

5 March 2022

Docket No. 20–10

**Comments on Conditions Created by Canadian Ballast Water Regulations in the
U.S./Canada Great Lakes Trade**

William Cody
Secretary, Federal Maritime Commission
800 North Capitol Street, N.W.
Washington, D.C. 20573

Dear Sec. Cody:

I am Professor Emeritus in Oceanography at Dalhousie University and an expert in studies of methods for testing the biological efficacy of ballast water management systems. In response to your request for comments, I offer a scientific assessment of additional developments since the issuance of the June 2020 Notice.

The central message is that at this time there is no final U.S. regulation that is compliant with the Vessel Incidental Discharge Act (VIDA), so a science-based assessment of the Petition would be premature.

These comments are intended for public view. Please post them in the Commission's Electronic Reading Room.

Sincerely,



John J. Cullen, Ph.D. FRSC
Department of Oceanography
Dalhousie University

Attachments (all approved for public release):

Comments on Conditions Created by Canadian Ballast Water Regulations in the U.S./Canada Great Lakes Trade

Appendix 1: Status of United States ballast water testing policy and the best available science in the fourth year after passage of the Vessel Incidental Discharge Act (VIDA)

Appendix 2: Comments on the Great Lakes Ballast Water R&D Plan, Version 4, submitted to the Great Waters Research Collaborative (29 March 2021)

Docket No. 20–10

Comments on Conditions Created by Canadian Ballast Water Regulations in the U.S./Canada Great Lakes Trade

John J. Cullen, Ph.D., Dalhousie University, Halifax, NS Canada

Responses to specific questions in the FMC request for comments:

1) EPA Rule: How should the Commission consider the status of the EPA’s proposed rule?

Summary:

The status of the EPA’s proposed rule is unresolved. If the EPA responds to detailed comments in the Federal Register and revises key elements of the proposed rule to conform with VIDA and the best available science, the comparison between U.S. and Canadian regulations, and the EPA’s assessment of best available technology for Great Lakes ballast water treatment, will be fundamentally altered. Investigation of the Petition is thus premature.

Details:

Key elements of EPA’s proposed rule that are important to the Petitioner’s arguments conflict with the Vessel Incidental Discharge Act (VIDA) and are not supported by the best available science. In particular, the proposed rule relies on the “live/dead” ETV staining protocol¹ for the assessment of ballast water management systems (BWMS), although VIDA mandated a return to the International Maritime Organization (IMO) standard (viability: capable of reproduction) and directed the U.S. Coast Guard (USCG) to adopt the most probable number (MPN) testing method — a BWMS testing methodology that is firmly based on best available science.² The USCG did not issue the required Final Policy Letter on testing methods. Summarized by Alpha Laval Tumba in a thoroughly documented brief, “In other words, EPA purports to use USCG’s failure to comply with VIDA as an excuse to do what Congress specifically prohibited: use staining methods to evaluate viable organism density.”³ Negative industry impacts caused by the lack of a Final Policy letter were highlighted by the Ballast Water Equipment Manufacturer’s Association.⁴

The issue of BWMS testing methods is directly relevant to the Petition, because one of its foundations is EPA’s conclusion that there is no best available technology (BAT) to meet the standard for operations in the Great Lakes. This conclusion is scientifically indefensible because the USCG-approved ETV staining method is unsuitable for testing BWMS that use UV

¹ 2010 Generic Protocol for the Verification of Ballast Water Treatment Technology.

² Cullen, J.J., 2019. The best available science describing type-approval testing methods and protocols for ballast water management systems that render nonviable organisms in ballast water. Posted in the Federal Register (<https://www.regulations.gov/comment/USCG-2019-0477-0007>). See also submissions by J.J. Cullen on the EPA proposed rule: <https://www.regulations.gov/comment/EPA-HQ-OW-2019-0482-0662> and <https://www.regulations.gov/comment/EPA-HQ-OW-2019-0482-0717> (Attachment: slide pack).

³ Comment submitted by Alfa Laval Tumba. <https://www.regulations.gov/comment/EPA-HQ-OW-2019-0482-0754>.

⁴ Comment submitted by the Ballast Water Equipment Manufacturer’s Association. <https://www.regulations.gov/comment/EPA-HQ-OW-2019-0482-0674>.

disinfection to render organisms nonviable:⁵ effectively treated discharge that meets the standard using MPN fails the ETV test.

On the grounds of best available science, all conclusions on the effectiveness of UV disinfection for treating Great Lakes ballast water should be set aside until results from suitable MPN-based testing methods are reviewed.

If the EPA and USCG respond to the well-documented comments on Federal Register and revise the proposed rule to respect VIDA and the best available science, the final rule will recognize MPN-based methodologies for enumerating organisms that are capable of reproduction. With that, the EPA will be compelled to revise its assessment of the efficacy of BAT for Great Lakes shipping and the comparison of U.S. and Canadian regulations will change fundamentally.

Conclusion: *It is premature to compare U.S. and Canadian regulations in the context of the Petition.*

This conclusion aligns with observations from Canada in their letter to the Federal Maritime Commission.⁶

2) Developments: What industry or scientific developments have an impact on this Petition? Have there been any relevant developments since the Commission's initial request for comments in June 2020?

Summary:

Research being conducted by the Great Waters Research Collaborative (GWRC) is highly relevant to the Petition. A public comment submitted in March 2021 showed how their R&D plan would have to be modified to capture recent scientific developments and align with the legal definition of "living" in VIDA. Actions taken by the GWRC in response to the scientific developments would have an impact on the assessments of BAT underlying the Petition. To date, there has been no response.

Details:

The EPA is relying on additional research on BAT for vessels operating on the Great Lakes,⁷ and this is surely relevant to the Petition. In March 2021, the Great Waters Research Collaborative (GWRC) solicited public comments on the Ballast Water R&D Plan.⁸ My comments described scientific developments that have an impact on the Petition, so they are included for the public record as Appendix 2. They were submitted on 29 March and acknowledged. The GWRC website was updated with "We are carefully considering each of the comments that we received, and a summarized version of the public comments and our responses will be available on this webpage as soon as possible."

⁵ See references in footnote 2 for a full discussion with links to evidence.

⁶ https://www2.fmc.gov/readingroom/docs/20-10/20-10_FMC_Letter_for_Sec.pdf/

⁷ "Additional research is needed before EPA could identify a standard that reasonably satisfies the statutory BAT requirements consistent with Section 903(g)(2)(B)(viii) of the VIDA which establishes a program for EPA, in collaboration with other federal agencies, to research and develop BWMS for use by vessels operating on the Great Lakes" (Proposed rule, p. 67850).

⁸ <https://www.uwsuper.edu/lrsi/gwrc/gllcisp/index.cfm> (viewed 3 March 2022). The site includes a link to the plan.

Firstly, I explained that by focusing their BWMS evaluations⁹ solely on testing with the stains-based ETV protocol, energy-efficient UV technologies were excluded from legitimate consideration under the terms of VIDA. Then, I showed that their approach for evaluating alternative viability testing methods (i.e., MPN) required revision because it is based on an unpublicized EPA document¹⁰ describing a controversial validation plan that does not consider relevant science since 2017.

There has been no response on the GWRC site to this or any other public comment. However, the GWRC has subsequently published a request for proposals on Evaluation of BWMS in Great Lakes Water that retained their original language specifying use of the ETV Protocol,¹¹ and a recent technical report on BWMS testing¹² illustrates continued reliance on the stains-based assessment of UV-treated discharge, with no consideration of its unsuitability for testing the efficacy of UV-disinfection using VIDA's definition of living.

These recent actions show that the research program funded through VIDA is testing the efficacy of Great Lakes ballast water treatment as if VIDA did not exist.

The evidence is consistent with the GWRC dismissing public comments without transparency. But given that the GWRC R&D Plan promises to promote “an inclusive, transparent, and collaborative process throughout project plan development and implementation” (p. 14), it is reasonable to expect that at some point the GWRC will address the fundamental incompatibilities between its assessments of Great Lakes ballast water treatment and VIDA's instructions on testing methods. When they do — and if they follow the best available science — their evaluations of BAT for treating Great Lakes ballast water must change, and so will the foundations of the Petition.

Concluding remarks

The issues at the root of these comments are the definition of a living organism in ballast water discharge, and how living organisms in discharge should be enumerated. The Vessel Incidental Discharge Act resolved both when it became law, but the implementing regulations have yet to take final form. Public comments on the EPA's proposed rule show that final U.S. regulations for Great Lakes ballast water discharge may differ significantly from their proposed draft, thereby changing comparisons with Canadian regulations. Regardless, at this time there is no final U.S. regulation that is compliant with VIDA, so a science-based assessment of the Petition would be premature.

⁹ Land-based BWMS Evaluation, Key Question 1. It is nearly identical to the Shipboard Evaluation question.

¹⁰ The EPA validation plan (dated 25 January 2018) has no document number or web link. It is an appendix to the unpublicized report: First, M.R., Validation of a most probable number-based assay in a freshwater environment (NRL Letter Report 6130/1929, 21-06-2019, approved for public release). The EPA plan was “developed under the auspices of the EPA ETV Program and...does not represent consensus among members of the Task Group, which failed to reach agreement on a number of issues (too numerous to list here) discussed over the years” (p. 32). I was a member of the Task Group.

¹¹ RFP: Shipboard Evaluation of the Effectiveness of IMO Compliant and U.S. Coast Guard Type Approved Ballast Water Management Systems in Great Lakes Water (27 May 2021).

https://www.uwsuper.edu/lrsi/gwrc/gllcisp/upload/RDPlan-YR1_ShipboardBWMSEval_RFP2_Final.pdf

¹² Polkinghorne, C., TenEyck, M., et al., 2022. Land-based evaluation of the effectiveness of the Optimarin ballast system in the Great Lakes, <http://digital.library.wisc.edu/1793/82759>. Tests conducted in September–October 2021.

Appendix 1

Status of United States ballast water testing policy and the best available science in the fourth year after passage of the Vessel Incidental Discharge Act (VIDA)

John J. Cullen
Dalhousie University
March 3, 2022

On December 4, 2018, the “Vessel Incidental Discharge Act” (VIDA) was signed into law. It instructed the US Coast Guard, in coordination with the US Environmental Protection Agency, to develop new national standards of performance for commercial vessel discharges, and the US Coast Guard to develop corresponding implementing regulations.

The VIDA included a significant change to the definition of “living” organisms in ballast water discharge, requiring the rejection of the Coast Guard’s “live/dead” testing method and the adoption of ballast water management system (BWMS) type-approval testing methods that enumerate organisms based on their ability to reproduce. The USCG was instructed to describe the methods in a Final Policy Letter, based on the best available science, taking into consideration a method that uses organism grow-out and most probable number (MPN) statistical analysis. The statutory deadline was December 4, 2019.

United States Coast Guard Final Policy Letter – A Draft Policy Letter was published in July, 2019, stating that the Coast Guard does not know of any suitable testing protocols that are based on best available science. This view was strongly challenged in the majority of 38 public submissions to the Federal Register. Hundreds of pages of documents rendered the Coast Guard’s statement untenable: The best available science clearly showed that the MPN Dilution Culture + Motility type-approval testing methodology satisfies the requirements of the VIDA and should be accepted for use in the enforcement of US ballast water discharge standards.

The legally mandated Final Policy Letter has yet to be published and there have been no responses to the public comments.

Proposed Rule for Standards of Performance – Also called for by the VIDA, the EPA’s Notice of Proposed Rulemaking: Vessel Incidental Discharge National Standards of Performance was published in the Federal Register for public comment in October, 2020. But, citing the Coast Guard’s failure to identify suitable testing protocols (despite a legal requirement to do so by December 2019), the proposed rule included no method for enumerating organisms in ballast water that are capable of reproduction. Again, public comments posted to the Federal Register amply demonstrated that MPN Dilution Culture + Motility was a suitable method that should be included in the rule.

No responses to the public comments have been posted, and the Coast Guard has not announced any progress on recognition of MPN-based methods.

Great Lakes research program – The VIDA also established a research program to research, develop, and pilot ballast water management systems for use by commercial vessels operating solely within the Great Lakes and Lake Champlain Systems. The Lake Superior Research Institute’s Great Waters Research Collaborative (GWRC), in collaboration with the U.S. Department of Transportation Maritime Administration, prepared a five-year Great Lakes Ballast

Water Research and Development Plan, posted for public comment with a March, 2021 closing.¹³ Responses were to be made available “as soon as possible”. Eleven months later, no response has been posted.

Summary – More than three years after the Vessel Incidental Discharge Act became law, and two years after they were required to do so, the US Coast Guard has yet to describe BWMS type-approval testing methods that enumerate organisms based on their ability to reproduce. Consequently, the EPA has no testing method for their proposed discharge standard that is suitable for all treatment technologies. The VIDA instructed the Coast Guard and EPA to consider the best available science. The science provides overwhelming support for MPN Dilution Culture + Motility as a suitable type-approval testing methodology. This science has not been challenged by the Coast Guard, the EPA, or Great Lakes researchers. Rather, there has been essentially no response. The requirements of the VIDA are still law and the best available science stands.

¹³ The comments I submitted are attached as Appendix 2.

Great Waters Research Collaborative
University of Wisconsin - Superior
Superior, WI 54880
USA
gwrc@uwsuper.edu

re: Comments on the Great Lakes Ballast Water R&D Plan, Version 4

As an expert in the study of methods for testing the efficacy of ballast water treatment technology, I welcome the opportunity to offer some comments on your Ballast Water R&D plan. My central message is that the plans for research on viability assessment methods should be revised to capture recent peer-reviewed research, IMO publications, and formal submissions to the EPA and USCG that are not considered in this version of the R&D plan.

Much of the information that I discuss is focused on restricted aspects of the R&D plan pertaining to the assessment of viability with the most probable number (MPN) methodology. Though technical and esoteric, the topic is important because the evaluation of MPN methods has wide-ranging implications for the regulation of ballast water treatment, with significant consequences for the shipping industry, manufacturers, NGOs and others. Implications specific to Great Lakes shipping will be recognized by some members of your Stakeholders Group and Project Planning Team.

Prior to drafting my comments, I mistakenly jumped to the conclusion that they would be shared with members of the Stakeholders Group and Project Planning Team. So, I included discussions of the implications for USCG/EPA policy and Naval Research Laboratory review that might not be directly addressable by the research team. Now, I recognize and accept that the research team will summarize public comments, keeping them anonymous. Rather than redrafting, I offer these comments with explicit permission for you to share them with members of your Stakeholders Group and Project Planning Team, if you see fit.

Sparing you the mind-numbing details that can be found in scientific publications and my formal submissions to the U.S. EPA and Coast Guard, I provide some footnoted references to back up my general statements. Thank you for considering this feedback on your plan. I welcome your response after you have had the opportunity to discuss it.

Sincerely,



John J. Cullen, Ph.D. FRSC
Department of Oceanography
Dalhousie University

Comments on the Great Lakes Ballast Water R&D Plan, Version 4

John J. Cullen, Ph.D., FRSC
Department of Oceanography, Dalhousie University, Halifax, NS, B3H 4R2 Canada

Broadly, I would like to contribute to Stakeholder Group Involvement as it relates to the evolution of project ideas (quotes from the R&D plan are indented):

the proposed projects outlined in this Ballast Water R&D Plan will evolve from conceptual project ideas (as currently described) to separate project plans containing scientifically defensible experimental design and fully-formed implementation details.

Below, I identify recent findings that should be addressed if proposed projects on viability assessment methods are to be scientifically defensible.

Research Area 1, Project 2: Land-Based BWMS Evaluation

Key question 1 –

Are there existing BWMS available on the global market (either type-approved under the IMO Convention or by the U.S. Coast Guard) that can treat Great Lakes ballast water effectively to meet the current U.S. discharge standards using existing test methods (i.e., Generic Protocol for the Verification of Ballast Water Treatment Technology; U.S.EPA, 2010)?

This question fails to capture recent findings and legislation. Specifically, in referring to “existing test methods”, it specifies only the ETV Protocol (U.S.EPA 2010). Now that VIDA is law, “living” includes organisms capable of reproduction, and — because it does not measure the concentration of organisms that are capable of reproduction — the ETV Stains Protocol is unsuitable for testing the efficacy of ballast water treatment designed to render organisms non-viable. Disinfection with UV is one such technology.

By identifying only one testing method — the stains-based ETV protocol — the question excludes UV technologies from legitimate consideration.

Respectfully, I suggest that the question should be expanded to include Most Probable Number (MPN) testing, as shown below **in bold**:

Are there existing BWMS available on the global market (either type-approved under the IMO Convention or by the U.S. Coast Guard) that can treat Great Lakes ballast water effectively to meet the [] U.S. discharge standards (**organisms capable of reproduction**) using existing test methods (**e.g.**, Generic Protocol for the Verification of Ballast Water Treatment Technology; U.S.EPA, 2010 **or the MPN serial dilution culture method + Motility method; IMO PPR 7/INF.10**)?

The fully-described and validated MPN serial dilution culture + Motility method has been approved by the IMO as being suitable for testing all treatment technologies.¹⁴ But to the best of my knowledge, there has been no systematic examination using suitable methods (i.e., MPN-based) of how UV-BWMS would perform under conditions in the Great Lakes. This is a data

¹⁴ The IMO approvals (BWM.2/Circ.61 and PPR 7/22/Add.1 Annex 5, page 2) are discussed in the summary of EPA-HQ-OW-2019-0482-0662, Comment (Attachment 1)
<<https://www.regulations.gov/comment/EPA-HQ-OW-2019-0482-0662>>.

gap that must be addressed if conclusions about the efficacy of BWMS are to be scientifically defensible.

Already, relevant results are available: low-energy UV systems have been shown to meet the discharge standards for viable organisms when IMO-approved MPN methods were used, while at the same time failing to meet the pre-VIDA “living” standard using ETV stains methods.¹⁵ These findings demonstrate that existing conclusions about BWMS efficacy in treating Great Lakes ballast water (i.e., based on the results from stains-based USCG type approvals) are incomplete.

Research Area 2, Project 2: Evaluating Alternative/Emerging Sample Analysis Methods for Ballast Water Treatment Technology Testing

Key question 1:

What are potential emerging or alternative viability assessment methods for BWMS biological efficacy evaluation, and how effective are those methods?

Approach:

Project 2: “...will utilize the process outlined in the U.S. Coast Guard VIDA viability draft policy letter (26 July 2019) for proposal and submission of a viability assessment method for Great Lakes ballast water samples...Using the validation approach developed by the U.S. EPA Office of Research and Development (2018), and considering the data requirements in the U.S. Coast Guard draft policy letter....”

The key question and research approach are based upon:

- the 26 July 2019 draft policy statement¹⁶ that “the Coast Guard does not know of any type-approval testing protocols for BWMS that render nonviable organisms in ballast water that are based on best available science”
- an unpublicized EPA document (25 January 2018)¹⁷ describing a controversial validation plan,¹⁸ and
- a provisional, unpublished testing protocol (Petri, 2015, final draft, 2017).¹⁹

Much has changed since this research project was designed late in 2017. Public responses to the USCG draft policy letter rendered the Coast Guard’s “does not know of any” statement untenable.²⁰ The unpublished Alternative Method protocol (Petri, 2015) has been replaced by a

¹⁵ Test results for stains vs MPN are discussed on p. 3 of EPA-HQ-OW-2019-0482-0662 Comment (Attachment 1).

¹⁶ Docket (USCG-2019-0477) <<https://downloads.regulations.gov/USCG-2019-0477-0001/content.pdf>>.

¹⁷ The EPA validation plan has no document number or web link. It is an appendix to the unpublicized report: First, M.R., Validation of a most probable number-based assay in a freshwater environment (NRL Letter Report 6130/1929, 21-06-2019, approved for public release). Kelsey Prihoda quickly and cordially provided a copy of the document on request.

¹⁸ The EPA validation plan was “developed under the auspices of the EPA ETV Program and...does not represent consensus among members of the Task Group, which failed to reach agreement on a number of issues (too numerous to list here) discussed over the years” (p. 32). I was a member of the Task Group.

¹⁹ The description of the alternative method is cited in the 2018 EPA document as an appendix to the plan, but it is not included in the NRL report.

²⁰ Example responses: Welschmeyer <<https://www.regulations.gov/comment/USCG-2019-0477-0004>>

DNV-GL <<https://www.regulations.gov/comment/USCG-2019-0477-0005>>

Cullen <<https://www.regulations.gov/comment/USCG-2019-0477-0007>>

The issue is summarized in slides from a conference presentation (ICAIS, Cullen) here:

<<https://zenodo.org/record/3531993#.YEpbry294nc>>.

published and validated IMO-approved testing methodology that has been presented and effectively defended by the USCG-approved Independent Testing Laboratory DNV-GL.²¹ And detailed peer-reviewed research on validation of the MPN method — including comparison with stains-based methods — has been published after the EPA document was drafted, rendering the EPA plan out of date.²²

Yet, when the report of the first study conducted by GWRC using the EPA validation framework was presented and reviewed in an NRL document in 2019, none of this science was considered.²³

Concluding comment

The Great Lakes Ballast Water R&D program is committed to scientific rigor. It follows that any plan for evaluating the efficacy of viability testing methods must capture recent findings in the peer-reviewed literature and other sources of best available science. So far, the research plan for viability testing methods has fallen short. Respectfully, I suggest that it is time to come to grips with information that is out there. If the published science is relevant — which it is — it should be considered.²⁴ If it is sound, it should be used in scientifically defensible experimental design and fully-formed implementation details, possibly as a complement to the original plan. If elements of the published research are found to be faulty, they should be called out and ultimately corrected in the peer-reviewed literature. One way or another, relevant published research should be captured in R&D plan. Conceivably, the research team is constrained by contractual obligations to follow the outdated EPA validation plan. If so, and if possible, the arrangements should be revisited to ensure that the R&D plan is scientifically defensible in the light of recent research.

²¹ Draft policy response from DNV-GL: USCG-2019-0477-0005.

²² See the Best Available Science report (Cullen, 2019) <<https://zenodo.org/record/2656597#.YEpCpS294nc>> that is cited by the IMO as documenting the validation of MPN + Motility (PPR 7/22/Add.1 Annex 5, page 2. PPR 7/22/Add.1 Annex 5, page 2).

Two publications on method validation are particularly relevant:

Cullen, J.J., 2018. Quantitative framework for validating two methodologies that are used to enumerate viable organisms for type approval of ballast water management systems. *Science of the Total Environment* 627, 1602-1626. (Content is summarized in the Graphical Abstract, Abstract and Table of Contents).

MacIntyre, H.L., Cullen, J.J., Rastin, S., Waclawik, M., Franklin, K.J., Poulton, N., Lubelczyk, L., McPhee, K., Richardson, T.L., Van Meerssche, E., Petri, B., 2019. Inter-laboratory validation of the serial dilution culture—most probable number method for enumerating viable phytoplankton. *Journal of Applied Phycology* 31, 491-503 (Published 21 July 2018).

²³ The report (First, M.R., 2019. NRL Letter Report 6130/1929), included draft results of the GWRC study. The report includes citations to some recent publications on validation of MPN, but no consideration of the quantitative validation framework described in those studies.

²⁴ An example of relevance: Factor of Agreement (FOA, the ratio of the MPN result divided by the ETV Method result) is centrally important to the EPA and GWRC validation plan. It is presented as a proxy for the detectability of living (= viable) organisms by the MPN method, i.e., the g-factor — growability. In the first GWRC trial (see First, 2019), 9 measures of FOA are reported. In a peer-reviewed study of comparative method validation, Cullen (2018) presents a full analysis of FOA based on 64 sets of measurements by the USCG-accepted testing facility DHI; 21 are from fresh water. The paper includes quantitative metrics for so-called growability, and acceptability criteria in a type-approval context. This information and much more in the published studies is directly relevant to the research plan and to the status of MPN + Motility as a validated method, but so far, none of it has been considered by the research team, NRL, the USCG or the EPA.