U.S. Department of Homeland Security
United States Coast Guard

Commanding Officer
United States Coast Guard
Marine Safety Center

US Coast Guard Stop 7430
2703 Martin Luther King Jr. Ave. SE
Washington D.C., 20593-7430
Staff Symbol: MSC
Phone: (202) 795-6729
Email: msc@uscg.mil

16710/P017660/jmk
Serial: E1-1504671
December 14, 2015

Alfa Laval Tumba AB
Attn: [redacted]
Hans Stahles väg 7
SE-147 80 Tumba, Sweden

Subj: REQUEST FOR APPROVAL OF THE USE OF THE MOST PROBABLE NUMBER (MPN) METHOD TO DETERMINE BIOLOGICAL EFFICACY OF THE ALFA LAVAL PUREBALLAST BALLAST WATER MANAGEMENT SYSTEM (BWMS)

Ref: (a) Your letter w/ attachments dated September 20, 2015
(b) U.S. Environmental Protection Agency (EPA) Generic Protocol for the Verification of Ballast Water Treatment Technologies, version 5.1, dated September 2010.
(c) Application for USCG Type Approval of by Alfa Laval, dated March 31, 2015

Dear [redacted]:

In reference (a), you requested approval of the Most Probable Number (MPN) method, per 46 Code of Federal Regulations (CFR) 162.060-10(b)(1), as an equivalent alternative to the method for determining the number of living organisms in the 10-50 μm size class specified in reference (b).[1] After consultation with the Coast Guard Headquarters Office of Operating and Environmental Standards and careful evaluation of your request, I do not consider the MPN method to be equivalent to the methods specified in reference (b). Since the efficacy of the Alfa Laval PureBallast Ballast Water Treatment System was evaluated using the MPN method, reference (c) is not approved.

Our review concluded that the MPN test method is not equivalent because it does not measure the efficacy of the ballast water treatment system to the performance standard required by the regulations. The regulations specifically require ballast water treatment systems to be evaluated based on their ability to kill certain organisms. Since the proposed MPN method assesses the viability of an organism to colonize after treatment, it measures to a different standard than that required by the regulations.

In the Preamble to the Final Rule which implemented the Ballast Water Discharge Standard and the procedures for BWMS type approval, the distinction between live/dead and viable/unviable was evaluated, explicitly discussed and the decision was made to use live/dead as the standard for evaluating the performance of BWMS (see 77 FR 17254 at 17275). Since the MPN method

[1] Coast Guard regulations at 46 CFR 162.060-5(d)(1) incorporate this protocol by reference.

does not measure performance to this standard, it is not an equivalent evaluation or test under the provisions of 46 CFR 162.060-10(b)(1).

In reference (a) you assert that the required tests are not appropriate because the design dosage of UV-irradiation in your system causes damage which prevents cell replication, but does not otherwise kill the target organisms during treatment. The fact that you have chosen to design your system in this manner, does not render the required tests non- applicable or impracticable for the evaluation of ballast water treatment systems. We are aware of other ballast water treatment systems, including one which uses UV-irradiation, which are undergoing evaluation using the required tests. As such, we find that the required tests are applicable and appropriate for the evaluation of ballast water treatment systems.

Pursuant to 46 CFR 159.001-2, you may appeal this decision as provided in 46 CFR 1.03-15. Your appeal should be addressed as follows:

Commandant (CG-5PS)
US Coast Guard Stop 7430
2703 Martin Luther King Jr. Ave. SE
Washington DC, 20593-7430

Our project number for this system is P017660. If you have any questions concerning our review, please contact Lieutenant Jason Kling at the number above.

Sincerely,

J. W. MAUGER
Captain, U. S. Coast Guard
Commanding Officer

Copy: Commandant, Office of Operating and Environmental Standards (CG-OES)
DNV-GL

U.S. Department of Homeland Security
United States Coast Guard

Commanding Officer
United States Coast Guard
Marine Safety Center

US Coast Guard Stop 7430
2703 Martin Luther King Jr. Ave. SE
Washington D.C., 20593-7430
Staff Symbol: MSC
Phone: (202) 795-6729
Email: msc@uscg.mil

16710/P018008/jmk
Serial: E1-1504662
December 14, 2015

DESMI Ocean Guard A/S
Attn: [redacted]
Lufthavnsvej 12
DK-9400 Norresundby
Denmark

Subj: REQUEST FOR APPROVAL OF THE USE OF THE MOST PROBABLE NUMBER (MPN) METHOD TO DETERMINE BIOLOGICAL EFFICACY OF THE DESMI RAYCLEAN™ BALLAST WATER MANAGEMENT SYSTEM (BWMS)

Ref: (a) Your letter w/enclosures dated March 19, 2015
(b) U.S. Environmental Protection Agency (EPA) Generic Protocol for the Verification of Ballast Water Treatment Technologies, version 5.1, dated September 2010.
(c) Application for USCG Type Approval of by DESMI Ocean Guard, dated March 19, 2015

Dear [redacted]:

In reference (a), you requested approval of the Most Probable Number (MPN) method, per 46 Code of Federal Regulations (CFR) 162.060-10(b)(1), as an equivalent alternative to the method for determining the number of living organisms in the 10-50 μm size class specified in reference (b).[1] After consultation with the Coast Guard Headquarters Office of Operating and Environmental Standards and careful evaluation of your request, I do not consider the MPN method to be equivalent to the methods specified in reference (b). Since the efficacy of the Desmi RayClean™ Ballast Water Treatment System was evaluated using the MPN method, reference (c) is not approved.

Our review concluded that the MPN test method is not equivalent because it does not measure the efficacy of the ballast water treatment system to the performance standard required by the regulations. The regulations specifically require ballast water treatment systems to be evaluated based on their ability to kill certain organisms. Since the proposed MPN method assesses the viability of an organism to colonize after treatment, it measures to a different standard than that required by the regulations.

In the Preamble to the Final Rule which implemented the Ballast Water Discharge Standard and the procedures for BWMS type approval, the distinction between live/dead and viable/unviable was evaluated, explicitly discussed and the decision was made to use live/dead as the standard

[1] Coast Guard regulations at 46 CFR 162.060-5(d)(1) incorporate this protocol by reference.

for evaluating the performance of BWMS (see 77 FR 17254 at 17275). Since the MPN method does not measure performance to this standard, it is not an equivalent evaluation or test under the provisions of 46 CFR 162.060-10(b)(1).

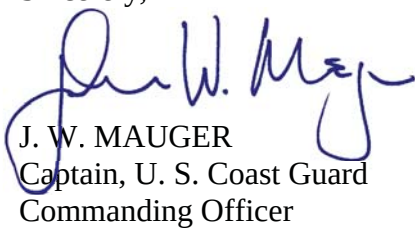
In reference (a) you assert that the required tests are not applicable or are impracticable because the design dosage of UV-irradiation in your system causes damage which prevents cell replication, but does not otherwise kill the target organisms during treatment. The fact that you have chosen to design your system in this manner, does not render the required tests non-applicable or impracticable for the evaluation of ballast water treatment systems. We are aware of other ballast water treatment systems, including one which uses UV-irradiation, which are undergoing evaluation using the required tests. As such, we find that the required tests are applicable and practicable for the evaluation of ballast water treatment systems.

Pursuant to 46 CFR 159.001-2, you may appeal this decision as provided in 46 CFR 1.03-15. Your appeal should be addressed as follows:

Commandant (CG-5PS)
US Coast Guard Stop 7430
2703 Martin Luther King Jr. Ave. SE
Washington DC, 20593-7430

Our project number for this system is P018008. If you have any questions concerning our review, please contact Lieutenant Jason Kling at the number above.

Sincerely,



J. W. MAUGER
Captain, U. S. Coast Guard
Commanding Officer

Copy: Commandant, Office of Operating and Environmental Standards (CG-OES)
DNV-GL

U.S. Department of Homeland Security
United States Coast Guard

Commanding Officer
United States Coast Guard
Marine Safety Center

US Coast Guard Stop 7430
2703 Martin Luther King Jr. Ave. SE
Washington D.C., 20593-7430
Staff Symbol: MSC
Phone: (202) 795-6729
Email: msc@uscg.mil

16710/P017634/jmk
Serial: E1-1504667
December 14, 2015

Hyde Marine Inc.
Attn: [redacted]
2000 McClaren Wood Drive
Coraopolis, PA 15108

Subj: REQUEST FOR APPROVAL OF THE USE OF THE MOST PROBABLE NUMBER (MPN) METHOD TO DETERMINE BIOLOGICAL EFFICACY OF THE HYDE GUARDIAN BALLAST WATER MANAGEMENT SYSTEM (BWMS)

Ref: (a) Your letter w/enclosures dated February 23, 2015
(b) U.S. Environmental Protection Agency (EPA) Generic Protocol for the Verification of Ballast Water Treatment Technologies, version 5.1, dated September 2010

Dear [redacted]

In reference (a), you requested approval of the Most Probable Number (MPN) method, per 46 Code of Federal Regulations (CFR) 162.060-10(b)(1), as an equivalent alternative to the method for determining the number of living organisms in the 10-50 μm size class specified in reference (b).[1] After consultation with the Coast Guard Headquarters Office of Operating and Environmental Standards and careful evaluation of your request, I do not consider the MPN method to be equivalent to the methods specified in reference (b).

Our review concluded that the MPN test method is not equivalent because it does not measure the efficacy of the ballast water treatment system to the performance standard required by the regulations. The regulations specifically require ballast water treatment systems to be evaluated based on their ability to kill certain organisms. Since the proposed MPN method assesses the viability of an organism to colonize after treatment, it measures to a different standard than that required by the regulations.

In the Preamble to the Final Rule which implemented the Ballast Water Discharge Standard and the procedures for BWMS type approval, the distinction between live/dead and viable/unviable was evaluated, explicitly discussed and the decision was made to use live/dead as the standard for evaluating the performance of BWMS (see 77 FR 17254 at 17275). Since the MPN method does not measure performance to this standard, it is not an equivalent evaluation or test under the provisions of 46 CFR 162.060-10(b)(1).

[1] Coast Guard regulations at 46 CFR 162.060-5(d)(1) incorporate this protocol by reference.

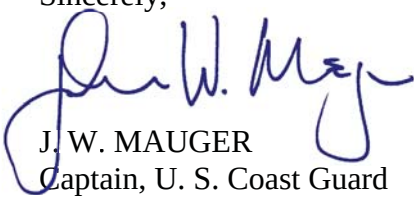
In reference (a) you assert that the required tests are not applicable because UV-irradiation as a disinfection product sterilizes organisms by disrupting their DNA and interrupting their ability to reproduce, but does not otherwise kill the target organisms during treatment. The fact that you have chosen to design your system in this manner, does not render the required tests non-applicable or impracticable for the evaluation of ballast water treatment systems. We are aware of other ballast water treatment systems, including one which uses UV-irradiation, which are undergoing evaluation using the required tests. As such, we find that the required tests are applicable and practicable for the evaluation of ballast water treatment systems.

Pursuant to 46 CFR 159.001-2, you may appeal this decision as provided in 46 CFR 1.03-15. Your appeal should be addressed as follows:

Commandant (CG-5PS)
US Coast Guard Stop 7430
2703 Martin Luther King Jr. Ave. SE
Washington DC, 20593-7430

Our project number for this system is P017634. If you have any questions concerning our review, please contact Lieutenant Jason Kling at the number above.

Sincerely,



J. W. MAUGER
Captain, U. S. Coast Guard
Commanding Officer

Copy: Commandant, Office of Operating and Environmental Standards (CG-OES)
DNV-GL

U.S. Department of Homeland Security
United States Coast Guard

Commanding Officer
United States Coast Guard
Marine Safety Center

US Coast Guard Stop 7430
2703 Martin Luther King Jr. Ave. SE
Washington D.C., 20593-7430
Staff Symbol: MSC
Phone: (202) 795-6729
Email: msc@uscg.mil

16710/P018787/jmk
Serial: E1-1504669
December 14, 2015

Trojan Marinex
Attn: [redacted]
3020 Gore Road
London, Canada N5V 4T7

Subj: REQUEST FOR APPROVAL OF THE USE OF THE MOST PROBABLE NUMBER (MPN) METHOD TO DETERMINE BIOLOGICAL EFFICACY OF THE TROJAN MARINEX™ BALLAST WATER MANAGEMENT SYSTEM (BWMS)

Ref: (a) Your letter dated February 5, 2015, (to include supplemental submissions)
(b) U.S. Environmental Protection Agency (EPA) Generic Protocol for the Verification of Ballast Water Treatment Technologies, version 5.1, dated September 2010.
(c) Application for USCG Type Approval of by Trojan Marinex, dated March 4, 2015

Dear [redacted]:

In reference (a), you requested approval of the Most Probable Number (MPN) method, per 46 Code of Federal Regulations (CFR) 162.060-10(b)(1), as an equivalent alternative to the method for determining the number of living organisms in the 10-50 μm size class specified in reference (b).[1] After consultation with the Coast Guard Headquarters Office of Operating and Environmental Standards and careful evaluation of your request, I do not consider the MPN method to be equivalent to the methods specified in reference (b). Since the efficacy of the Trojan Marinex™ Ballast Water Treatment System was evaluated using the MPN method, reference (c) is not approved.

Our review concluded that the MPN test method is not equivalent because it does not measure the efficacy of the ballast water treatment system to the performance standard required by the regulations. The regulations specifically require ballast water treatment systems to be evaluated based on their ability to kill certain organisms. Since the proposed MPN method assesses the viability of an organism to colonize after treatment, it measures to a different standard than that required by the regulations.

In the Preamble to the Final Rule which implemented the Ballast Water Discharge Standard and the procedures for BWMS type approval, the distinction between live/dead and viable/unviable was evaluated, explicitly discussed and the decision was made to use live/dead as the standard for evaluating the performance of BWMS (see 77 FR 17254 at 17266). Since the MPN method

[1] Coast Guard regulations at 46 CFR 162.060-5(d)(1) incorporate this protocol by reference.

does not measure performance to this standard, it is not an equivalent evaluation or test under the provisions of 46 CFR 162.060-10(b)(1).

In reference (a) you assert that the required tests are not practicable because the design dosage of UV-irradiation in your system causes damage which prevents cell replication, but does not otherwise kill the target organisms during treatment. The fact that you have chosen to design your system in this manner, does not render the required tests non- applicable or impracticable for the evaluation of ballast water treatment systems. We are aware of other ballast water treatment systems, including one which uses UV-irradiation, which are undergoing evaluation using the required tests. As such, we find that the required tests are applicable and practicable for the evaluation of ballast water treatment systems.

Pursuant to 46 CFR 159.001-2, you may appeal this decision as provided in 46 CFR 1.03-15. Your appeal should be addressed as follows:

Commandant (CG-5PS)
US Coast Guard Stop 7430
2703 Martin Luther King Jr. Ave. SE
Washington DC, 20593-7430

Our project number for this system is P018787. If you have any questions concerning our review, please contact Lieutenant Jason Kling at the number above.

Sincerely,

J. W. MAUGER
Captain, U. S. Coast Guard
Commanding Officer

Copy: Commandant, Office of Operating and Environmental Standards (CG-OES)
DNV-GL