 1. However, based on the available testing data, it is clear that while five types of BWMS are able to reach IMO D-2/Phase 1, none of the systems evaluated by the Panel performed at 100 times or 1000 times the Phase 1 standard.” (Executive Summary, p. 4)

Summary

Considering *both* the analyses presented in Chapter 3 and Chapter 4, the former Panel concluded that no technologies provided adequate information to support the assertion that they *demonstrated* an ability to meet any standard more stringent than IMO D-2/USCG Phase 1. This conclusion was based on the data reviewed and described in Chapter 4 and incorporating all the considerations with respect to sample size and analyses methods described in Chapter 3 and Appendix C.

As noted above, answering the question ‘Does it work?’ is only possible if the answer to “can we judge if it works?” is ‘yes.’ Thus, since sampling and analysis was determined to be inadequate to judge meeting any standard more stringent than the current IMO D-2/USCG Phase 1 level, a technology evaluation beyond this level was not meaningful.

The former Panel went further than these direct data analyses and specifically pointed out the limitations of the available assessment information to answer the charge question with respect to any standard more stringent than IMO D-2/USCG Phase 1 in Chapter 6.

Work Group Conclusion

The Work Group finds that the conclusions about shipboard treatment efficacy in the SAB report, *Efficacy of Ballast Water Treatment Systems: a Report by the Science Advisory Board*, were supported by the data that were provided to the former Panel. Further, the Work Group finds that the conclusions are supported by the analyses conducted by the former Panel, and these analyses are documented in the Ballast Water Report. In reaching this conclusion, the Work Group considered the Ballast Water Report and supporting materials available to the former Panel, meeting minutes and public comments from the former Panel deliberations, and materials and oral responses provided during the fact-finding.

The Work Group notes that details of the *qualitative* interpretation of non-detect result frequency (the number of zero values in the data tables for the reviewed technology documents) were presented in Chapter 4, with reference to the statistical sampling limitations discussed in Chapter 3 and Appendix C. The qualitative nature of these analyses was confirmed during the fact-finding call. However, the Work Group found that the connections between the sampling and analysis issues discussed in Chapter 3 and the conclusions drawn regarding technology assessment in Chapter 4 were at times difficult to follow in the Report. Further, the relevance of data presented in several places (Table 3.1 and Table C-1) to the issues in Chapter 4 was incompletely explained in the Report. The links between the conclusions drawn in Chapters 3 and 4 were not always clear, and the Report would have benefited from more attention to the distinction between the ability of a technology to meet a standard and the ability of analytical methods to *demonstrate* that a technology is meeting the standard. We conclude that the issue brought to the SAB for its consideration represents a difference of opinion in the interpretation of the data and in the conclusions that can be drawn from the data available at the time of the Ballast Water Report. Such differences of opinion in methods of data interpretation and conclusions to be drawn from data analyses are not indications of error. The deliberations of the SAB, its panels and work groups are not intended to, nor could they be expected to, eliminate all such differences of opinion.

In summation, the Work Group concludes the Ballast Water Report does not contain a substantial scientific error. The Work Group concludes that the report, *Efficacy of Ballast Water Treatment Systems: a Report by the Science Advisory Board*, presents sound scientific judgements using appropriate analyses and reasonable interpretation of the data available to the authoring panel.

Work Group Recommendations to the SAB

The Work Group recommends the SAB take No Action on the requested correction to the report.

Appendix A. Draft. Procedural Policy on Considering Whether to Make Corrections to a Completed SAB Report

Procedural Policy on Considering Whether to Make Corrections to a Completed SAB Report

Purpose of this Procedural Policy

This policy describes a process whereby the chartered SAB (Board) may consider whether or not to make a correction to a final SAB report that has been transmitted to the EPA Administrator. The process is intended to be an avenue for determining whether a final report contained a substantial scientific error at the time of its release and, if a correction should be issued. A substantial scientific error is defined as an error in the reporting, characterization or analysis of data available to the authoring panel at the time of the advisory activity that is misleading or that invalidates findings or conclusions of the final report.

Background on the SAB Report Development Process

The Board often conducts its work using committees and panels formed to include a balance of specialized expertise needed to address the charge for a particular advisory activity. With rare exceptions (e.g., if the subject matter falls within an exemption under the Government in the Sunshine Act), SAB reports are developed on the basis of public deliberations in meetings that are announced in advance in the Federal Register and on the SAB website. SAB committees and panels also consider any comments (written or oral) provided by the public on the EPA review materials or the SAB draft advisory report. The chartered SAB reviews and approves draft reports prepared by its committees and panels, using a public process guided by quality review questions that focus on the draft report's clarity, technical accuracy and responsiveness to the EPA charge. An SAB report becomes final only after the chartered SAB approves the report for transmission to the EPA Administrator.

Process to Address Concerns Raised About a Completed SAB Report

The Committee on Publication Ethics (COPE), a forum for editors and publishers of peer reviewed journals, provides retraction guidelines²⁰ for technical publications, where the retraction is “a mechanism for correcting the literature and alerting readers to publications that contain such seriously flawed or erroneous data that their findings and conclusions cannot be relied upon” and notes that “unreliable data may result from honest error or from research misconduct.” In addition, the Federal Research Misconduct Policy²¹ notes that research misconduct “does not include honest error or differences of opinion.” In keeping with best practice among scientific journals, and consistent with guidance from the Council of Scientific Editors²², the SAB will apply the following framework for evaluating whether a technical correction to a final SAB report is warranted.

²⁰ Committee on Publication Ethics Retraction Guidelines, available at www.publicationethics.org.

²¹ 65 FR 76260-76264, December 6, 2000. Also see information at: <http://ori.hhs.gov/federal-research-misconduct-policy>.

²² Council of Science Editors White Paper on Promoting Integrity in Scientific Journal Publications, 2012 Update. Available at www.CouncilScienceEditors.org.

All science discussions by the Board on the need to consider a correction to a final SAB report will take place in a public meeting with opportunities for public input.

If a concern is raised about the technical accuracy of an SAB report that has been transmitted to the EPA Administrator, the SAB Staff Office will facilitate the following process:

- 1) The SAB Chair, in consultation with the SAB Staff Office, reviews the issue and makes a preliminary recommendation that either (a) no change to the SAB report appears to be warranted, or (b) that the issue merits consideration by the Board. This preliminary recommendation is shared with the chartered SAB via email for concurrence. If the Board concurs that no change to the SAB report is merited, the request for a change will be considered closed and documented with a letter to the requestor.
- 2) If the Board finds that the issue merits its consideration, the SAB Staff Office works with the Chair to initiate the Board's reconsideration of specific aspects of the final report. The Board's efforts may be facilitated by a Work Group of SAB members, with additional experts as needed, that is formed to conduct fact-finding and develop preliminary recommendations for the Board's consideration.
- 3) The Board's discussion of the matter, including recommendations from a Work Group, if applicable, will be conducted in an open public meeting in accordance with the requirements of FACA and agency policy.
- 4) The results of the Board's deliberations will be documented in a letter to the Administrator and posted on the SAB website.

Possible outcomes of the Board's fact-finding and deliberations about an alleged error in a final SAB report include, but are not limited to, the following:

- A) No action. The Board could decide that no action is warranted because the alleged error is unsubstantiated and in the Board's judgment the SAB report presents sound scientific judgements founded in appropriate analysis and reasonable interpretation of the data available to the authoring panel.
- B) Correction. The Board could decide that a report contains errors (e.g., in reported data values, results of statistical analyses and the like) that may be misleading but do not invalidate the overall findings and conclusions of the report. The Board would prepare a brief correction or erratum to provide the corrected values or analyses.
- C) Retraction or Partial Retraction. The Board could decide that the report contains substantial scientific errors that lead to unreliable findings. The Board would issue a retraction or, if the errors effect only a portion of the report's conclusions, a partial retraction of the report. COPE recommends that "retraction should usually be reserved for publications that are so seriously flawed (for whatever reason) that their findings or conclusions should not be relied upon." (COPE 2009)

Appendix B. Charge to the Work Group on Ballast Water Shipboard Treatment Efficacy in the Efficacy of Ballast Water Treatment Systems: a Report by the Science Advisory Board (EPA-SAB-11-009)

MEMORANDUM

FROM: Dr. Jeanne VanBriesen, Chair /s/

TO: Members of the Science Advisory Board Work Group on Ballast Water Shipboard Treatment Efficacy in “Efficacy of Ballast Water Treatment: a Report by the SAB”

DATE: July 25, 2016

SUBJECT: Preparation of recommendation to the Chartered SAB

This memorandum and attachments will provide you with information and a plan to prepare for our discussions to develop recommendations for the chartered Science Advisory Board (SAB) regarding possible corrections to the 2011 report, Efficacy of Ballast Water Treatment Systems: a Report by the EPA Science Advisory Board (EPA-SAB-11-009).

Charge to the Work Group:

As directed by the SAB, this Work Group will review whether the conclusions about shipboard treatment efficacy in the SAB report, Efficacy of Ballast Water Treatment Systems: a Report by the Science Advisory Board, were supported by the data that were provided to the panel.

In response to inquiries from some members of the former Ecological Processes and Effects Committee Augmented for the Ballast Water Advisory (the former Panel) and Dr. Ingrid Burke (current SAB member), the SAB convened a Work Group under the auspices of the chartered SAB to review conclusions in the 2011 SAB report and the information and analyses used to support the conclusions. The SAB is not seeking new data regarding ballast water treatment system efficacy. The inquiry will focus on review of the data and analyses underlying the report and the related conclusions.

The Work Group will hold a public teleconference to hear comments from interested members of the public and identify any information needs regarding whether the conclusions about shipboard treatment efficacy in the SAB report are supported by the data that were provided to the panel. The purpose of the Work Group is to assist the SAB in considering whether or not to make a correction to the SAB report.

Subsequent to the teleconference, the Work Group will develop a memorandum with a recommendation for deliberation by the chartered SAB at a future meeting. We will use a similar format as the SAB’s Screening Review of the Semi-Annual Regulatory Agenda to present the

Work Group's recommendation, documenting the process and information used by the Work Group to develop its recommendation.

As this is the first time the SAB has been asked to consider corrections to a final SAB report, the Staff Office drafted a process whereby the SAB may consider whether or not to make a correction to a final SAB report that has been transmitted to the EPA Administrator. The process is intended to be an avenue for correcting a final report that at the time of its release contained a substantial scientific error. The draft process, which is attached, has been discussed by the SAB but has not been adopted at this time. In the present case, it will be used as a framework to develop the Work Group recommendations of whether or not a correction to the report is warranted.

Expected Outcomes of the Fact-finding and Public Teleconference

The Work Group will hold a public teleconference on August 12, 2016 from 12:00 p.m. to 4:00 p.m. The purpose of the public teleconference is to allow the Work Group to hear public comment from interested parties to present their perspectives on the topic under consideration. A draft agenda is attached. It is anticipated that authors of correspondence received by EPA, SAB and the SAB Staff Office regarding the conclusion on discharge standard and testing methods will be available on the teleconference as well as members of the public that register as speakers. Members of the former Panel have been informed of the teleconference and asked to contact the DFO if they are interested in participating in the teleconference.

Work Group members will have the opportunity to hear and ask questions of the public commenters and discuss any additional information they may need to develop recommendations for the Board. The Work Group members may have preliminary discussions regarding drafting the memorandum and recommendations.

Following the teleconference, the Work Group will develop draft recommendations for review and concurrence. There may be an additional non-public teleconference to discuss the Work Group's draft memorandum. The Work Group's recommendations will be considered by the chartered SAB at a separate public meeting/teleconference of the Chartered SAB in the fall. The final SAB conclusions will be sent to the Administrator.

Available Meeting Materials

Available materials will be posted on the Work Group meeting page SAB website at: <https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCalBOARD/2BF6E4715508B06785257FE9004F819F?OpenDocument>

The materials will also be emailed to Work Group members. Materials include:

Efficacy of Ballast Water Treatment Systems: a Report by the EPA Science Advisory Board (EPA-SAB-11-009)

EPA's response to *Efficacy of Ballast Water Treatment Systems: a Report by the EPA Science Advisory Board*

Correspondence regarding the corrections to the Ballast Water Report
Letter from Dr. Andrew Cohen and signatories, March 2, 2015,

Letter from Dr. Andrew Cohen, May 11, 2015
Letters from Dr. Judith Meyer, April 26, 2015 and March 7, 2016
Letter from Dr. Ingrid Burke, January 26, 2016

Additional information regarding the Panel's deliberations

Data on the efficacy of shipboard ballast water treatment provided to the former Panel
Meeting agendas and Meeting Minutes for the Ballast Water Advisory Panels deliberations

Enclosures:

- a. Meeting Agenda
- b. Process to address Corrections to SAB reports
- c. Efficacy of Ballast Water Treatment Systems: a Report by the EPA Science Advisory Board (EPA-SAB-11-009)
- d. Agency response to Efficacy of Ballast Water Treatment Systems: a Report by the EPA Science Advisory Board (EPA-SAB-11-009)
- e. Correspondence regarding the corrections to the Ballast Water Report
- f. Table of meeting agendas and meeting minutes with hyperlinks

Appendix C. Summary of Public Teleconference of the Chartered Science Advisory Board Work Group on Ballast Water Shipboard Treatment Efficacy in the *Efficacy of Ballast Water Treatment Systems: a Report by the Science Advisory Board (EPA-SAB-11-009)*. August 12, 2016

Introduction

The Environmental Protection Agency (EPA) chartered Science Advisory Board (SAB) convened a subset of members to gather and review information and analyze the underlying data on ballast water treatment efficacy to assist the SAB in considering information regarding conclusions about shipboard treatment efficacy in the SAB report, *Efficacy of Ballast Water Treatment Systems: a Report by the Science Advisory Board (EPA-SB-11-009)*. This Work Group was charged to develop recommendations for deliberation by the SAB on the report's underlying data and related conclusions. The SAB is not seeking new data regarding ballast water treatment system efficacy and will focus its inquiry on the data underlying the conclusions in the report.

A public teleconference was held on August 12, 2016. Public notice for the teleconference was given in the Federal Register on July 18, 2016ⁱ. The notice stated that neither the Federal Advisory Committee Act (FACA) nor EPA policy requires meetings of Work Groups under the auspices of a chartered federal advisory committee to provide notice or conduct public meetings. Public notice of this teleconference was provided to assist the Work Group in obtaining public comment from interested parties on the topic under consideration. The SAB Staff Office invited all the members of the former Ballast Water Advisory Panel (hereafter referred to as the former Panel).

Summary of Teleconference

Mr. Thomas Carpenter, Designated Federal Officer (DFO) for the chartered SAB, formally opened the meeting and noted the SAB is an independent, expert federal advisory committee chartered under the authority of the Federal Advisory Committee Act (FACA). The SAB is empowered by law, the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA), to provide advice to the EPA Administrator on scientific and technical issues that support the EPA's decisions. He stated that the SAB consists entirely of special government employees (SGEs) appointed by EPA to their positions. As SGEs, chartered SAB members are subject to all applicable ethics laws and implementing regulations. EPA has determined that advisors participating in this meeting have no financial conflicts of interest or appearance of a loss of impartiality under ethic regulations specified in 5 CFR §2635 relating to the topics of this meeting. Mr. Carpenter noted that members of the Work Group include: Dr. Jeanne VanBriesen, Chair of the Work Group, Drs. Ingrid Burke, Joel Ducoste, Jim Mihelcic, and Daniel Stram.

Dr. Jeanne VanBriesen

Dr. VanBriesen stated that the purpose of the teleconference was to conduct fact finding for the Work Group to develop recommendations regarding whether the conclusions about shipboard treatment efficacy in the SAB report, *Efficacy of Ballast Water Treatment Systems: a Report by the Science Advisory Board*, were supported by the data that were provided to the panel. She briefly reviewed the agenda and thanked the Work Group members and members of the former panel for participating on the call. She noted that Deborah Nagle, Director, Water Permits Division, Office of Water, is available to answer questions from the Work Group members and there were two speakers Dr. Burke and Cohen. She noted no other members of the public requested to address the Work Group. Participants in the August 12, 2016 teleconference are listed in Attachment 1.

Speakers

Dr. VanBriesen introduced Dr. Ingrid Burke a member of the Chartered SAB and Work Group. Dr. Burke said she was glad to have an open transparent process to address these issues and identified two main issues: the first being process and the second being substance. Dr. Burke stated she has become concerned about how committees are conducting their work. She noted that committees identify experts to develop responses to charge questions and the ensuing reviews place faith in the work conducted by the experts of subcommittees with specific expertise to finalize the report. She stated that her understanding of this case is that the data reviewed in by the former Ballast Water Advisory Panel was not seen by the entire former panel. She noted that some members of the former panel reviewed the data some years after the report was finalized and at that point they disagreed with conclusions in the report. Dr. Burke also requested that the Work Group in addition to their response to the charge that the conclusions in the report were merited include comments on process for meetings to mitigate the potential propagation of decisions on issues developed by committees and panels. Dr. Burke noted that there are two issues she hopes the Work Group will consider 1) whether the conclusions in the 2011 report are merited based on data that was available at that time and 2) whether there should be an evaluation of available new data to produce a new report.

Dr. Burke did not discuss the data or conclusions and deferred that discussion to the former panel members to conclude her remarks.

Dr. VanBriesen introduced Dr. Andrew Cohen a member of the former panel. Dr. Cohen agreed to present information on his re-analysis of the data available for the Ballast Water Advisory Panel and conclusions that may be derived from that analysis. Dr. Cohen provided informationⁱⁱ to the panel regarding a subset of the data as an illustrative example of his re-analysis. It includes the standards as defined in the SAB report and results from data on the Ecochlor treatment system for two organism size categories, >50µm and 10-50µm.

Dr. Cohen provided a chronology of the re-analysis of data that he and Dr. Fred Dobbs conducted and asserted that the re-analysis contradicted the conclusions in the 2011 Ballast Water Report. He stated that the conclusions from the 2011 SAB report were incorrect and formed the basis for the current ballast water regulation adopted by the Coast Guard and EPA.

He summarized the Ballast Water Advisory Panel assignment of data evaluation to a subgroup of the former panel, described the International Maritime Organization (IMO) discharge standards for the two size categories of organisms and EPA's request to evaluate the data to determine if a system could meet a more restrictive standard of ten-fold (10x) or hundred-fold (100x) reduction of the (IMO) standard. He noted those conclusions are included in the quality review draft and the final report provided to the Administrator in 2011.

Dr. Cohen noted that 2011 Ballast Water Report found that test results for 5 treatment types meet the IMO standard and concludes that no treatment type met the 10x reduction or the 100x reduction of the IMO standard.

Dr. Cohen then discussed the EcoChlor data on page 2 of his presentation. He stated that from his re-analysis of the data reviewed by the former Panel for the larger organisms (>50µm) shows that the 10 trial results Ecochlor system meets the IMO standard and a 10x reduction of the IMO. He noted that eight of the 10 results indicate that this system could meet a 100x reduction of the IMO standard. He also asserted that these data show that, with reasonable improvement, this system could meet 100x reduction of the IMO standard.

Dr. Cohen proceeded to page three of his presentation and the results of his re-analysis for organisms in the 10-50µm size category. He stated that each of the ten trials resulted in <0.11 live organisms/mL. Dr. Cohen noted that these results are based on sampling size of 9mL rather than the 10 ml required in the protocol. No live organisms were found in the sample volume and the results are reported as less than 1/9 of a live organism. He notes that this result is below the 10x reduction of the IMO standard and almost as low as the 100x reduction of the IMO standard. The average concentration for all trial results is less than the 10x and 100x reduction of the IMO standard. He stated that the results in this table are all below detection limits therefore one cannot conclude anything about what the limits are for this systems performance. There are data for two other treatment types (Balpure and PeraClean systems) presented in the supplemental materialsⁱⁱⁱ to Dr. Cohen's March 2015 letter to Administrator McCarthy.

Dr. Cohen stated that these results show that three systems can meet the 10x and may have met the 100x reduction of the IMO standard contrary to the conclusions in the 2011 SAB Ballast Water Report.

Dr. Cohen noted that some members of the former Ballast Water Advisory Panel disagree that the conclusions reached in the 2011 Ballast Water Advisory Report are erroneous. He presented a few general observations from his perspective and a chronology of his interaction with members of the former Ballast Water Advisory Panel in 2014 and 2015. He stated that the 2011

report does not address how these systems have not met the 10x and could meet 100x reductions based on the reported results.

Dr. Cohen described the interactions among the former Ballast Water Advisory Panel and referred the Work Group to the series of emails he provided as public comments^{iv}. Dr. Cohen described his recollection of the subgroup's presentation during the former Ballast Water Advisory deliberations and his communications with members of the former panel between 2014 and 2015.

Clarifying questions for Drs. Burke and Cohen.

Dr. VanBriesen thanked Drs. Burke and Cohen for their remarks and noted that no other members of the public requested to address the Work Group. She noted that the Work Group heard in these comments both, issues of process and issues of substance. She encouraged members to focus on the issues of substance associated with this Work Group's charge: to review whether the conclusions about shipboard treatment efficacy in the SAB report, *Efficacy of Ballast Water Treatment Systems: a Report by the Science Advisory Board*, were supported by the data that were provided to the former panel. She asked Work Group if they had any clarifying questions of Drs. Burke and Cohen.

Dr. James Mihelcic asked for clarification on the specific sections of the report provided to Work Group members and the status of new data. Dr. VanBriesen confirmed the Work Group will focus on Chapter 4 but will review the full report and asked if any of the members of the former Panel could elaborate on the status new data available since the report was finalized.

Dr. Cohen offered that quite a bit of additional information is available; however, it was his sense that the Work Group was not gathering new information. The available information varies by treatment systems. He noted there are data for new systems, and some of those data are publicly available.

Dr. Mario Tamburri agreed that there is quite a bit of new data that is of higher quality and more transparent than what the former panel received. There is much more reliable data than was available at the time of the report. Dr. Tamburri asked to make an additional comment that was not a response to the clarifying questions and agreed to wait as requested by Dr. VanBriesen requested.

Dr. VanBriesen noted there were no other clarifying questions from Work Group members and stated she had several questions regarding the re-analysis of the data. She referred to the first set of test results on page 2 of Dr. Cohen's handout and asked Dr. Cohen if he could confirm the sample sizes and protocol for organisms > 50 um and reported concentration of 0 or 0.33. Dr. Cohen noted the sample size volume was 3 m³ per trial. Dr. VanBriesen asked if they were three 1 m³ replicates or a whole sample? Dr. Cohen would need to confirm but believes they were

replicates for each trail evident from the way the data were presented and he has confirmed the total sample volume was 3 m³ with the laboratory conducting the analysis.

Dr. VanBriesen asked about the smaller size class presented on page 3 of the handout and if he could confirm the original sample size and the subsample protocol used for the analysis? Dr. Cohen noted that he is referring to the sample size analyzed he is not sure of the original sample size. In regard to the sampling he believed the total sample size was 9 mL taken three times.

Dr. VanBriesen asked if the 9mL total sampled taken as three replicates at separate times, the start, middle, and end of the discharge. Dr. Cohen noted that this system has a 200 m³ holding tank for treated water and the samples are taken from the draw of that tank but could not describe the sampling protocol.

Dr. VanBriesen asked if the samples were filtered? Dr. Cohen was not aware if the samples were whole water samples, or filtered resuspensions. They may have been whole water sample or resuspensions of the filtered sample.

The Work Group did not have further questions, and Dr. VanBriesen recognized Dr. Nicholas Welshmeyer to address this sampling and protocol issue for live organisms. Dr. Welshmeyer noted that Dr. VanBriesen's question regarding sampling are very important. He noted information to address these questions was not available in the data provided to the former panel. He explained that planktonic sampling has unique characteristics that need to be considered in addition to the testing results. The convention is to concentrate organisms in a net and subsample the "caught end" of the sample. This can lead to misconceptions about what is being counted. For example, one could report that 3 m³ were sampled and the analyst may only have sampled and analyzed a subset of the caught end.

Dr. Welshmeyer provided an example and noted that Lemieux et al. (2008)²³ assessed how to count zooplankton and estimated that 60 m³ of water was needed to fulfill Poisson statistical distributions based on the counts of the net, the caught end, or a portion of the catch that was counted. It was later realized that the analysis only counted 5% of the net. The undersampling required revision to the paper and points out the importance of knowing the original sample size and portion analyzed. It was not clear to the former Panel's subgroup, whether the catch, caught end or a fraction was counted because this information was not provided in the documentation of the technologies. This undersampling created an uncertainty with the results of zero live organisms being detected and removes confidence that the catch was accounted for in the analysis of these data. Dr. Welshmeyer noted the metric in question is counting one live cell, and the data presented by Dr. Cohen should not be reported as zero but should be reported as <0.33.

²³ Lemieux, E.J., S. Robbins, K. Burns, S. Ratcliff, and Penny Herring (USCG) 2008. Evaluation of Representative Sampling for Rare Populations Using Microbeads. U.S. Department of Homeland Security, United States Coast Guard, Office of Operating and Environmental Standards, Washington, DC 20593-0001.

Dr. VanBriesen recognized Dr. Tamburri. He noted that sample volume size is not the only central issue in the review of the data provided to the former panel. The subgroup did not conduct a statistical analysis of the data. They reviewed the quality of the data available and this is described in the April 26, 2015 letter from Dr. Judith Meyer's^v chair of the former panel. He said it is important to consider how the volume was collected and what analytical method was used to judge whether the organism counted was live, dead, or present. Dr. Tamburri notes that the methods used in the provided data were unproven, unvalidated and many times inappropriate. For example, sample collection at the beginning, middle and end sampling requires different statistical analysis than time integrated sampling. He restated that he stands by the issues presented in Dr. Meyer's letters.

Dr. VanBriesen thanked Dr. Tamburri and asked if Work Group members had specific questions

Dr. Stram asked Dr. Tamburri to confirm his understanding that reducing the original sample to a volume for analysis is more complex than simply reducing the volume. Dr. Tamburri agreed that the sample reduction or concentration may have complicating issues and further explained that there are two issues, collection and analysis. He noted that sample collection has implications on the detection limits for analysis, for example, periodic sampling and time integrated sampling. One needs to know whether the sample is a representative grab sample or is taken isokinetically. There can also be issues in replication or how the sample was analyzed. At the time these data were generated the ETV protocol had not been finalized and differences in sample holding and counting method can lead to different results.

Dr. Burke asked whether the subgroup would have changed its conclusion on ballast water management systems if all the details of the sampling and data analysis had been available at the time of review? Dr. Tamburri noted that the subgroup tried to be as inclusive as possible in their analysis of the data. None of the data met the requirements of the ETV protocol, and in reality, none of the data were acceptable for quantitative analysis. Drs. Burke and VanBriesen sought clarification that it would not have mattered what the data showed – the quality of the data was such that it should not be used to provide quantitative results.

Dr. Tamburri noted that the subgroup initiated a quantitative analysis of the information provided to the former Panel and stopped. The subgroup did not try to perform quantitative analysis because the methods to collect and analyze the sample were either unknown, unvalidated, unapproved methods or lacked documentation of quality control protocols. The subgroup initiated the qualitative analysis presented in the report because the data would not support a quantitative analysis.

Dr. VanBriesen noted that these issues are complex and include representative sampling, necessary sample size subsampling, enumeration of live organisms and asked how much of this was part of the deliberations and discussed by the former Panel. Dr. Tamburri referred to Dr. Meyers' letters that discuss these complexities and the subgroup's approach. Drs. Cohen and

Chapman did recollect these issues being discussed by the former panel. Drs. Welshmeyer and Reynolds recollect the discussions and noted they were also considered in whether treatment system could reach a 100-fold reduction. Dr. VanBriesen asked if the Work Group members have any questions for the Office of Water or have requests for additional information.

Dr. Ducoste asked whether the laboratory reports could be made available to the Work Group?

Dr. VanBriesen and Mr. Carpenter confirmed the docket material was available to the Work Group.

Dr. Mihelcic asked how the Office of Water used the SAB ballast water report to develop the Vessel General Permit? Deborah Nagle, Director, Water Permits Division and Dr. VanBriesen both noted that the question is outside of Work Group's charge and Ms. Nagle declined to respond.

Dr. VanBriesen asked if at the time were there any agency reports or guidance available that during the former panel's deliberative period not reviewed by the former panel. Ms. Juhi Saxena noted that the Office of Water provided a white paper with a list of references and materials. She also noted that there were no reports that she knew of that were not available to the panel.

Dr. Reynolds identified himself as a member of the former panel and asked if he could respond to questions regarding the former panel's deliberations on data quality He noted that these issues were discussed in terms sample sizes, subsampling, of the reliability of results (i.e., does a zero represent no live organisms and what might the coefficient of variation around a result). Dr. Reynolds found the approach to be reasonable.

Dr. Burke asked if Dr. Reynolds could clarify the term reasonable.

Dr. Reynolds noted that there was usually a positive result in all the data sets reviewed. When live organisms were seen in the results- a positive result - it confirmed that the limits of detection were not met. They did not meet the ETV standard of five consecutive tests that included detection of a live organism.

Dr. Welchmeyer noted that this same conversation occurred in the Ballast Water Advisory Panel discussion of the metric and the ability to derive a final concentration based on the protocol requirement from 3 m³, the metric for this analysis is one live organism after all the microscopy was completed. There are many papers regarding the needed sample size and positive results to provide sufficient statistical power. Efforts to increase sample sizes and the required concentrations of the sampled volume itself kills organisms.

Dr. Burke sought clarification that organisms need to be present and alive to have high quality data and the sampling protocol works against this requirement. Dr. Welshmeyer agreed with that summarization and noted the ability to measure is pushed to find one organism even if it is at the

lower limit of detection. The current method is pushed to its limit by finding one live organism through microscopy.

Dr. VanBriesen asked whether the currently available data have improved since the report was finalized. All the members of the former panel stated that they believe the information currently available is improved from the 2009 data provided to the former panel. Dr. Tamburri noted that the U.S. Coast Guard has a management system to collect data on the IMO standards used for certification. He also noted that since the SAB report the USGS has not identified any system that can be certified to meet the USGS standard. Several former panel members were aware that the newly available data for treatment systems, increases sample volumes, and the ability to meet the IMO standards.

Dr. VanBriesen noted that Work Group members had no other questions. The DFO adjourned the teleconference.

Attachment 1

Participants in the Public Teleconference EPA Chartered Science Advisory Board Work Group on Possible Corrections to SAB Report on the Efficacy of Ballast Water Treatment August 12, 2016

Members of the chartered Science Advisory Board Work Group on Possible Corrections to SAB
Report on the Efficacy of Ballast Water Treatment

Dr. Jeanne VanBriesen, Chair

Dr. Ingrid Burke

Dr. Joel Ducoste

Dr. James R. Mihelcic

Dr. Daniel Stram

SAB Staff Office

Mr. Thomas Carpenter, Designated Federal Officer

Mr. Christopher Zarba, Director, Science Advisory Board Staff Office

Mr. Thomas Brennan Deputy Director, SABSO

Members of the Former Ballast Water Advisory Panel

Dr. Andrew Cohen

Dr. Peter Chapman

Dr. Fred Dobbs

Dr. Kevin Reynolds

Dr. Mario Tamburri

Dr. Nicholas Welshmeyer

Office of Water

Ms. Deborah Nagle, Director, Water Permits Division, Office of Wastewater Management

Juhi Saxena, WPD

Mr. Jack Faulk WPD

Josh Emerson, WPD

Members of the Public Requesting the Teleconference Information

Gail E Roderick, US Coast Guard (USCG)

Steve E. Glover, Transportation and Logistics Engineering Group MSFC AS 42

Debra DiCianna, Eastern Research Group

Carolyn Junemann Department of Transportation

Amena Saiyid, Bloomberg BNA

Matthew Melewski, the Boutique Firm PLC

Mira Hube, Algoma Central Corporation
Thomas Rayburn, Lake Carriers' Association
David LaRoss, Inside EPA
Debbie Duckworth, USCG
Steve E. Glover, NASA
John Morris, U.S. Coast Guard\
Matt Klasen, US EPA
Claudia Copeland, Congressional Research Service

References

ⁱ Notification of a Public Teleconference of a Work Group under the Auspices of the Chartered Science Advisory Board Citation: Vol 81 Number 137 Pages 46672 <https://www.gpo.gov/fdsys/pkg/FR-2016-07-18/pdf/2016-16929.pdf>

ⁱⁱ Presentation from Dr. Andrew Cohen, Center for Research on Aquatic Bioinvasions
[https://yosemite.epa.gov/sab/sabproduct.nsf//54BDB7954A866EA285257FFF007FB84F/\\$File/COHEN+PresentationData.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf//54BDB7954A866EA285257FFF007FB84F/$File/COHEN+PresentationData.pdf)

ⁱⁱⁱ Public comment submitted by Dr. Andrew Cohen: Supplemental Material for Cohen and signatories letter of March 2, 2016.
[https://yosemite.epa.gov/sab/sabproduct.nsf//1CCD6488B73DF68F8525800C00781B3E/\\$File/Supplemental+Material+for+Cohen+et+al++Letter+of+322015.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf//1CCD6488B73DF68F8525800C00781B3E/$File/Supplemental+Material+for+Cohen+et+al++Letter+of+322015.pdf)

^{iv} Public comment submitted by Dr. Andrew Cohen: Email correspondence from Drs. Drake and Tamburri. Subject: Re: All former members of the SAB Panel on Ballast Water treatment technology. February 12, 2015.
[https://yosemite.epa.gov/sab/sabproduct.nsf/5C695AD6FF4A68008525800C007F0BB5/\\$File/Drake_Tamburri_2122015_Redacted.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/5C695AD6FF4A68008525800C007F0BB5/$File/Drake_Tamburri_2122015_Redacted.pdf)

Public comment submitted by Dr. Andrew Cohen: Email correspondence from Drs. Dobbs and Cohen. Subject: Continued Discussion - All Former members of the SAB panel on Ballast Water. February 13, 2016.
[https://yosemite.epa.gov/sab/sabproduct.nsf/6751DFA6CE791AD08525800C007EFBF6/\\$File/Dobbs_Cohen_+2132015_email_Redacted.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/6751DFA6CE791AD08525800C007EFBF6/$File/Dobbs_Cohen_+2132015_email_Redacted.pdf)

^v Correspondence regarding the corrections to the Ballast Water Report. Letter from Dr. Judith Meyer, April 26, 2015.
[https://yosemite.epa.gov/sab/sabproduct.nsf//11EB9DB6908ABD9B85257FFF007072E8/\\$File/Meyer+Letter+April+26+2015.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf//11EB9DB6908ABD9B85257FFF007072E8/$File/Meyer+Letter+April+26+2015.pdf)

Correspondence regarding the corrections to the Ballast Water Report. Letter from Dr. Judith Meyer, March 7, 2016
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