

28 September 2019

US Coast Guard
S.T. Brady, CAPT COMDT (CG-OES)

Comments on Draft Policy Letter on the Coast Guard's process to accept proposed Type-Approval testing protocols for Ballast Water Management Systems (BWMS) that render organisms in ballast water Nonviable

Mouawad Consulting AS is a Norwegian-based private company, specializing in the field of Ballast Water Management, and delivering type approval consultancy services for more than 28 manufacturers of Ballast Water Management Systems (BWMS). This involves active R&D, testing, reporting and following up type approval applications with the USCG.

The comments we offer on the subject matter are based on that experience, in addition to the experience of the CEO, Jad Mouawad, establishing and developing the BWM services at DNV GL from 2007 to 2013.

Specific comments to the Draft Policy Letter

1 – Section 9 (c)

We support the procedures included in Paragraph 9 (c) as it adequately provides transparent information on how a BWMS was type approved. Specifically, paragraph (1) is important in the documentation of the BWMS.

2 – Section 6, Last Paragraph

We do not agree with the statement made, as we believe that the USCG is indeed aware of type-approval testing protocols for BWMS that render nonviable organisms in ballast water that are based on best available science.

This statement is based on the following:

a) Efforts made by the joint committee of the USCG and US EPA together with the UV-based BWMS community

The EPA, in close cooperation with the USCG, U.S. Naval Research Laboratory and leading scientists, Independent Labs (NSF), manufacturers of UV-based BWMS and professors from the US and other countries, led a committee work on the subject of validation of testing protocols for Ballast Water Management Systems (BWMS) that render organisms in ballast water Nonviable for the course of many years. The work of the committee culminated in parallel testing for validation of the Most Probable Number (MPN) method in various USCG approved testing sub-laboratories, resulting in a comprehensive report on the method that was presented to both the EPA and the USCG.

The report, including results and testing protocols followed using the MPN method, is well within the hands of the USCG for several years. The report's conclusion is that the MPN method is indeed the best available technology for type-approval testing protocols for BWMS that render nonviable organisms in ballast water.

- (i) Has the USCG reviewed the report submitted and deemed it unfit to justify including the MPN method as best available technology?
- (ii) If Yes, can the USCG share the detailed review done in order to identify the flaws that made the USCG conclude that the proposed method by all of the currently functioning USCG approved sub-labs, is not adequate for the purposes of type approval testing?
- (iii) If No, can the USCG explain why they have not considered the report, and so concluding that they are not aware of the MPN method?

b) The USCG is aware of the MPN method since 2015

Paragraph 19.11 of the USCG Ballast Water Frequently Asked Questions (24 April 2018) mentions the MPN method, as well as requests and consequent denial of acceptance, of four applications by Alfa Laval, DESMI, Hyde and Trojan.

- (i) Is the USCG aware of the MPN method as described by each testing protocol of their approved sub-labs? (Golden Bear, NIVA, DHI and others)?
- (ii) Has the USCG concluded that this MPN method is not adequate for the purposes of type approval under the VIDA regulation?
- (iii) If yes, can we receive the detailed analysis by the USCG explaining why the MPN method is not deemed appropriate, all the time documentation on validation has been submitted (ref. report mentioned in question (a) above)?

c) Comments on the term Render Nonviable in the VIDA regulation

Section 903 (a)(1)(U) of Reference (a) included in the Draft Policy letter includes the following definition of the term Render Nonviable:

QUOTE

“(U) RENDER NONVIABLE. — The term ‘render nonviable’, with respect to an organism in ballast water, means the action of a ballast water management system that renders the organism permanently incapable of reproduction following treatment.

UNQUOTE

The MPN method as applied for over a century in determining viability of organisms in water, assumes the growth time for such organisms to be in the range of 14 days, and the inability of organisms to grow within that timeframe assumes it to be permanent.

It seems that the USCG has an issue accepting the MPN method as validated to prove organisms permanently incapable of reproduction following treatment. However, the regulation calls for best available technology, and not the perfect technology. As such, and given the long history of the MPN method in water treatment, the extensive testing and validation done by USCG approved sub-labs worldwide, where the conclusion was that the MPN indeed is the best available technology to prove viability of organisms, it seems more appropriate to us if the USCG had put forward the MPN method as described in the report which was presented due to joint efforts that included both USCG and EPA; and asked industry for comments on the MPN protocol.

- (i) Why hasn't the USCG considered putting forward the MPN protocol proposed by the joint EPA led UV Technology committee, as a proposed method compliant with VIDA?
- (ii) How does the USCG anticipate validation methods to prove that a given non-viability method (for example MPN) prove that organisms are "permanently incapable" of reproduction?
- (iii) If the report by the EPA led UV Technology committee does not present sufficient evidence that best available science is the MPN method; what does the USCG expect from the scientific, research and industry community?

As a final comment on this subject, we believe it is more appropriate if the USCG explained to the aforementioned community who worked in good faith with the EPA and the USCG, to achieve validation based on best available science, to why the work done is not sufficient and what would be a sufficient work.

d) Comments on the term Best Available Science in the VIDA Regulation

On two occasions in Reference (a) included in the Draft Policy letter, US regulators refer to the term *best available science*.

In April 2016, Dennis D. Murphy and Paul S. Weiland published an article on *Guidance on the Use of Best Available Science under the U.S. Endangered Species Act*.

(access: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4887529/>)

- (i) Has the USCG sought guidance from this article or other legal and scientific publications on the interpretation of the term *Best Available Science* in the VIDA regulation?
- (ii) Why hasn't the USCG considered the MPN method to be *Best Available Science* for the purposes of testing protocols for Ballast Water Management Systems (BWMS) that render organisms in ballast water Nonviable?
- (iii) Which reference does the USCG use in setting guidance or guidelines of what *Best Available Science* is?

e) International Maritime Organization (IMO) Circular BWM.2/Circ.61

The Marine Environment Protection Committee (MEPC) of the IMO approved in May 2017, the use of the MPN method for enumeration of viable organisms for type approval of BWMS.

Paragraph 4.54 of MEPC 71/17 states the following:

QUOTE

4.54 Consequently, the Committee approved BWM.2/Circ.61 on *Guidance on methodologies that may be used for enumerating viable organisms for type approval of ballast water management systems* (PPR 4/21, annex 4). *[extra text in the same paragraph deleted as deemed not relevant for this discussion]*

UNQUOTE

Document PPR 4/21 annex 4, includes a clear description of the MPN method as suitable for enumerating viable organisms. The protocol, and the consequent approval by the MEPC, were not objected to or abstained from the approval, by the US Delegation to the IMO.

This means that by not abstaining from this approval, the US has accepted the use of MPN as stated in PPR 4/21 annex 4.

The USCG did not use that method in its previous and current type approvals because the applicable CFR asked for living organisms; but now that the VIDA regulation opened for viable organisms, the maritime industry expects the USCG to follow the tacit acceptance the US has given at the IMO, through the MEPC resolution.

- (i) Why did the USCG not follow the IMO approved MPN method as described in PPR 4/21 annex 4? It is obvious that the US delegation approved that method as part of BWM.2/Circ.61 with no objections.
- (ii) Will the USCG consider adopting the IMO approved MPN method without further ado, since they have already approved it together with the other IMO member states already in 2017?

3 – Section 8, First Paragraph, Second sentence

The Second sentence of the First Paragraph of Section 8 includes the following wording, in line with the VIDA regulation:

QUOTE

BWMS type-approval testing for systems that render organisms nonviable will incorporate protocols based on viability and will be subject to the same level of rigor currently used for type-approval laid out in references (b) and (c).

UNQUOTE

As background, the approved FDA/CMFDA methods under references (b) and (c) in the Draft Policy Letter, has been identified with to include significant flaws including false positives (i.e. organisms staining while they are actually dead).

- (i) Can the USCG explain how the FDA/CMFDA method has been evaluated to be adequate for type approval testing of BWMS?
- (ii) Can the USCG explain how the rigorousness of the approved FDA/CMFDA method is quantified, and so used as reference to be applied for future methods to be approved?

Given that the published information in the *Generic Protocol for the Verification of Ballast Water Treatment Technology* (ETV Protocol) as supporting documentation for the FDA/CMFDA staining methodology, is much less comprehensive than the information submitted to the USCG and the EPA as part of the aforementioned joint effort by the world's testing community, it seems to us that MPN has not been subjected to the same level of rigor currently used for type-approval.

- (iii) Will the USCG consider the already submitted MPN method and what is the level of rigorousness that the USCG will apply to it? How can that be quantified compared to the same rigor applied for the FDA/CMFDA method?

4 – Market considerations

The uptake of BWMS into the sailing fleet of commercial vessels will take place between 2019 and 2024. The application of staining (living) or MPN (viable) standards for type approval plays a significant role in the energy consumption and operational reliability of BWMS.

With the proposed draft policy, the USCG is ignoring all past efforts that were done to prove that the MPN is best available science and is therefore pushing the validation of MPN many years ahead in time. Given the window of installation of the world fleet, type approval following the viable method will be ineffective to catch that window and manufacturers of BWMS will not be able financially or sufficiently justify running new tests to comply with the new enumeration technique.

The USCG is therefore effectively blocking the intent in the VIDA for use of viable organisms, by delaying the implementation of such method until such time when such implementation is no longer viable for manufacturers of BWMS.

Whether this is intentional or not, this is unfortunate for the complete implementation of ballast water management on the world fleet and is creating unnecessary divide between discharges in the US and elsewhere.

Considering that the US delegation to the IMO already approved the MPN method during the 71st session of MEPC, we urge the USCG to use that method as published in BWM.2/Circ.61.

Best,

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