The Best Available Science Supports Most Probable Number (MPN) Testing Methods for Type Approval of Ballast Water Management Systems

John J. Cullen

Department of Oceanography, Dalhousie University, Halifax, NS, Canada

John.Cullen@Dal.CA

21st International Conference on Aquatic Invasive Species
April 27-31, 2019
Montréal, QC, Canada

DALHOUSIE UNIVERSITY

TROJAN technologies

Cullen, J.J., 2019. The best available science supports most probable number (MPN) testing methods for type approval of ballast water management systems, 21st International Conference on Aquatic Invasive Species, Montréal, QC, Canada, pp. 1-37. doi: 10.5281/zenodo.3531993


The global shipping fleet will be installing *many* ballast water management systems — soon
Canada
United States
Russia
Poland
Ukraine
Kazakhstan
Mongolia
China
Spain
Turkey
Iraq
Iran
Afghanistan
Pakistan
India
Thailand
Algeria
Libya
Egypt
Saudi Arabia
Mali
Niger
Chad
Sudan
Nigeria
Ethiopia
Kenya
DRC
Brazil
Bolivia
Botswana
Australia
South Pacific Ocean
Southern Ocean
https://www.marinetraffic.com/en/ais/home/

BWMS type approval is required

DNV

DET NORSKE VERITAS

TYPE APPROVAL CERTIFICATE

CERTIFICATE NO. P-14780

This is to certify that the
Ballast Water Management System

with type designation(s)
Trojan Marinex BWT™ Model 150, Model 250, Model 500, Model 750, Model 1000, Model 1250 and Model 1500

issued to
Trojan Technologies
London, Canada

is found to comply with
Resolution MEPC.174(58)
DNV Type Approval Program No.771.91
Det Norske Veritas' Rules for Classification of Ships

Application
This is to certify that the Ballast Water Management System listed above has been examined and tested in accordance with the requirements of the specifications contained in Guidelines contained in Resolution MEPC.174(58) and DNV Rules stated above. This Certificate is valid only for the Ballast Water Management System referred to above.

This Certificate is issued on behalf of the Norwegian Maritime Directorate.

This Certificate is valid until 2017-12-31

Issued at Høvik on 2014-03-07

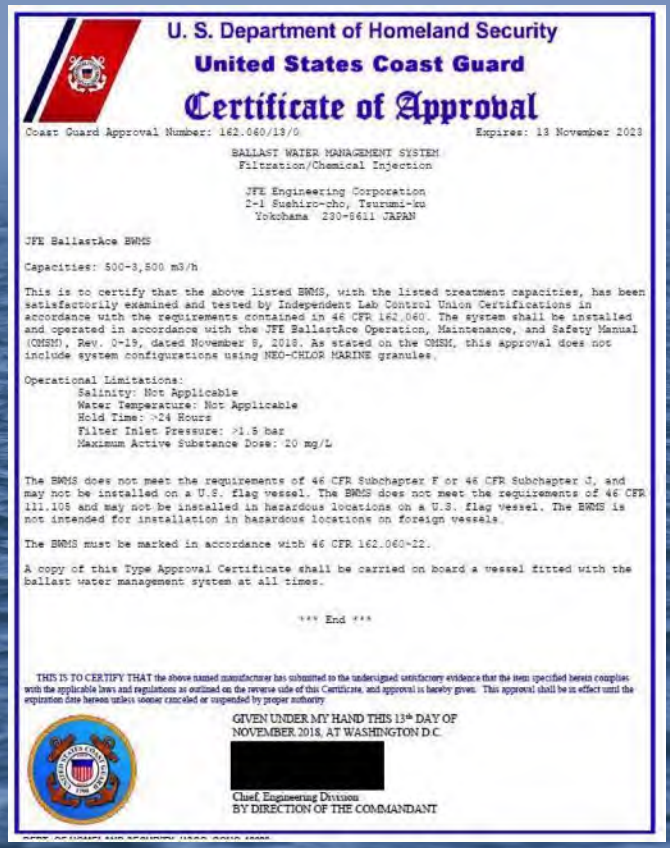
DNV local station: Montreal

Approval Engineer: Andreas Cappelen

for Det Norske Veritas AS

Dag Sæle-Nilsen
Head of Section

IMO



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

Coast Guard Approval Number: 162.060/13/0 Expires: 13 November 2023

BALLAST WATER MANAGEMENT SYSTEM
Filtration/Chemical Injection

JFE Engineering Corporation
2-1 Suehiro-cho, Tsurumi-ku
Yokohama 230-8611 JAPAN

JFE BallastAce BWMS

Capacities: 500-3,500 m3/h

This is to certify that the above listed BWMS, with the listed treatment capacities, has been satisfactorily examined and tested by Independent Lab Control Union Certifications in accordance with the requirements contained in 46 CFR 162.060. The system shall be installed and operated in accordance with the JFE BallastAce Operation, Maintenance, and Safety Manual (OMSM), Rev. 0-19, dated November 8, 2018. As stated on the OMSM, this approval does not include system configurations using NEO-CHLOR MARINE granules.

Operational Limitations:
Salinity: Not Applicable
Water Temperature: Not Applicable
Hold Time: >24 Hours
Filter Inlet Pressure: >1.5 bar
Maximum Active Substance Dose: 20 mg/L

The BWMS does not meet the requirements of 46 CFR Subchapter F or 46 CFR Subchapter J, and may not be installed on a U.S. flag vessel. The BWMS does not meet the requirements of 46 CFR 111.105 and may not be installed in hazardous locations on a U.S. flag vessel. The BWMS is not intended for installation in hazardous locations on foreign vessels.

The BWMS must be marked in accordance with 46 CFR 162.060-22.

A copy of this Type Approval Certificate shall be carried on board a vessel fitted with the ballast water management system at all times.

*** End ***

THIS IS TO CERTIFY THAT the above named manufacturer has submitted to the undersigned satisfactory evidence that the item specified herein complies with the applicable laws and regulations as outlined on the reverse side of this Certificate, and approval is hereby given. This approval shall be in effect until the expiration date hereon unless sooner canceled or suspended by proper authority.

GIVEN UNDER MY HAND THIS 13th DAY OF NOVEMBER 2018, AT WASHINGTON D.C.

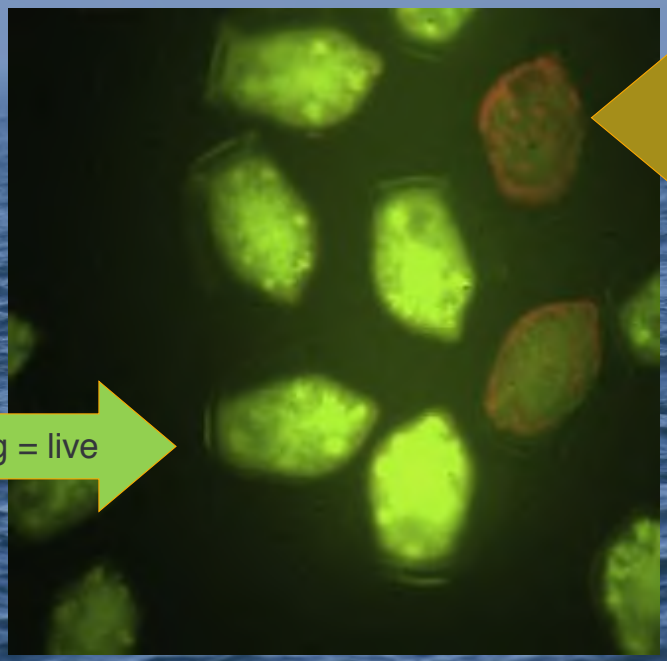
[redacted]

Chief, Engineering Division
BY DIRECTION OF THE COMMANDANT

USCG

The U.S. Coast Guard *live / dead* test for type approval

Vital Stains + Motility



Unstained and unmoving = dead

Stained or moving = live

This is for organisms ≥10 µm to < 50 µm

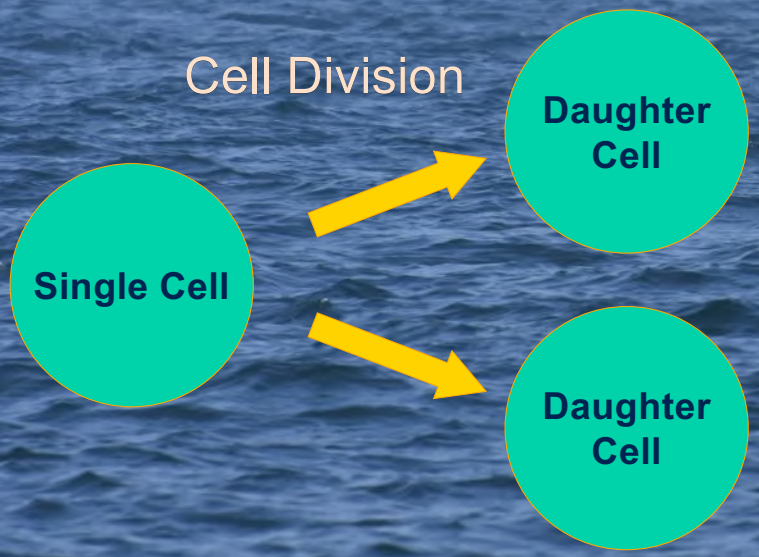
nominally protists

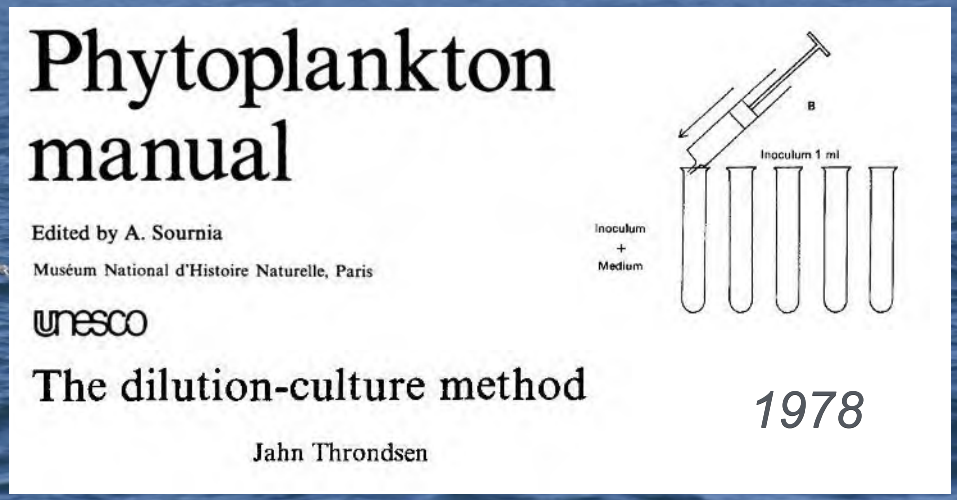
"ETV protocol"

U.S. Environmental Protection Agency
Environmental Technology Verification Program

Image from Fux et al. (2010) *Toxicon* 56:1487-96.

Most Probable Number Dilution Culture (MPN) enumerates *viable cells* — those capable of reproduction





Heterotrophs are assessed by motility


No reproduction, no invasion
Simple as that
Cullen
ICAIS Montréal – 2019

Zombie Phytoplankton!

Treatment with ultraviolet radiation (UV) can stop reproduction without killing

Not capable of reproduction but classified as undead

Super-simple Summary:

Treat with low-energy UV

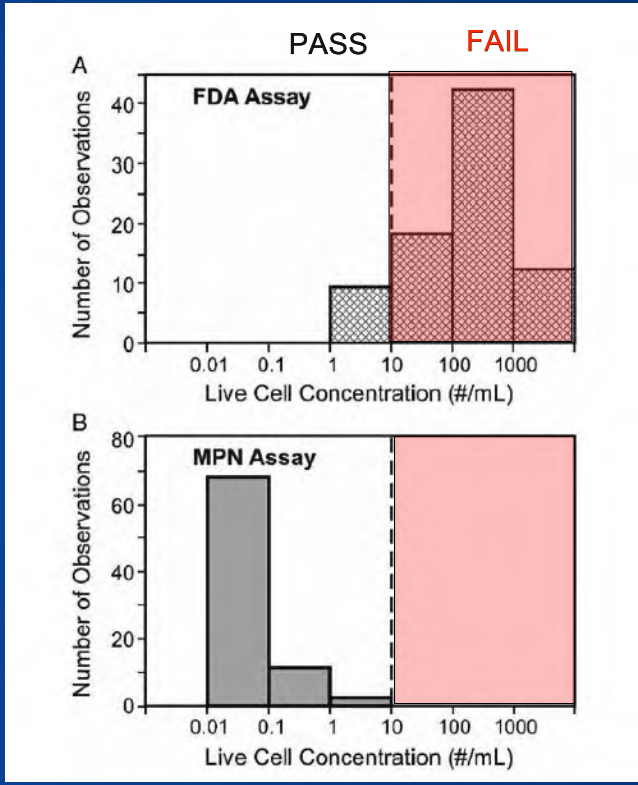
Test with MPN: PASS

Test with stains: FAIL

Correct answer: PASS

See also Blatchley et al, 2018. Environ Sci Technol 52, 8075-8086.

UV-Treated Discharge



Wright and Welschmeyer 2015. J. Mar. Eng. Tech. 14, 9-18

Super-simple solution for the USCG:

Accept MPN Dilution Culture + Motility and align with the IMO

Document prepared with consent of the United States delegation, led by the USCG.

(January 2017)

INTERNATIONAL MARITIME ORGANIZATION

BWM.2/Circ.61
Annex, page 1

ANNEX

GUIDANCE ON METHODOLOGIES THAT MAY BE USED FOR ENUMERATING VIABLE ORGANISMS FOR TYPE APPROVAL OF BALLAST WATER MANAGEMENT SYSTEMS

Table: Methodologies that may be used for enumerating viable organisms for type approval of BWMS

Methodologies for enumerating viable organisms	Organism size class or indicator	Assessed criteria of viability	Examples of how the methodologies are applied	Applicability to ballast water treatment technologies
FDA/CMFDA + Motility	Viable organisms ≥ 10 µm to < 50 µm	Membrane integrity, enzyme activity, motility	PPR 4/7, appendix 1; PPR 4/INF.10	Suitable for assessing treatment technologies intended to kill or remove organisms
MPN Dilution Culture + Motility	Viable organisms ≥ 10 µm to < 50 µm	Reproduction capacity, motility	PPR 4/7, appendix 2	Suitable for assessing all treatment technologies

Consensus agreement

INTERNATIONAL MARITIME ORGANIZATION

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The United States Coast Guard has yet to align with the global consensus

2016 USCG rejection of MPN stands

MPN Working Group of the ETV has no published results after 5 years

7/12/2016: Final action on ballast water management system appeals

POSTED BY LT KATIE BRAYNARD ON JULY 12, 2016 · (LEAVE A COMMENT)

USCG cannot test low-energy UV treatment systems suitably

INTERNATIONAL MARITIME ORGANIZATION

BWM.2/Circ.61
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Stains are not suitable for low-energy UV

Legislated solution: VIDA

PUBLIC LAW 115–282—DEC. 4, 2018

FRANK LOBIONDO COAST GUARD AUTHORIZATION ACT OF 2018

Vessel Incidental Discharge Act of 2018.

TITLE IX—VESSEL INCIDENTAL DISCHARGE ACT

33 USC 1251 note.

SEC. 901. SHORT TITLE.

This title may be cited as the "Vessel Incidental Discharge Act of 2018".

33 USC 1322 note.

SEC. 902. PURPOSES; FINDINGS.

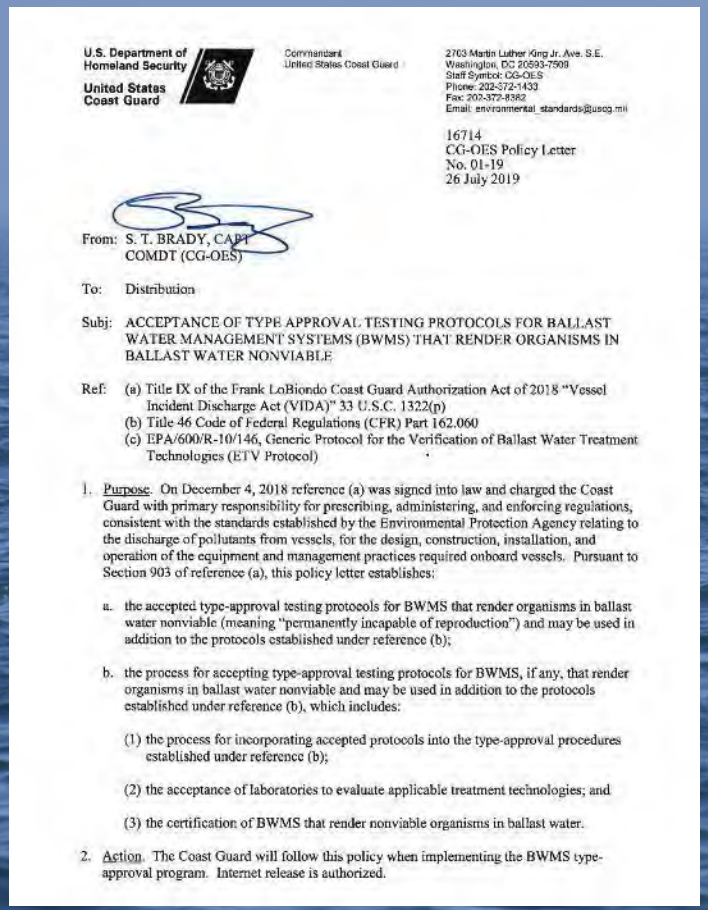
(a) PURPOSES.—The purposes of this title are—

(1) to provide for the establishment of uniform, environmentally sound standards and requirements for the management of discharges incidental to the normal operation of a vessel;

Instructions in VIDA

- USCG with EPA must develop a new policy
  (by Dec 4, 2019)
- It will describe type-approval testing methods, if any, for BWMS that render organisms nonviable
- It shall take into consideration organism grow-out and MPN
- Start with a draft policy letter based on best available science
  (due June 4, 2019 for public comment)

Draft Policy Letter Surprises Many



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

Commandant
United States Coast Guard

2703 Martin Luther King Jr. Ave. S.E.
Washington, DC 20593-7509
Staff Symbol: CG-OES
Phone: 202-372-1433
Fax: 202-372-8382
Email: environmental_standards@uscg.mil

16714
CG-OES Policy Letter
No. 01-19
26 July 2019

From: S. T. BRADY, CAPT
COMDT (CG-OES)

To: Distribution

Subj: ACCEPTANCE OF TYPE APPROVAL TESTING PROTOCOLS FOR BALLAST WATER MANAGEMENT SYSTEMS (BWMS) THAT RENDER ORGANISMS IN BALLAST WATER NONVIABLE

Ref: (a) Title IX of the Frank LoBiondo Coast Guard Authorization Act of 2018 "Vessel Incident Discharge Act (VIDA)" 33 U.S.C. 1322(p)
(b) Title 46 Code of Federal Regulations (CFR) Part 162.060
(c) EPA/600/R-10/146, Generic Protocol for the Verification of Ballast Water Treatment Technologies (ETV Protocol)

1. Purpose. On December 4, 2018 reference (a) was signed into law and charged the Coast Guard with primary responsibility for prescribing, administering, and enforcing regulations, consistent with the standards established by the Environmental Protection Agency relating to the discharge of pollutants from vessels, for the design, construction, installation, and operation of the equipment and management practices required onboard vessels. Pursuant to Section 903 of reference (a), this policy letter establishes:

   a. the accepted type-approval testing protocols for BWMS that render organisms in ballast water nonviable (meaning "permanently incapable of reproduction") and may be used in addition to the protocols established under reference (b);

   b. the process for accepting type-approval testing protocols for BWMS, if any, that render organisms in ballast water nonviable and may be used in addition to the protocols established under reference (b), which includes:

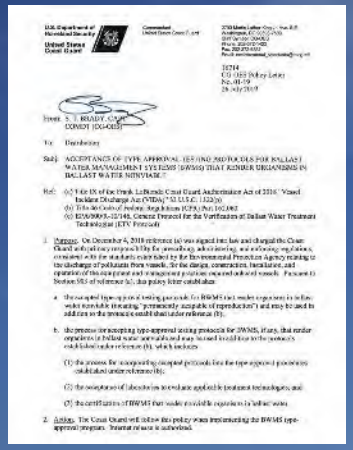
      (1) the process for incorporating accepted protocols into the type-approval procedures established under reference (b);

      (2) the acceptance of laboratories to evaluate applicable treatment technologies; and

      (3) the certification of BWMS that render nonviable organisms in ballast water.

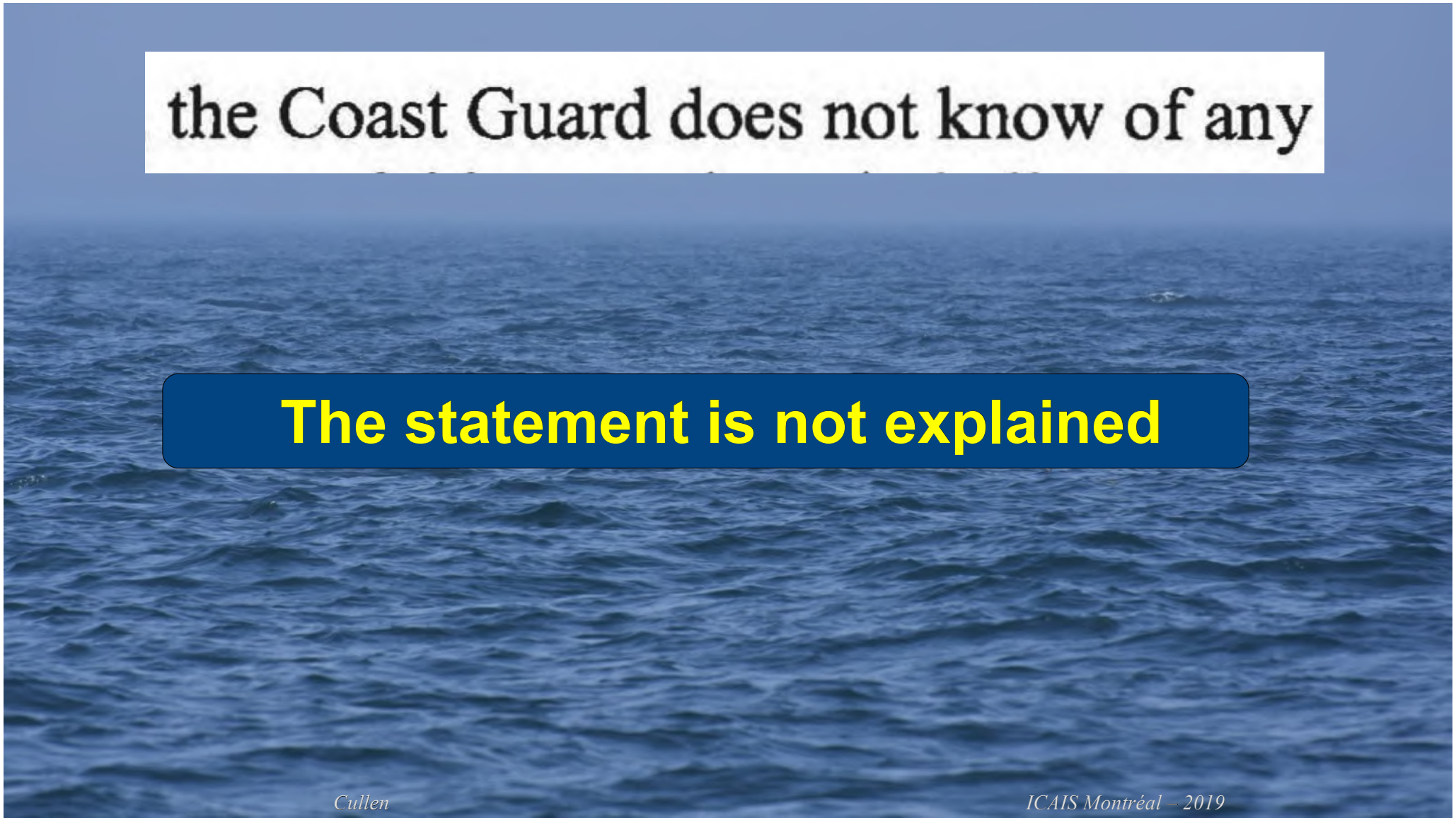
2. Action. The Coast Guard will follow this policy when implementing the BWMS type-approval program. Internet release is authorized.

…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.



Draft Policy Letter

- **No description of a method:**
  "the Coast Guard does not know of any"
- **Not one mention of MPN**
- **Describes a process for submitting protocols that *might* be accepted**
- **Tremendous amount of work (prep and review), much of it repetitive**
- **Timeline to first MPN-based type approval unknown — years?**
- **Uncertainty among all stakeholders**


the Coast Guard does not know of any
The statement is not explained

It *cannot* mean this:

…the Coast Guard **does not know** about the MPN + Motility methodology

It must mean this:

The Coast Guard *denies* that MPN + Motility type-approval testing protocols are based on the best available science

Best available science disagrees

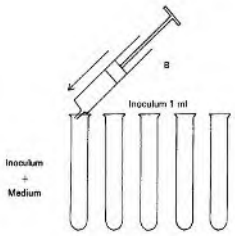
Phytoplankton manual

Edited by A. Sournia

Muséum National d'Histoire Naturelle, Paris

unesco

The dilution-culture method



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Jahn Throndsen

Science of the Total Environment

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journal homepage: www.el

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Department of Oceanography, Dalhousie University, Halifax, Nova Scotia B3H 4R2, Canada

Environmental Science & Technology

Policy Analysis

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The Biological Basis for Ballast Water Performance Standards: "Viable/Non-Viable" or "Live/Dead"?

Ernest R. Blatchley III,*,† John J. Cullen,‡ Brian Petri,§ Keith Bircher,∥ and Nicholas Welschmeyer⊥

J Appl Phycol (2016) 28:279–298
DOI 10.1007/s10811-015-0601-x

Received: 31 January 2015 / Accepted: 21 April 2015 / Published online: 24 May 2015
© The Author(s) 2015. This article is published with open access at Springerlink.com

On the use of the serial dilution culture method to enumerate viable phytoplankton in natural communities of plankton subjected to ballast water treatment

John J. Cullen[1] · Hugh L. MacIntyre[1]

J Appl Phycol (2018) 30:1073–1094
DOI 10.1007/s10811-017-1254-8

CrossMark

Enumerating viable phytoplankton using a culture-based Most Probable Number assay following ultraviolet-C treatment

18) 1090–1100

ScienceDirect

Bulletin

om/locate/marpolbul

UV fluences required for compliance with ballast water discharge standards using two approved methods for algal viability assessment

Kim Lundgreen[a,*], Henrik Holbech[a], Knud Ladegaard Pedersen[a], Gitte Ingelise Petersen[b], Rune Røjgaard Andreasen[c], Christaline George[d], Guillaume Drillet[d,e], Martin Andersen[f]

SUB-COMMITTEE ON POLLUTION PREVENTION AND RESPONSE
4th session
Agenda item 7

IMO INTERNATIONAL MARITIME ORGANIZATION

PPR 4/7
12 October 2016
Original: ENGLISH

REVIEW OF THE GUIDELINES FOR APPROVAL OF BALLAST WATER MANAGEMENT SYSTEMS (G8)

Analysis methods for determining the viability of organisms in the 10 to 50 µm size class

Submitted by Denmark and Norway

Environmental Science & Technology Letters

Letter

pubs.acs.org/journal/estlcu

Algal DNA Repair Kinetics Support Culture-Based Enumeration for Validation of Ultraviolet Disinfection Ballast Water Treatment Systems

Natalie M. Hull,[†] Mythili R. Isola,[†] Brian Petri,[‡] Po-Shun Chan,[‡] and Karl G. Linden*,[†]

[†]Civil, Environmental, and Architectural Engineering, University of Colorado, Boulder, Colorado 80309, United States
[‡]Trojan Technologies, London, ON N5V 4T7, Canada


regulations.gov
Your Voice in Federal Decision-Making
Advanced Search
Draft Policy Letter on the Coast Guard's process to evaluate proposed type- approval testing methods and protocols for ballast water management systems that render nonviable organisms in ballast water
Docket Browser
Return to Docket Folder Summary
Docket ID: USCG-2019-0477 Agency: Coast Guard (USCG) Parent Agency: Department of Homeland Security (DHS)
Summary:
Draft Policy Letter on the Coast Guard
Filter Results By...
Document Type
Clear Filter
Notice (1)
Proposed Rule (0)
Rule (0)
Supporting & Related Material (1
Other (0)
Public Submission
Posted
Search All
Comments Due
Search All
Document SubType
View All
Narrow By Document SubType
So do most of the commenters: manufacturers, shipping, testing labs, researchers
Submitter Name: Nick Welschmeyer
Comment Submitted by Steven Sawhill, U.S. Government & Public Affairs DNV GL, USA Inc.
DNV GL proposes to include a protocol for the MPN+motility method into the final policy letter. DNV GL is submitting comments to the draft policy letter in 3 attached files: A...
Public Submission | Posted: 09/20/2019 | ID: USCG-2019-0477-0005
Submitter Name: Steven Sawhill
Comment Submitted by Mark Riggio, Hyde Marine
See attached file(s)
Public Submission | Posted: 09/25/2019 | ID: USCG-2019-0477-0006
Submitter Name: Mark Riggio
Comment Submitted by Ernest Blatchley
Thank you for the opportunity to comment on this draft policy letter. Attached please find a letter I have written in response to the draft policy. Also attached

Quick review of the best available science

Phytoplankton manual

Edited by A. Sournia

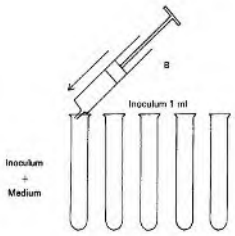
Muséum National d'Histoire Naturelle, Paris

unesco

The dilution-culture method

1978

Jahn Throndsen



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Science of the Total Environment 627 (2018) 150

Contents lists available at ScienceDirect

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journal homepage: www.elsevier.com/lo

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n 135 (2018) 1090–1100

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lution Bulletin

ELSEVIER

journal homepage: www.elsevier.com/locate/marpolbul

MARINE POLLUTION BULLETIN

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†Civil, Environmental, and Architectural Engineering, University of Colorado, Boulder, Colorado 80309, United States
‡Trojan Technologies, London, ON N5V 4T7, Canada

Documentation freely available on the permanent public record

The best available science describing type-approval testing methods and protocols for ballast water management systems that render nonviable organisms in ballast water

John J. Cullen

Department of Oceanography, Dalhousie University, Halifax, Nova Scotia B3H 4R2, Canada

 This report was submitted to the United States Coast Guard and U.S. Environmental Protection Agency on 4 March 2019 and first posted online 1 May 2019; doi: 10.5281/zenodo.2656597.

MPN Dilution Culture has been used for decades to enumerate viable phytoplankton with unknown culturing requirements

Preliminary Studies of Nanoplankton and Ultraplankton Systematics and Abundance by a Quantitative Culture Method.

By

E. W. Knight-Jones,
Marine Biological Station, Bangor.
J. du Conseil

1951

Phytoplankton manual

Edited by A. Sournia
Muséum National d'Histoire Naturelle, Paris

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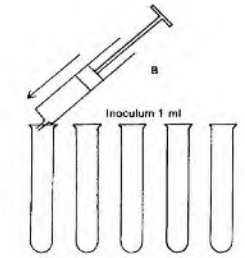

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2015

MPN Dilution Culture + Motility has been used for years in type-approval testing of BWMS and has been fully endorsed by USCG-approved laboratories

USCG-accepted Independent Laboratory:

DNV·GL

Contributed to 14 of the 21 USCG type approvals

Contributed to 16 type approvals for Norway (IMO)

USCG-accepted testing facilities:

DHI

MPN since 2010

CAL MARITIME GOLDEN BEAR FACILITY

MPN since 2010

NIVA Norwegian Institute for Water Research

MPN since 2006

Suitable testing protocols have been published
They are based on best available science

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An Analysis Method for

Determining the Viability of Organisms ≥ 10 µm and < 50 µm

Using MPN Dilution Culture + Motility

A protocol proposed to the USCG as part of the comments to the CG-OES Policy Letter No. 01-19, dated 26 July 2019

Submitted by

DNV GL (Independent Laboratory to the USCG for type approval testing of BWTS)

DHI (laboratory in Denmark for analyzing the biological efficacy of BWTS)

NIVA (laboratory in Norway for analyzing the biological efficacy of BWTS)

GBRC (laboratory in California for analyzing the biological efficacy of BWTS)

MPN-based methods assess *permanent* loss of viability

Environmental Science & Technology LETTERS

Letter

pubs.acs.org/journal/estlcu

Algal DNA Repair Kinetics Support Culture-Based Enumeration for Validation of Ultraviolet Disinfection Ballast Water Treatment Systems

Natalie M. Hull,[†] Mythili R. Isola,[†] Brian Petri,[‡] Po-Shun Chan,[‡] and Karl G. Linden*[,†]

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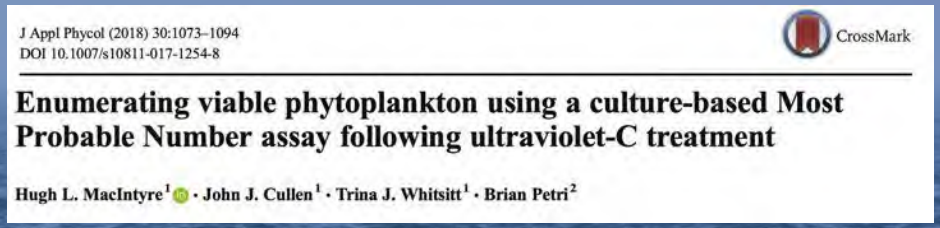

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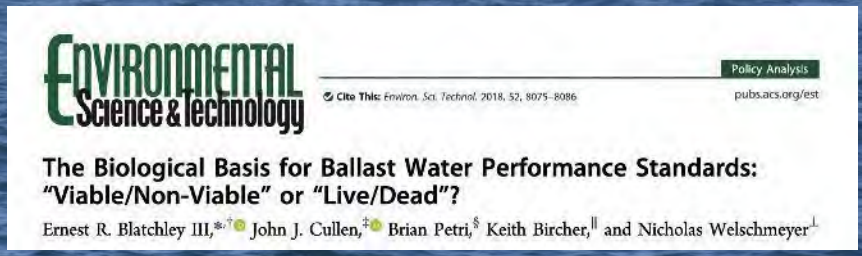


Environmental Science & Technology

Policy Analysis

Cite This: Environ. Sci. Technol. 2018, 52, 8075−8086

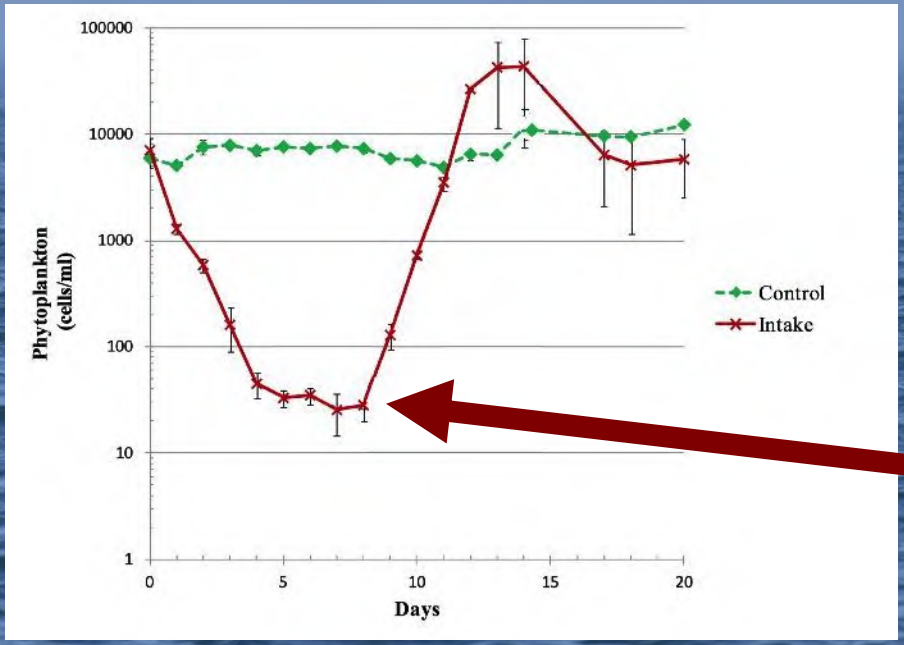
pubs.acs.org/est

The Biological Basis for Ballast Water Performance Standards: "Viable/Non-Viable" or "Live/Dead"?

Ernest R. Blatchley III,*[,†] John J. Cullen,[‡] Brian Petri,[§] Keith Bircher,[∥] and Nicholas Welschmeyer[⊥]

- Damage from UV is repaired quickly or not at all
- The MPN Dilution Culture method promotes any repair that might occur
- Two-week incubation is enough to render the risk of delayed recovery negligible

Is "regrowth" evidence of delayed recovery?

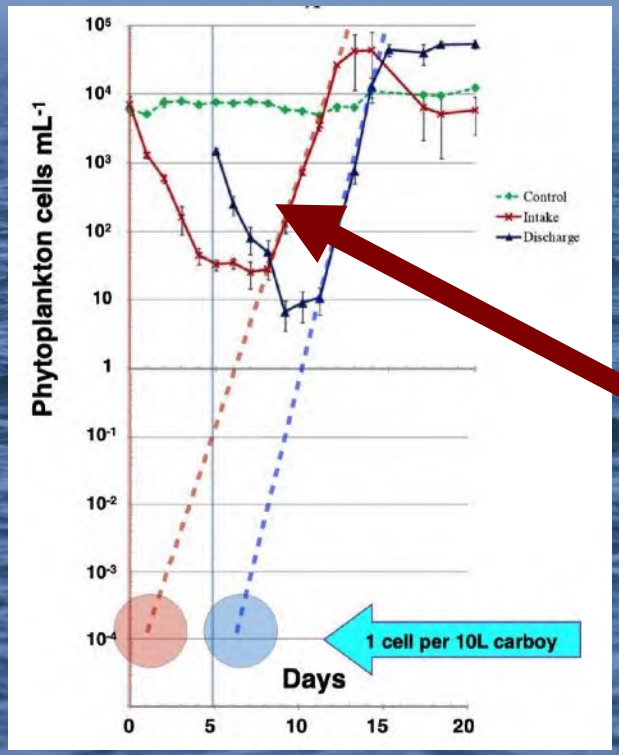


Growth first detected eight days after treatment

Liebich et al., 2012. Aquatic Invasions 7, 29-36
Shown by Cullen and MacIntyre, ICAIS 2016

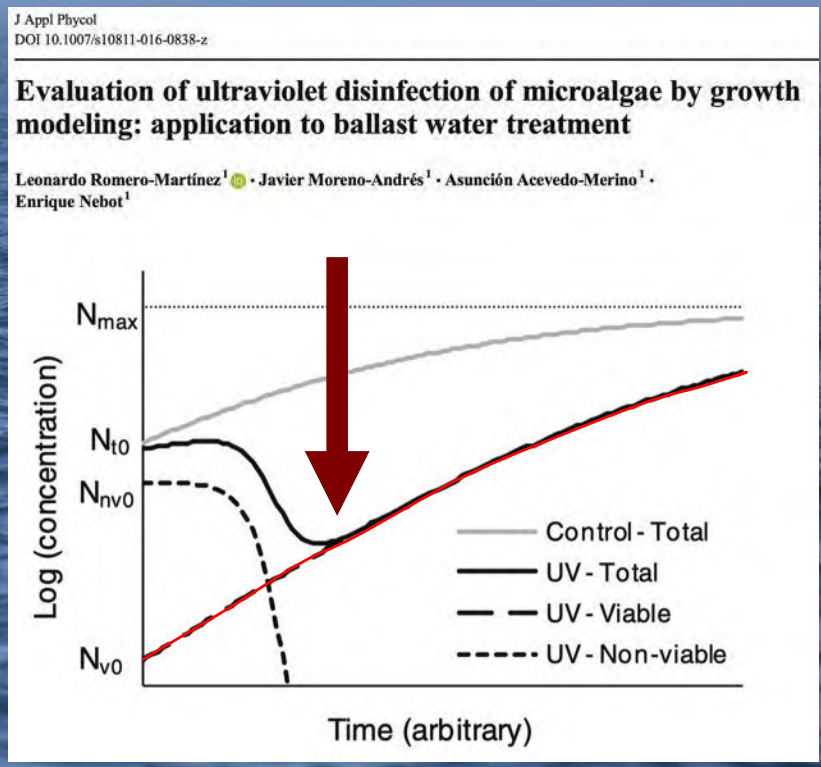
Delayed detection is not a demonstration of delayed growth "nonviable means permanently nonviable"

Apparent "regrowth" is survivors emerging



Liebich et al., 2012. Aquatic Invasions 7, 29-36
Shown by Cullen and MacIntyre, ICAIS 2016

Prediction of growth modeling with no delayed recovery



MPN + Motility has been thoroughly validated

J Appl Phycol (2018) 30:1073–1094
DOI 10.1007/s10811-017-1254-8

Enumerating viable phytoplankton using a culture-based Most Probable Number assay following ultraviolet-C treatment

Hugh L. MacIntyre[1] · John J. Cullen[1] · Trina J. Whitsitt[1] · Brian Petri[2]

Journal of Applied Phycology (2019) 31:491–503
https://doi.org/10.1007/s10811-018-1541-z

Inter-laboratory validation of the serial dilution culture—most probable number method for enumerating viable phytoplankton

Hugh L. MacIntyre[1] · John J. Cullen[1] · Shannah Rastin[1] · Magdalena Waclawik[1] · Kimberly J. Franklin[1] · Nicole Poulton[2] · Laura Lubelczyk[2] · Kate McPhee[2] · Tammi L. Richardson[3] · Elise Van Meerssche[3] · Brian Petri[4]

SUB-COMMITTEE ON POLLUTION PREVENTION AND RESPONSE
4th session
Agenda item 7

INTERNATIONAL MARITIME ORGANIZATION

PPR 4/7
12 October 2016
Original: ENGLISH

REVIEW OF THE GUIDELINES FOR APPROVAL OF BALLAST WATER MANAGEMENT SYSTEMS (G8)

Analysis methods for determining the viability of organisms in the 10 to 50 µm size class

Submitted by Denmark and Norway

Science of the Total Environment 627 (2018) 1602–1626
Contents lists available at ScienceDirect
Science of the Total Environment
journal homepage: www.elsevier.com/locate/scitotenv

Review

Quantitative framework for validating two methodologies that are used to enumerate viable organisms for type approval of ballast water management systems

John J. Cullen
Department of Oceanography, Dalhousie University, Halifax, Nova Scotia B3H 4R2, Canada

6th IMarEST Ballast Water Technology Conference, 12-13 January 2017, London, UK
https://doi.org/10.24868/bwtc6.2017.010

The case for using the Most Probable Number (MPN) method in ballast water management system type approval testing

John J. Cullen[a], Hugh L. MacIntyre[a]
[a]Department of Oceanography, Dalhousie University, Halifax, Nova Scotia, Canada B3H 4R2,

J. Phycol. 52, 572–589 (2016)

DOI: 10.1111/jpy.12415

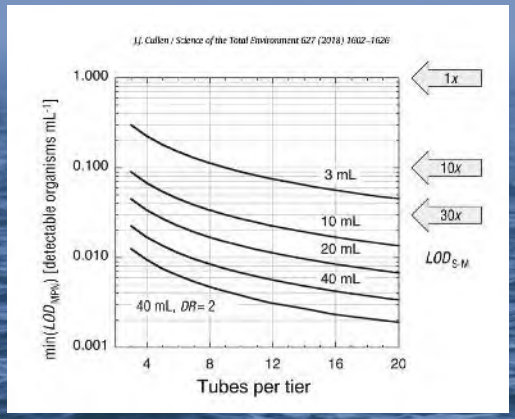
CLASSIFICATION OF PHYTOPLANKTON CELLS AS LIVE OR DEAD USING THE VITAL STAINS FLUORESCEIN DIACETATE AND 5-CHLOROMETHYLFLUORESCEIN DIACETATE[1]

Hugh L. MacIntyre[2] and John J. Cullen
Department of Oceanography, Dalhousie University, PO Box 15000, Halifax, Nova Scotia B3H 4R2, Canada

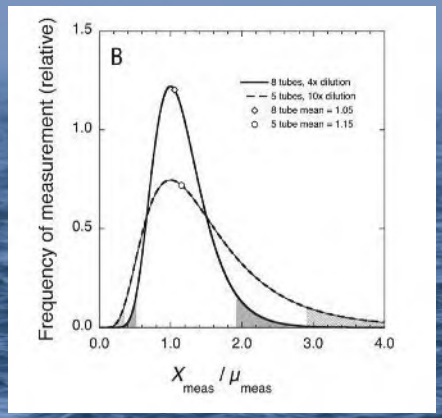
Cullen

Quantitative and rigorous

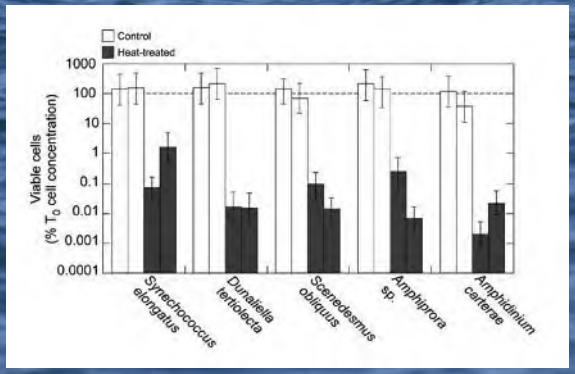
Limit of detection



Precision

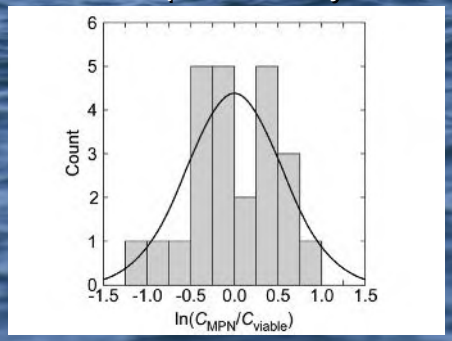


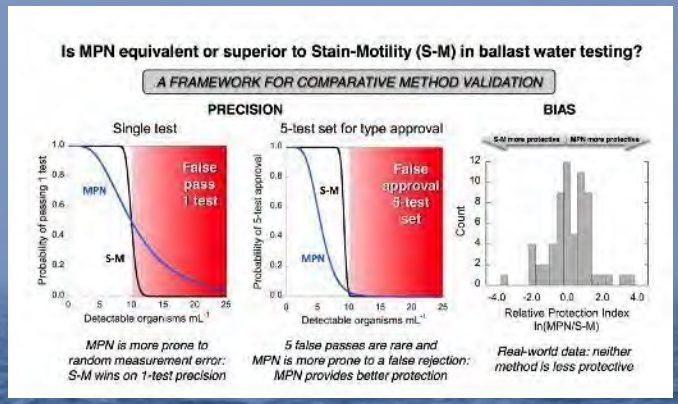
Bias (false positive/negative)



see next slide for reference

Interlaboratory comparison
Reproducibility





Expert assessment of bias

Table 3: MPN Dilution Culture-Motility Method

	Bias on number of living 10 to 50 µm organisms	Probable magnitude
Autotrophs		
Inclusion of > 50 µm autotrophs Water samples are not screened through a 50 µm filter to remove > 50 µm autotrophs, which can result in an overestimation bias.	Overestimate	In many cases this bias is expected to be small, as > 50 µm autotrophs are typically rare (< 3% Chl in > 50 µm size fraction, Welschmeyer, personal communication). Additionally, the majority of BWMS include a filtration step designed to remove the organisms in the > 50 µm size
		class down to < 10 organisms/m³. Where filtration is part of the treatment, the Discharge Treated sample will have very few organisms that are > 50 µm, reducing the potential overestimation bias.
Inclusion of <10 µm autotrophs Samples may or may not be filtered on a 10 µm filter and resuspended, to remove < 10 µm autotrophs. **Where 10 µm filtration is not employed,** < 10 µm autotrophs will be present in the sample. This will result in an overestimation bias.	Overestimate	This bias can be large depending upon the mixtures of taxa in a given sample.
Non-growing autotrophs Some species of autotrophs may not be able to grow (reproduce) in the supplied culture conditions (media, temperature, light). This can result in an underestimation bias.	Underestimate	This bias can be minimized by providing optimal incubation conditions (general growth media; preparation of media using sterilized local water to which the community is already acclimated, incubation temperatures near ambient, low to intermediate light levels). Attempts to measure the bias have been made. The work showed that the bias approached 0% as higher level taxonomy was applied, and any bias was balanced by the ability of the MPN assay to detect and enumerate species that were below the detection limit of microscopic methods.

Validated to a higher standard than for FDA/CMFDA + Motility

USCG-2019-0477-0007

Comment to the USCG draft policy letter CG-OES No. 01-19
John J. Cullen

https://www.regulations.gov/document?D=USCG-2019-0477-0007

Performance attributes	Validation data provided?	
	FDA/CMFDA + Motility validation	MPN + Motility documents
Range of resolution	**NO**	**YES**
Lower limit of detection	**NO**	**YES**
Upper limit	Not applicable	**YES**
Precision	**NO**	**YES**
Repeatability (base method, laboratory)	**NO**	**YES**
Reproducibility (base method, laboratory)	**NO**	**YES**
Trueness / bias (base method, laboratory)	**NO**	**YES**
Trueness / bias (natural samples)	**YES** (partial)	**YES** (partial)
Quantitative acceptance criteria for validation	**NO**	**YES**
Quantitative comparative validation	Not applicable at the time	**YES** (equivalent protection)
Status of Method Validation (USCG)	**Accepted**	**Not accepted**

Equivalent or better protection

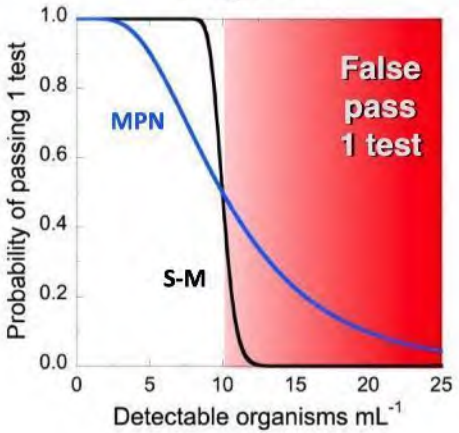
Science of the Total Environment 627 (2018) 1602-1626

Is MPN equivalent or superior to Stain-Motility (S-M) in ballast water testing?

A FRAMEWORK FOR COMPARATIVE METHOD VALIDATION

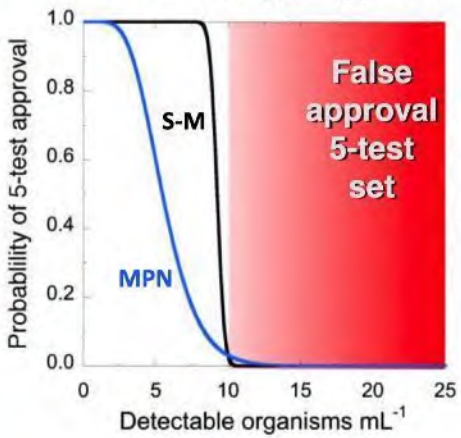
PRECISION

Single test



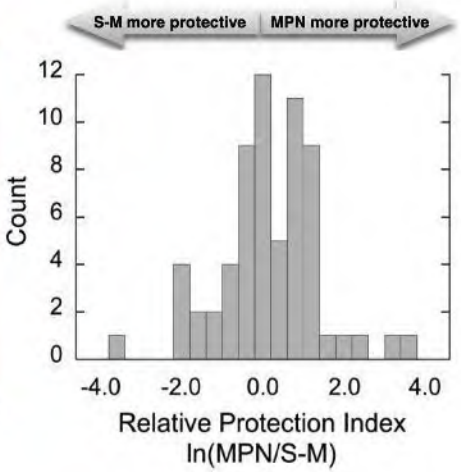
MPN is more prone to random measurement error: S-M wins on 1-test precision

5-test set for type approval



5 false passes are rare and MPN is more prone to a false rejection: MPN provides better protection

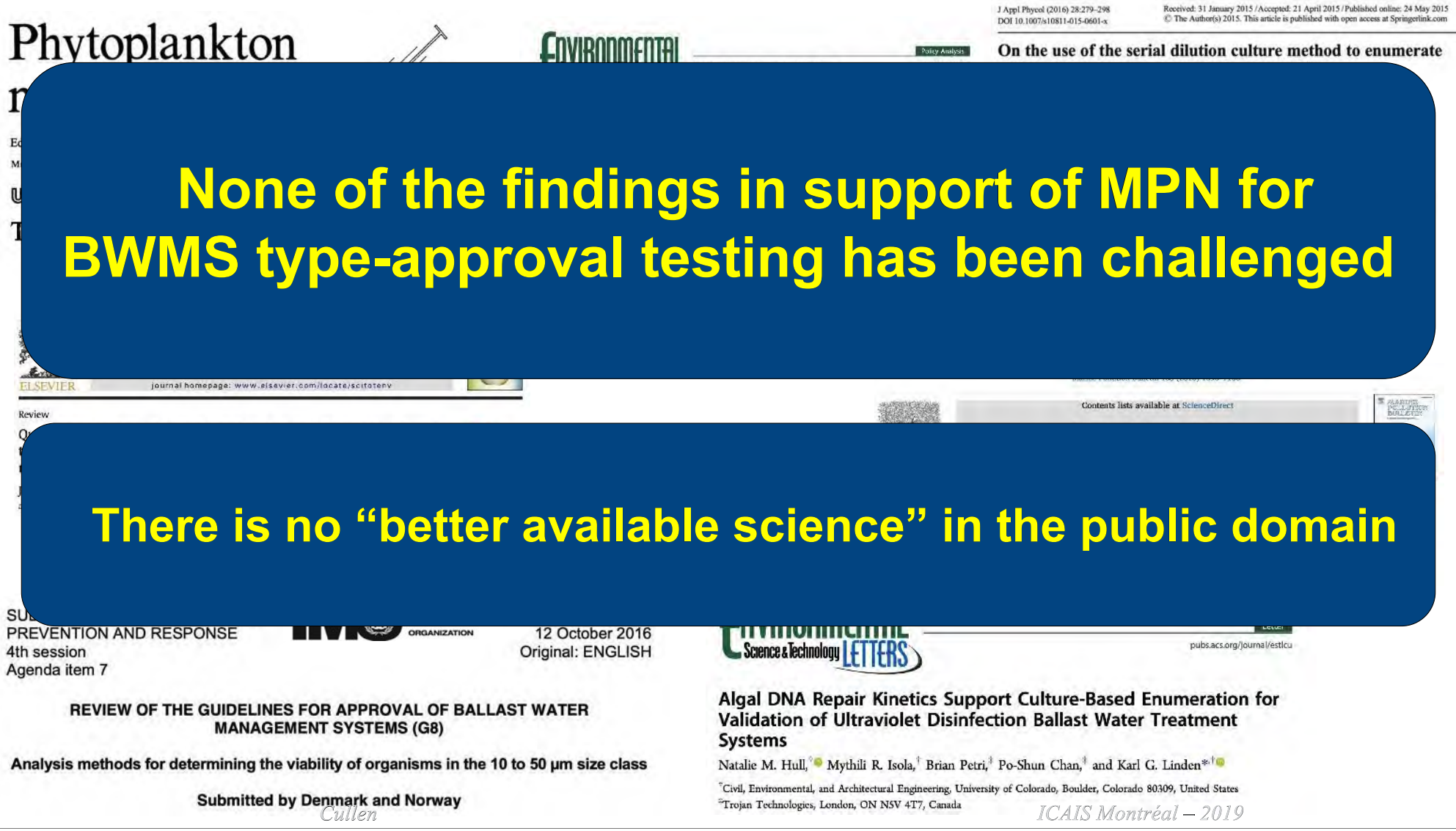
BIAS



Real-world data: neither method is less protective

None of the findings in support of MPN for BWMS type-approval testing has been challenged

There is no "better available science" in the public domain



Conclusions

MPN + Motility is well established in ballast water testing, fully consistent with the description in VIDA, and firmly grounded in the best available science.

The science supports acceptance of a generic MPN + Motility protocol for inclusion in the USCG Final Policy.

Benefits of accepting MPN + Motility and moving on with protection of coastal environments

- Alignment with IMO and Canadian ballast water policy
- Equivalent or better protection of the environment
- Consistent and predictable framework for shipowners
- Path for approval of low-energy UV treatment
- Eliminate unnecessary and burdensome work
  - manufacturers, laboratories, regulators, contractors, lawyers…
- More resources for Homeland Security and better ballast water treatment

Editorial:

Moving on would be good

Thank you

Acknowledgement: This effort was supported by Trojan Technologies. The content of this presentation is solely the responsibility of the author.